

1 State of Alaska
2 Department of Commerce, Community and Economic Development
3 Division of Corporations, Business and Professional Licensing
4

5 Alaska Board of Pharmacy
6

7 FINAL MINUTES OF THE MEETING
8

9 November 14 - 15 - In-Person and Teleconference via OnBoard
10

11 By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62,
12 Article 6, a scheduled meeting of the Board of Pharmacy was held in-person at the
13 Robert Atwood Building, Suite 1550 in Anchorage, Alaska and at the State Office
14 Building, 9th Floor, Conference Room A in Juneau, Alaska on November 14 and 15,
15 2019. This meeting was scheduled to begin at 9:00 a.m., but was postponed to 1:17p.m.
16

17 Agenda Item 1 Call to Order/Roll Call Time: 1:17 p.m.
18

19 The **November 14, 2019** meeting day was called to order by Chair, Rich Holt at 1:11 p.m.
20

21 Board members present, constituting a quorum:
22

23 Richard Holt, PharmD #PHAP2008, MBA – *Chair*
24 Leif Holm, PharmD #PHAP1606 (via telephone)
25 Phil Sanders, RPh #PHAP776 (via telephone)
26 James Henderson, RPh #PHAP1683 (via telephone)
27 Lana Bell, RPh #PHAP893
28 Tammy Lindemuth, Public Member
29 Sharon Long, Public Member (Absent)
30

31 Division staff present:
32

33 Christianne Carrillo, Occupational Licensing Examiner
34 Laura Carrillo, Executive Administrator
35 Marilyn Zimmerman, Paralegal
36 Sonia Lipker, Senior Investigator
37 Carl Jacobs, Investigator
38
39
40

41 Members from the public present:
42

43 Jessica Adams, Telepharm (via phone)
 44 Lorry Walmsley, Walgreens (via phone)
 45 Lauren Call, CVS (via phone)
 46 William Cover, NABP (Anchorage)
 47 Molly Gray, (Alaska Pharmacy Association; in Anchorage)
 48 Michael Herron, #128756, Walgreens (via phone)

50 **Agenda Item 2 Review/Approve Agenda Time: 1:14 p.m.**

51
 52 Chair Holt informed the board that due to the postponement of the meeting, agenda items #1 –
 53 (roll call/call to order, review/approve agenda, ethics disclosures, and review/approve minutes)
 54 were to proceed beginning at after 1:00 p.m., followed by Bill Cover’s NABP presentation at 1:30
 55 p.m., consent agreements at 2:30 p.m., the investigative update at 3:00 p.m., and old business
 56 as time permits.

57
 58 **On a motion duly made by Lana Bell, seconded by Tammy Lindemuth, and approved**
 59 **unanimously, it was:**

60
 61 **RESOLVED to accept the November 14th agenda as amended.**

	APPROVE	DENY	ABSTAIN	ABSENT
63 Leif Holm	x			
64 Richard Holt	x			
65 Phil Sanders	x			
66 Lana Bell	x			
67 Tammy Lindemuth	x			
68 James Henderson	x			
69 Sharon Long				x

70
 71
 72 The motion passed with no further discussion.

73
 74 **Agenda Item 3 Ethics Time: 1:17 p.m.**

75
 76 There were no ethics disclosures.

77
 78 **Agenda Item 4 Review/Approve Meeting Minutes Time: 1:17 p.m.**

79
 80 The board reviewed the meeting minutes from March 7 – 8, 2019 and June 27, 2019.

81
 82 **On a motion duly made by Phil Sanders to approve the March 7 – 8, 2019 and June 27, 2019**
 83 **meeting minutes as written, seconded by Lana Bell, and approved unanimously, it was:**

84

85 **RESOLVED to accept the March and June meeting minutes as written.**

86
87

	APPROVE	DENY	ABSTAIN	ABSENT
89	Leif Holm	x		
90	Richard Holt	x		
91	Phil Sanders	x		
92	Lana Bell	x		
93	Tammy Lindemuth	x		
94	James Henderson	x		
95	Sharon Long			x

96
97

The motion passed with no further discussion.

98
99

TASK 1

100 Laura Carrillo will send Chair Holt the final minutes for signature.
101 *(Pending)*

102
103

Agenda Item 5 Old Business

Time: 1:24 a.m.

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108

William “Bill” Cover with the National Association of Boards of Pharmacy (NABP) was attending in Anchorage to present to the board programs and services offered by the national association, including:

109

NABP Clearinghouse

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Mr. Cover informed the board that Clearinghouse is a national database of educational, licensure, and disciplinary information on pharmacists, wholesale drug distributors, pharmacies, pharmacy owners, technicians, interns, manufacturers, and controlled substance licenses. Mr. Cover added that any such actions can be found through the ePortal. The reporting and utilization of the Clearinghouse is part of the NABP’s constitution and bylaws, for which Alaska is a participating member. Mr. Cover added that the NABP is required by the federal government to report adverse actions to the National Practitioner Databank (NPDB), but also requires from states to report to the Clearinghouse. Chair Holt inquired if this process is done on the back end, to which Mr. Cover confirmed. Ms. Carrillo explained that the division signs an agreement allowing the NABP to act as an authorized agent for reporting, adding that she would follow-up with Marilyn Zimmerman as she was also included in earlier discussions for this service. Chair Holt also inquired whether we’re currently participating in this, to which Bill stated that the NABP staff is doing this on states’ behalf by reviewing meeting minutes then reporting to the NPDB.

123

124

DMPEPOS: Durable medical equipment, prosthetics, orthotics, and supplies accreditation

125

program.

126 Mr. Cover indicated that NABP works to ensure facilities can continue to provide durable medical
127 equipment legally and to ensure that Medicare beneficiaries receive the appropriate products,
128 services, and patient care. The program has a policy and procedures review to be submitted by the
129 facility, followed by a license verification process to ensure relevant licenses are current and active,
130 then unannounced on-site surveyor inspections to confirm the submitted policies and procedures
131 are in place.

132

133 Pre-NAPLEX

134 To help prepare applicant for the NAPLEX test experience, the NABP provides content similar
135 to the live questions. The pre-test is available online and includes 100 questions to be completed in
136 140 minutes. Mr. Cover indicated that the attempt limit is two times and must take it within seven
137 days.

138

139 VIPPS (Verified Internet Pharmacy Practice Sites Accreditation)

140 This service was launched in 1999, and Mr. Cover indicated the NABP currently tracks 10,000
141 websites that offer prescription drugs across the word. The board was informed that 95% of
142 these websites are operating are out of compliance with US laws, for example, those that provide
143 counterfeit drugs. Compliant internet pharmacies are placed on a list on their '.pharmacy' to
144 designate it as a compliant pharmacy for improved consumer awareness and patient safety. There
145 has been a number of state boards that have utilized this so that there's a guidepost of what
146 Internet pharmacies to use that are safe. Pharmacies placed on this are assessed for patient privacy,
147 security of prescription orders, quality assurance, and consultation between pharmacists and
148 patients.

149

150 Verified Pharmacy Program

151 Launched in 2012, this program was developed to fill gaps in non-resident pharmacy system and
152 provide states complete information needed to make licensing decisions. Mr. Cover stated that 48
153 states utilize VPP in some manner. Currently, this is required by Michigan for all non-resident
154 sterile compounding pharmacies and also required in other states like Virginia and Utah. Tammy
155 Lindemuth inquired what two states aren't current participating, to which Bill stated it was in
156 Hawaii and California; California does inspections themselves and Hawaii is not inspecting in-state
157 pharmacies at this time so are holding same standard to non-resident pharmacies. Bill noted that
158 the 48 number would need to be looked at further since Alaska is not currently participating
159 either.

160

161 *Christianne Carrillo left the room at 1:43 p.m.*

162 *Christianne Carrillo returned to the room at 1:45 p.m.*

163

164 Virtual wholesaler – virtual manufacturer

165 Mr. Cover stated that within last 5-10 years, the topic of "virtuals" has come into existence. The
166 common question is, why are these entities entering the supply chain? Mr. Cover stated that part
167 of it is the logistics aspect and noted that for virtual manufacturers, these individuals, firms, or
168 entities who owns the drug never physically takes possession of it within their own facility. The

169 pros were stated as: high utilization of third party logistics providers which creates the efficient
170 movement of prescription drugs across the supply chain. The cons were stated as: numerous
171 examples of virtuals that operate in a residence, which can create issues with compliance and
172 record keeping inspections. Virtuals provide opportunities for counterfeit products to be
173 introduced into the supply chain, so is the reason why states introduce regulations to better
174 monitor them. Mr. Cover further stated that virtual wholesalers are sometimes referred to as being
175 a broker, but brokers actually take possession of the drug. Federal law under DSCSA states that
176 two pharmacies can't distribute without using a wholesale drug distributor; one must be licensed
177 as a wholesale drug distributor in order to conduct business legally.

178
179 NABP Services for distributors

180 Mr. Cover indicated that VAWD is in compliance with DSCSCA, which brings a uniform
181 compliance assessment for wholesale distributors. DSCSCA changed how states can license and
182 regulate wholesale distribution of drugs; many states had wholesale drug distributors, third-party
183 logistics providers, outsourcing facilities, manufacturers, 503B facilities, etc. that were licensed
184 under one category, which conflicts with current federal law as they require distinct licenses for
185 authorized trading partners.

186
187 VAWD Accreditation

188 Mr. Cover stated that a common question is how long it takes to gain VAWD accreditation, which
189 can be in as little as 2-3 months, but generally will take 6-9 months. Now that Alaska is
190 participating in VAWD, this brings the number of states participating in this service to 47.

191
192 Wholesale Distributor Inspection (WDI) program

193 Launched in fall 2019, similar to VAWD, but is based on NABP's long established expertise and
194 experience in protecting patients. Mr. Cover stated the main difference is that there is no policy
195 and procedure remediation or in-depth transactional review required with VAWD. WDI involves
196 unannounced inspections within 8 weeks of licensure. Following a review of inspections post-
197 licensure, it was found that many wholesale distributors were not aligned with requirements in
198 terms of sanitation, compliance, and not even knowing with DCSAC is. Mr. Cover indicated that
199 one of the benefits of the program is that the results of WDI inspections can be available within
200 the existing e-Profile, and that it offers an integrity and security review. Mr. Cover then proceeded
201 to share with the board images of what results look like in the eProfile, including a screen shot of
202 business hours to see when facilities are available for inspections, schematic diagrams, and store
203 front photos.

204
205 Lana Bell inquired to Mr. Cover what the different roles are between the NABP and the
206 NNCPDP. What is the current relationship between the two between the Internet pharmacies?
207 Ms. Bell recalled that the NABP used to issue a pharmacy identification number, which NCPDP
208 now does. Mr. Cover stated that it was sold to the NCPDP about 25 years ago, and is used for
209 reimbursement and e-prescribing purposes, which that happens outside of the NABP. VPPS is
210 about pharmacies that have an online presence. Mr. Cover addressed pharmacies who attempt to
211 change their name to avoid being detected as pharmacy with disciplinary history. ACPE is

212 involved in collecting continuing education verification, then sending the information to the
 213 NABP for assignment of unique identifiers. Tammy Lindemuth inquired as to how many in-state
 214 wholesale drug distributors we currently have in Alaska, to which Chair Holt indicated, to his
 215 recollection, that we have three.

216
 217 Chair Holt reminded the board that they now regulate three new license types and to keep in mind
 218 that at present, they are accepting a self-inspection where the applicant may just be checking a
 219 box, alluding to the fact it may behoove the board to repeal the self-inspection option and instead
 220 just require the VAWD accreditation.

221
 222 **On a motion duly made by Rich Holt to authorize the National Association of Boards of**
 223 **Pharmacy (NABP) to act as the board’s agent for reporting disciplinary actions to the**
 224 **National Practitioner Databank (NPDB), seconded by Lana Bell, and approved**
 225 **unanimously, it was:**

226
 227 **RESOLVED to authorize the NABP as an adverse action reporting agent to the**
 228 **NPDBP.**

	APPROVE	DENY	ABSTAIN	ABSENT
230 Leif Holm	x			
231 Richard Holt	x			
232 Phil Sanders	x			
233 Lana Bell	x			
234 Tammy Lindemuth	x			
235 James Henderson	x			
236 Sharon Long				x

237
 238
 239 The motion passed with no further discussion.

240
 241 **TASK 2**
 242 Laura Carrillo will send Marilyn Zimmerman the signed authorized agent paperwork naming the
 243 NABP as the authorized agent of the Alaska Board of Pharmacy for reporting adverse disciplinary
 244 actions against licensure.

245 *(Pending; Laura Carrillo signed the document on 11/19/2019, which will then need to be signed by the executive*
 246 *director of the NABP)*

247
 248 **Agenda Item 7 Consent Agreements Time: 2:28 p.m.**

249
 250 *Marilyn Zimmerman entered the room at 2:28 p.m.*

251 *Marilyn Zimmerman left the room at 3:35 p.m.*
 252 Marilyn Zimmerman joined the board to discuss consent agreements and potential board actions.

254 On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), and seconded
 255 by James Henderson, the board unanimously moved to enter executive session for the
 256 purpose of discussing subjects that tend to prejudice the reputation and character of any
 257 person, provided the person may request a public discussion.

258
 259 **RESOLVED** to enter into executive session in accordance with AS 44.62.310(c)(2).

260
 261 Staff members, Laura Carrillo and Marilyn Zimmerman were authorized to remain in the room.

262
 263 *Off record for executive session at 2:35 p.m.*

264 *On record for public discussion at 3:01 p.m.*

265
 266 Chair Holt clarified for the record that no motions were made during executive session, but were
 267 ready to entertain motions.

268
 269 On a motion duly made by Rich Holt to accept the default revocation for Arielle Vargas,
 270 pharmacy technician #PHAC4905, case #2019-000308, and seconded by Lana Bell, it was:

271
 272 **RESOLVED** to accept the default revocation for pharmacy technician, Arielle
 273 Vargas.

	APPROVE	DENY	ABSTAIN	ABSENT
275 Leif Holm	x			
276 Richard Holt	x			
277 Phil Sanders	x			
278 Lana Bell	x			
279 Tammy Lindemuth	x			
280 James Henderson	x			
281 Sharon Long				x

282
 283
 284 The motion passed with no further discussion.

285
 286 On a motion duly made by Rich Holt to accept the default revocation for Kao Saelee,
 287 pharmacy technician #111460, case #2019-000307, and seconded by Lana Bell, it was:

288
 289 **RESOLVED** to accept the voluntary surrender for pharmacy technician, Kao
 290 Saelee.

	APPROVE	DENY	ABSTAIN	ABSENT
292 Leif Holm	x			
293 Richard Holt	x			

295	Phil Sanders	x	
296	Lana Bell	x	
297	Tammy Lindemuth	x	
298	James Henderson	x	
299	Sharon Long		x

300
301 The motion passed with no further discussion.

302
303 **TASK 3**

304 Rich Holt will sign the license actions for Arielle Vargas and Saelee Koa and return them to the
305 division.
306 *(Complete; Laura Carrillo forwarded the documents to Chair Holt for signature via email on 11/20/2019).*

307
308 Hearing nothing further on actions, the board returned to discussion on consent agreements to
309 address outstanding continuing education audits, which are not actually consent agreements but
310 were scheduled for discussion under this agenda item. Ms. Carrillo noted to the board that the
311 continuing education audits for Dorothy Luchansky and Merry Gregg were inadvertently closed
312 during the board’s March 7 – 8, 2019 meeting, but that their documentation was in need of further
313 review. It was also indicated to the board that Tina Horn and Joan Bittner still needed to provide
314 additional documentation; however, Ms. Zimmerman noted that Joan Bittner had since submitted
315 the outstanding documents for her audit on June 5th, 2019.

316
317 **TASK 4**

318 Marilyn Zimmerman will forward Joan Bittner’s CE documentation submitted in June, and Ms.
319 Carrillo will upload her documentation to OnBoard on November 22nd for the board’s next
320 monthly review and voting period.
321 *(Complete; Marilyn Zimmerman provided the documentation to Laura Carrillo on 11/15/2019; Laura Carrillo*
322 *will post the documentation in OnBoard by 11/21/19; audit closed 12/27/2019).*

323
324 **TASK 5**

325 Laura Carrillo will follow-up with Marilyn Zimmerman as to whether Tina Horn had since
326 completed her audit.
327 *(Complete; Marilyn Zimmerman confirmed with Laura Carrillo that Ms. Horn’s CE audit was closed in April*
328 *2019).*

329
330 **TASK 6**

331 Laura Carrillo will further assess the continuing education documents for Dorothy Luchansky and
332 Merry Gregg.
333 *(Completed on 11/20/2019; was referred for further review).*

334
335 **Agenda Item 6 Investigative Report Time: 3:01 p.m.**

336

337 *Carl Jacobs and Sonia Lipker Zimmerman entered the room at 3:01 p.m.*

338 *Carl Jacobs and Sonia Lipker Zimmerman left the room at 3:35 p.m.*

339
340 Investigator Carl Jacobs presented the investigative report, which included cases from May 22,
341 2019 to October 30, 2019. During this review period, the investigative unit opened 15 cases,
342 closed 9, and are still reviewing 3 cases. These cases included matters related to fraud or
343 misrepresentation, violation of licensing regulation, unlicensed practice or activity, application
344 falsification, unprofessional conduct, incompetence, negligence, unethical conduct, and other
345 application issues.

346 Investigator Jacobs informed the board there were three matters to review.

347
348 **On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), and seconded**
349 **by James Henderson, the board unanimously moved to enter executive session for the**
350 **purpose of discussing subjects that tend to prejudice the reputation and character of any**
351 **person, provided the person may request a public discussion.**

352
353 **RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).**

354
355 Staff members, Laura Carrillo, Carl Jacobs, and Sonia Lipker were authorized to remain in the
356 room.

357
358 *Off record for executive session at 3:10 p.m.*

359 *On record for public discussion at 3:35 p.m.*

360
361 Chair Holt clarified for the record that no motions were made during executive session, but were
362 ready to entertain motions.

363
364 **On a motion duly made by Rich Holt to accept the imposition of civil fine for Hallandale**
365 **Pharmacy, registration #PHAO1184, case #2018-001271, and seconded by Lana Bell, it**
366 **was:**

367
368 **RESOLVED to accept the imposition of civil fine for Hallandale Pharmacy.**

	APPROVE	DENY	ABSTAIN	ABSENT
370 Leif Holm	x			
371 Richard Holt	x			
372 Phil Sanders	x			
373 Lana Bell	x			
374 Tammy Lindemuth	x			
375 James Henderson	x			
376 Sharon Long				x

377
378 The motion passed with no further discussion.

379
 380 **On a motion duly made by Rich Holt to accept the imposition of civil fine for Southside**
 381 **Pharmacy 3, registration #108014, case #2019-000253, and seconded by Lana Bell, it was:**
 382

383 **RESOLVED to accept the imposition of civil fine for Southside Pharmacy 3.**
 384

	APPROVE	DENY	ABSTAIN	ABSENT
385 Leif Holm	x			
386 Richard Holt	x			
387 Phil Sanders	x			
388 Lana Bell	x			
389 Tammy Lindemuth	x			
390 James Henderson	x			
391 Sharon Long				x

392
 393
 394 The motion passed with no further discussion.
 395

396 **On a motion duly made by Rich Holt to accept the voluntary surrender for Distinguished**
 397 **Pharmaceuticals, registration #PHAO1378, case #2017-000945 and 2019-001230, and**
 398 **seconded by Lana Bell, it was:**
 399

400 **RESOLVED to accept the voluntary surrender for Distinguished Pharmaceuticals.**
 401

	APPROVE	DENY	ABSTAIN	ABSENT
402 Leif Holm	x			
403 Richard Holt	x			
404 Phil Sanders	x			
405 Lana Bell	x			
406 Tammy Lindemuth	x			
407 James Henderson	x			
408 Sharon Long				x

409
 410
 411 The motion passed with no further discussion.
 412

413 **TASK 7**

414 Rich Holt will sign the license actions for Hallandale Pharmacy, Southside Pharmacy 3, and
 415 Distinguished Pharmaceuticals, and will return them to the division.

416 *(Complete; Laura Carrillo forwarded the documents to Chair Holt for signature via email on 11/20/2019; sent*
 417 *12/05/2019).*
 418

419 **Agenda Item 9 Old Business**

Time: 3:44 p.m.

420 Hearing nothing further on actions, Chair Holt moved to addressing old business topics. Chair
421 Holt pointed the board to the March 7 – 8, 2019 meeting minutes where it was, “resolved to
422 submit to the AAG a request for input on whether the board can weigh in on a federal rule,
423 particularly the issue concerning DEA guidance on transferring of controlled substance
424 prescriptions.”

425
426 **TASK 8**

427 Ms. Carrillo will submit a request for legal opinion on whether the board can weigh in on DEA
428 guidance during an open commenting period.

429 *(Complete; Requested via deputy director on 11/22/2019, received LAW guidance on 12/11/2019).*

430
431 **Agenda Item 7 Regulation Projects (from day 2 agenda) Time: 3:48 p.m.**

432
433 The board then moved to discussing old and tabled regulation projects.

434
435 12 AAC 52.470 (Refills)

436 The board reviewed public comment on this proposal, including Chair Holt’s comment that not
437 all prescriptions are written for 30 days, for example, birth control issued for a 28 supply, or
438 creams, ointments, inhalers, issued for less than 30 days, so the board needs to consider other
439 types of prescriptions where this supply day limit may not apply. need to think about types of
440 prescriptions where this may not apply. Chair Holt suggested the board exclude prescriptions that
441 aren’t typically issued for 30 days to 90 days. Leif Holm stated the intent is to have the ability to
442 increase the days’ supply for the patients’ benefit, so working through the wording is the goal.

443
444 James Henderson inquired as to what any unintended consequences would be of amending this
445 section, to which Chair Holt Rich stated there would be consequence of having to again amend
446 this section once the board is able to regulate nationally certified technicians. Mr. Henderson
447 further inquired whether the change is needed since the actions must be done under the direct
448 supervision of the pharmacist, regardless of whether it’s a technician or an intern. The board
449 discussed it may not be necessary to specifically name technicians and interns since they’re already
450 required to perform under the supervision of a pharmacist.

451
452 **On a motion duly made by Rich Holt, to amend 12 AAC 52.470(d), seconded by Lana Bell**
453 **and approved unanimously to read , “the pharmacist, nationally certified pharmacy**
454 **technician or pharmacist intern may dispense any quantity of drug on an original or refill**
455 **prescription drug order so long as the 1.) total quantity of dosage units dispensed does not**
456 **exceed the total quantity of dosage units authorized by the prescriber on the prescription**
457 **drug order, including refills; and 2.) the drug is not a federal or state scheduled controlled**
458 **substance.” it was:**

459
460 **RESOLVED to amend 12 AAC 52.470(d).**

461
462

APPROVE	DENY	ABSTAIN	ABSENT
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463	Leif Holm	x	
464	Richard Holt	x	
465	Phil Sanders	x	
466	Lana Bell	x	
467	Tammy Lindemuth	x	
468	James Henderson	x	
469	Sharon Long		x

470

471 The motion passed with no further discussion.

472

473 **TASK 9**

474 Laura Carrillo will forward the board’s proposed amendment to 12 AAC 52.470(d) and associated
 475 regulations FAQ relating to refills to the publications specialist for cursory review by the
 476 Department of Law.

477 *(Complete; Ms. Carrillo completed the regulations FAQ for this section on 11/20/2019).*

478

479 **Agenda Item 5 PDMP Update Time: 4:02 p.m.**

480

481 Enhancements

482 Ms. Carrillo discussed NarxCare, license integration, the compliance module, RxCheck, and
 483 clinical alerts. She also reviewed the board’s PDMP report, which indicates at least 100%
 484 compliance with mandatory registration, noting that pharmacists have the highest registration and
 485 use compliance rate among all provider types required to register with the PDMP despite being
 486 the only profession not required to perform patient queries. The full report can be found at:
 487 [https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/PrescriptionDrugMonitoring](https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/PrescriptionDrugMonitoringProgram/PDMPBoardReports.aspx)
 488 [gProgram/PDMPBoardReports.aspx](https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/PrescriptionDrugMonitoringProgram/PDMPBoardReports.aspx)

489

490 Military PDMP

491 Ms. Carrillo informed the board that the military launched their own PDMP in December and that
 492 continued efforts are underway to determine how military providers will register since there are a
 493 number of military prescribers and dispensers already registered with the state PDMP.

494

495 Grants

496 Ms. Carrillo also discussed the current grants from the Bureau of Justice Administration, the
 497 Centers for Disease Control and Prevention (CDC), and an upcoming grant to implement the
 498 Medicaid Support Act.

499

500 Staffing

501 Ms. Bell inquired as to what the status was with staffing. Ms. Carrillo informed the board that the
 502 division was actively recruiting to fill the PDMP manager and occupational licensing examiner
 503 position.

504

505 **Agenda Item 10** **Recess**

Time: 4:16 p.m.

506
507 Chair Holt motioned to recess until November 15th at 9:15 a.m. The board went off record at 4:16
508 p.m.
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545 State of Alaska
546 Department of Commerce, Community and Economic Development
547 Division of Corporations, Business and Professional Licensing

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549 Alaska Board of Pharmacy

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551 FINAL MINUTES OF THE MEETING

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553 November 14 - 15 - In-Person and Teleconference via OnBoard

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555 By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62,
556 Article 6, a scheduled meeting of the Board of Pharmacy was held in-person at the
557 Robert Atwood Building, Suite 1550 in Anchorage, Alaska and at the State Office
558 Building, 9th Floor, Conference Room A in Juneau, Alaska on November 14 and
559 15, 2019.

560
561 These are draft minutes that have not yet been approved by the board.

562
563 Agenda Item 1 Call to Order/Roll Call Time: 9:17 a.m.

564
565 The November 15, 2019 meeting day was called to order by Chair, Rich Holt at 9:17 a.m.

566
567 Board members present, constituting a quorum:

568
569 Richard Holt, PharmD #PHAP2008, MBA – *Chair*
570 Leif Holm, PharmD #PHAP1606 (via telephone)
571 Phil Sanders, RPh #PHAP776 (via telephone)
572 James Henderson, RPh #PHAP1683 (via telephone)
573 Lana Bell, RPh #PHAP893
574 Tammy Lindemuth, Public Member
575 Sharon Long, Public Member (Absent)

576
577 Division staff present:

578
579 Laura Carrillo, Executive Administrator

580
581 Members from the public present:

582
583 Adam Chelser, Cardinal Health (via phone)
584 Molly Gray, (Alaska Pharmacy Association; in Anchorage)

585
586 Agenda Item 2 Review/Approve Agenda Time: 9:20 p.m.

587 The board reviewed the agenda for day 2. Chair Holt noted to the board that agenda item #5
588 would be struck as the board reviewed those comments during their June 27th, 2019 meeting.
589 Chair Holt also noted that public comment would be entertained at 10:40 a.m.

590
591 **On a motion duly made by Lana Bell to approve the day 2 meeting minutes as amended,**
592 **seconded by Tammy, and approved unanimously, it was:**

593
594 **RESOLVED to accept the day 2 agenda as amended.**

	APPROVE	DENY	ABSTAIN	ABSENT
597 Leif Holm	x			
598 Richard Holt	x			
599 Phil Sanders	x			
600 Lana Bell	x			
601 Tammy Lindemuth	x			
602 James Henderson	x			
603 Sharon Long				x

604
605 The motion passed with no further discussion.

606
607 **Agenda Item 3 Implemented Regulations**

Time: 9:22 p.m.

608
609 Ms. Carrillo pointed the board to their packet on the new regulations that went into effect on
610 10/31/19, which included regulations for non-resident wholesale drug distributors, outsourcing
611 facilities, and third-party logistics providers. The board was informed that the applications for
612 these new license types were posted on 10/25/19, and that the board has since received 3
613 applications for non-resident wholesale drug distributors, and 1 application from an outsourcing
614 facility. Ms. Carrillo also informed the board that the Indian Health Service Exemption form was
615 also created and is currently posted. Ms. Carrillo then addressed the new FAQs document and
616 asked the board for input.

617
618 Question #1: I am already registered in Alaska as an out-of-state pharmacy. Do I need to maintain
619 my non-resident pharmacy registration in addition to obtaining an outsourcing facility, third-party
620 logistics (3PL), or non-resident wholesale drug distributor license?

621 Chair Holt commented that this answer needs to be clarified such that applicants/licensees know a
622 separate application and license is required if the facility operates distinct but concurrent lines of
623 business. For example, if an out-of-state pharmacy is already registered in Alaska, the way the
624 current answer reads seems to imply that if the same facility also operates as an outsourcing
625 facility, a new registration wouldn't be required. The board agreed and Ms. Carrillo indicated she
626 would make this correction.

627
628 Question #3: What is the business license versus the professional license?

629 James Henderson commented that the first sentence should read, "...from the board" rather than
630 "by the board."

631

632 Question #17: We are an outsourcing facility intending on compounding patient-specific
633 prescriptions. Is this permissible in Alaska?

634 Chair Holt commented that the Good Compounding Practices published in 2008 have also been
635 adopted by reference in regulation, which should be stated in this answer.

636

637 **TASK 10**

638 Laura Carrillo will amend question #1 of the new license type FAQs initially dated 11-05-19 to
639 clarify that facilities engaged in separate lines of business must obtain a license for the respective
640 licensing category, e.g.: an out-of-state pharmacy also operating as an outsourcing facility.

641 *(Complete; Ms. Carrillo amended the response to this question and forwarded the updated document to the division's*
642 *publications specialist for posting on 11/20/2019).*

643

644 **TASK 11**

645 Laura Carrillo will amend question #3 of the new license type FAQs initially dated 11-05-19 to
646 clarify that facilities obtain the professional license from the board.

647 *(Complete; Ms. Carrillo amended the response to this question and forwarded the updated document to the division's*
648 *publications specialist for posting on 11/20/2019).*

649

650 **TASK 12**

651 Laura Carrillo will amend question #17 of the new license type FAQs initially dated 11-05-19 to
652 mention 12 AAC 52.440, which is the section formally adopting Good Compounding Practices.

653 *(Complete; Ms. Carrillo amended the response to this question and forwarded the updated document to the division's*
654 *publications specialist for posting on 11/20/2019).*

655

656 **Agenda Item 4 Division Update/Board Report**

Time: 9:34 a.m.

657

658 *Sharon Walsh joined the room at 9:30 a.m.*

659 *Sharon Walsh left the room at 9:48a.m.*

660

661 Right-touch regulation

662 Deputy Director, Sharon Walsh, joined the board to provide the division's deregulation
663 presentation. Deputy director Walsh reminded the board that the division director, Sara
664 Chambers, had sent out a memo back in July informing boards to start thinking about professional
665 licensing reform. The main idea of this presentation was for boards to create a more streamlined
666 application process, to identify inefficiencies, and discuss/remove outdated regulations. Chair Holt
667 expressed that the board is currently doing this, for example, passing regulations allowing the
668 executive administrator to review and approve applications where there is no adverse disciplinary
669 or criminal history associated with the applicant. Ms. Carrillo added that she has been maintaining
670 a running list of outdated or unnecessary regulations, and suggested the board form a workgroup
671 or subcommittee to further discuss this. Tammy inquired whether her understanding is correct in

672 that the subcommittee meet, then present the findings to the board, who ultimately makes the
673 decision, to which Ms. Carrillo indicated the understanding was correct. Phil Sanders expressed his
674 support of forming a subcommittee. Lana Bell recommended the board chair choose a member.
675

676 Budget report

677 The board addressed the board’s budget report, to which deputy director Sharon Walsh indicated
678 she would be happy to provide this to them, but would need some time to review. Ms. Carrillo
679 indicated she would email the report to Ms. Walsh, who would review and then return to present
680 their budget report to the board.

681
682 Chair Holt called for break at 10:00 a.m.
683

684 *Off record at 10:00 a.m.*

685 *On record at 10:20 a.m.*
686

687 **On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and approved**
688 **unanimously to form a subcommittee consisting of Rich Holt and Tammy Lindemuth to**
689 **evaluate the ideas for redundant or unnecessary statutes/regulations to conform to the**
690 **right-touch regulations performed by Deputy director Sharon Walsh, it was:**

691
692 **RESOLVED to form a subcommittee consisting of Rich Holt and Tammy**
693 **Lindemuth to further the board’s progress on creating regulatory efficiencies.**
694

695

	APPROVE	DENY	ABSTAIN	ABSENT
696 Leif Holm	x			
697 Richard Holt	x			
698 Phil Sanders	x			
699 Lana Bell	x			
700 Tammy Lindemuth	x			
701 James Henderson	x			
702 Sharon Long				x

703
704 The motion passed with no further discussion.
705

706 **TASK 13**

707 Ms. Carrillo will forward the document titled, “Ideas for Redundant or Unnecessary Regulations.”
708 to Rich Holt and Tammy Lindemuth to assist their subcommittee’s right-touch regulation
709 discussion.

710 *(Complete; Ms. Carrillo forwarded this document on 11/20/19 along with the right-touch regulation workbook*
711 *and clarification on public noticing a subcommittee).*
712

713 **Agenda Item 11 CSAC Update**

Time: 10:20 a.m.

714 Tammy Lindemuth presented her update for the Controlled Substance Advisory Committee
715 (CSAC). Ms. Lindemuth reminded the board and advised the public that as of the board's March
716 2019 meeting, she was designated as the board's chair of the CSAC. Rob Henderson with
717 Department of Law was previously in charge of the meeting because LAW houses the resources
718 for scheduling. Rebecca Cain from Dept. of Law informed Tammy that Cat Reynolds would assist
719 with scheduling. Tammy reached out to Cat Reynolds for assistance but has not heard back. Ms.
720 Carrillo indicated to the board that the legislative change didn't affect AS 08.80 that would
721 otherwise provide the board with resources adequate for scheduling and note taking. Ms. Carrillo
722 inquired as to when the CSAC last met, to which Ms. Bell indicated in was in July 2018.

723

724 **TASK 14**

725 Laura Carrillo will ask director Chambers to reach out to Rebecca Cain at the Dept. of Law to
726 inquire what the status of the CSAC is as it's been difficult to convene. Laura Carrillo will also
727 reach out to Shiloh Werner, who is the last secretary associated with writing the meeting minutes
728 for the CSAC at their last meeting on July 16, 2018.

729 *(Complete; Ms. Carrillo requested follow-up with Department of Law through director Chambers and deputy*
730 *director Walsh via email on 11/20/19; Shiloh Werner is no longer listed as a contact; division director's secretary*
731 *reached out to the department of law on 11/21/219).*

732

733 **Agenda Item 4 Division Update/Board Report Time: 10:30 a.m.**

734

735 *Sharon Walsh joined the room at 10:26 a.m.*

736 *Sharon Walsh left the room at 10:50 a.m.*

737

738 Deputy director Walsh again joined the room to present the board's budget report for FY19
739 Quarter 4. Ms. Walsh informed the board that their cumulative surplus is more than expenditures,
740 adding that there seemed to be a concern with their revenues as indicated by a requested fee
741 analysis. Ms. Walsh added that the total revenue was \$1,016,259 and that the total direct
742 expenditures was \$613,280. Total direct expenditures: 613,280k total direct expenditures. It was
743 noted that from the 2016 – 2017 biennium to the 2018 – 2019 biennium, the board saw an
744 increase in total revenue of \$2,000. It was also noted that there was a decrease in investigative
745 expenditures by about \$19,000 from 2016 – 2017 to 2018, but that there was an increase in
746 indirect expenditures by \$118,000. Lana Bell inquired as to what these indirect expenditures costs,
747 to which Ms. Walsh stated it could include real estate costs paid to the department of
748 administration, IT charges, and admin expenses. Lana Bell inquired whether IT services for
749 managing the PDMP is driving that cost upwards, to which Ms. Carrillo stated it likely isn't
750 because Appriss Health is our subcontractor and manages the system for us. Ms. Walsh indicated
751 these costs can change and is not always known to the division.

752

753 Leif Holm commented that seems to be a reoccurring theme of indirect expenditures and how the
754 board never really understands this, and expressed the need for the board to have more clear
755 information on this. Chair Holt inquired as to which categories contribute to the indirect
756 expenditures. Sharon Walsh indicated she would look into what these are on the object code. Lana

757 stated it's difficult to have a discussion on the budget because there's no control of what
758 contributes to their budget trends. Chair Holt advised the board to remember the new applications
759 just went into effect, which will elevate the board's revenue over time. Ms. Bell commented that
760 the board has made sacrifices to lower costs, for example, not meeting face-to-face, which has
761 brought its own challenges, such as Internet and connection issues, but that it would be helpful to
762 discussions to know what exact costs are driving the board to lose money.

763
764 **Agenda Item 6 Public Comment Time: 10:50 a.m.**

765
766 Molly Gray commented on the important need to hold a public comment period and concerns
767 from the public that this was being limited. Ms. Gray also invited a board member to present at
768 their upcoming annual convention in February.

769
770 Daniel Nelson commented on how the board of pharmacy is addressing the opioid epidemic, in
771 part how they were responding to the recent high-profile arrests due to negligent opioid
772 prescribing practices. Mr. Nelson commented that prescriptions have been filled for years and that
773 they have the corresponding responsibility to ensure prescriptions are dispensed per DEA
774 guidelines and board law. Mr. Nelson then commented on the pharmacist letter from January as
775 well as the press-release in which he expressed the delivery was in a heavy-handed manner. The
776 message that was conveyed seem to state loud and clear that pharmacists are not doctors, and that
777 they must fill the prescriptions or place their license in jeopardy, which led pharmacists to fill
778 prescriptions they weren't comfortable with. Mr. Nelson added that we need to work together
779 with prescribing boards to address this. Finally, Mr. Nelson reiterated the importance of holding
780 public comment.

781
782 Ms. Carrillo commented that she has been working with prescribing boards since January 2019 to
783 come up with a joint statement to release, adding that there's been input from the dental board
784 and the nursing board. The joint statement from July can be found at pdmp.alaska.gov, but the
785 finalized version is currently being worked on.

786
787 Chair Holt addressed the letters sent in January 2019 and reiterated that the corresponding
788 responsibility is a federal law, since the board of pharmacy can't tell pharmacists whether or not to
789 dispensed. Ms. Bell stated the feedback she received on this letter was positive. Ms. Lindemuth
790 acknowledge the importance of public comment and would be sure to include this moving
791 forward.

792
793 **Agenda Item 7 Regulation Projects Time: 10:50 a.m.**

794
795 The board then moved to discussing tabled regulations from previous meetings.

796
797 12 AAC 52.095(d)(8) – Application for pharmacist license by reciprocity

798 The board discussed accepting electronic primary source verification in lieu of accepting a
799 verification on form provided by the department. Ms. Carrillo stated that states are moving to
800 align with this trend to be more proactive and accommodate different verification sources.

801
802 12 AAC 52.865(b) – Reporting and reviewing PDMP information
803 The board considered making an explicit change to include zero reporting to clarify for
804 pharmacies that days in which there were no dispensations for federally scheduled II – IV
805 controlled substances must still be reported to the PDMP as a “zero report”. Ms. Bell and Mr.
806 Sanders indicated this may be challenging for those pharmacies who must submit manually,
807 especially on days in which they are closed for business on weekends. Ms. Carrillo pointed to the
808 time computation in (e), which excludes weekends. Chair Holt added that it also excludes holidays.
809 Ms. Bell stated it could be very problematic for smaller pharmacies that don’t have automatic
810 reporting systems.

811
812 12 AAC 52.423(d) - Remote pharmacy license
813 The board discussed adding a new subsection (d) addressing the telemedicine business registry.
814 Ms. Carrillo explained that the telemedicine business registry is simply a request for placement to
815 be on the registry. The introduction of this section is a solution to close the loop with the
816 requirements that went into effect following the telemedicine legislation in June 2016. To be
817 placed on the registry, the pharmacy must have a professional license and business license. Ms.
818 Bell inquired whether this helped to assist Mr. Holm in his remote pharmacy. Mr. Holm indicated
819 the regulations took too long to be effective, but the issue was more so related to insurance
820 reimbursements. Mr. Holm also added that patients had very positive experience with accessibility
821 to a remote pharmacy. Ms. Bell then inquired whether it’s necessary for a pharmacist to be on site
822 if there’s another pharmacy that can be open.

823
824 12 AAC 52.140(b)(1)(3) and (6) – Pharmacy technician license
825 (b)(1): Chair Holt indicated to the board that the proposed amendment isn’t a substantive change
826 but just a change to require the application to be notarized.
827 (b)(3): Chair Holt indicated there was an individual who didn’t graduate with a diploma so wasn’t
828 issued a license. Ms. Lindemuth indicated that the GED is recognized as the equivalent to the high
829 school diploma; “its equivalent” is proposed to be struck. Ms. Carrillo inquired to the board why
830 “equivalent” would be struck, particularly for foreign pharmacy technician applicants as their
831 country may not recognize GEDs. Mr. Sanders inquired as to whether there is an accepted list of
832 equivalent programs, to which Chair Holt indicated there was not. Ms. Bell recommended the
833 language, “high school diploma, GED, or secondary education equivalent”. Mr. Henderson
834 recommended adding, “or board approved equivalent.” Ms. Carrillo inquired as to whether a
835 nationally certified technician credential could be included in this proposed section in lieu of a
836 high school diploma or equivalent, to which Chair Holt indicated this section shouldn’t be too
837 specific. The board continued to discuss how this should be amended for inclusivity.
838 (b)(6): the proposed amendment was to require affidavits good moral character consistent with
839 application requirements for other license types. The board agreed with this proposal.

840

841 **TASK 15**

842 Rich Holt will come up with language for the proposed section, 12 AAC 52.140(b)(3), relating to
843 post-secondary education.

844 *(Pending)*.

845

846 12 AAC 52.230(c)(e)(g)(h) – Pharmacy technicians

847 (e): Ms. Bell suggested that “regularly” be struck since the board doesn’t define this term.

848 (g): Chair Holt commented that just because someone passed the certification with no experience,
849 it doesn’t necessarily mean they’re an ideal or competent candidate, so it was proposed to add
850 experience requirements. Mr. Holm stated that it’s still up to the pharmacist as to what the
851 technician can do, and added that with the hours requirement, if a matter was looked at from a
852 liability standpoint, it would be a good idea to have a minimum standard for experience hours. Mr.
853 Henderson and Ms. Lindemuth opined the amendment would provide a good safety measure. Mr.
854 Holm stated on the other hand, it may seem arbitrary and the board may not be able to justify this
855 requirement, to which Mr. Sanders agreed, adding someone could be technically qualified but not
856 practically qualified. James stated that in (f), since there’s a 40-hour requirement for compounding
857 sterile pharmaceuticals, the board could propose a minimum hour-requirement for non-sterile
858 compounding.

859

860 **On a motion duly made by Lana Bell to strike the word “regularly” in 12 AAC 52.230(e),**
861 **seconded by Tammy Lindemuth, and approved unanimously, it was:**

862

863 **RESOLVED to amend strike the proposed amendments to 12 AAC 52.230(e),**

864

	APPROVE	DENY	ABSTAIN	ABSENT
865 Leif Holm	x			
866 Richard Holt	x			
867 Phil Sanders	x			
868 Lana Bell	x			
869 Tammy Lindemuth	x			
870 James Henderson	x			
871 Sharon Long				x

872

873 The motion passed with no further discussion.

874

875
876 **On a motion duly made by Lana Bell to strike 12 AAC 52.230(f), seconded by Tammy**
877 **Lindemuth, and approved unanimously, it was:**

878

879 **RESOLVED to repeal 12 AAC 52.230(f) relating to pharmacy technicians’ involvement in**
880 **preparation of sterile pharmaceuticals.**

881

	APPROVE	DENY	ABSTAIN	ABSENT
--	---------	------	---------	--------

882

883	Leif Holm	x	
884	Richard Holt	x	
885	Phil Sanders	x	
886	Lana Bell	x	
887	Tammy Lindemuth	x	
888	James Henderson	x	
889	Sharon Long		x

890
891 The motion passed with no further discussion.

892
893 **On a motion duly made by Lana Bell to strike 12 AAC 52.230(g)(h) of the proposed**
894 **amendments, seconded by Tammy Lindemuth and approved unanimously, it was:**

895
896 **RESOLVED to amend strike the proposed amendments to 12 AAC 52.470(g)(h).**

	APPROVE	DENY	ABSTAIN	ABSENT
899	Leif Holm	x		
900	Richard Holt	x		
901	Phil Sanders	x		
902	Lana Bell	x		
903	Tammy Lindemuth	x		
904	James Henderson	x		
905	Sharon Long			x

906
907 Further discussion: Mr. Henderson inquired whether it is mentioned elsewhere in the regulations
908 that technicians must conspicuously display their license, suggesting that it might be most
909 appropriate to transfer that section under 12 AAC 52.230(e). Chair Holt added that the display of
910 licensure is under 12 AAC 52.990.

911
912 **TASK 16**
913 Rich Holt will rewrite the verbiage relating to conspicuous display of pharmacy technician
914 licensure under 12 AAC 52.990 for board consideration for placement elsewhere.
915 *(Pending).*

916
917 Chair Holt called for break at 12:00 p.m.

918
919 *Off record at 12:00 p.m.*
920 *On record at 12:08 p.m.*

921
922 The board returned to discussion on regulation projects. Chair Holt returned to discussion on 12
923 AAC 52.230(f), asking for confirmation on the board that repealing this section would not impact

924 ability of technician to do sterile compounding because the regulation states “all personnel
925 participating in sterile compounding” and does not specify or limit which type of roles can
926 participate.

927
928 12 AAC 52.235(a)(b)(c)(d)(e) – Approved nationally certified pharmacy technician functions (new
929 section)

930 Chair Holt moved to discussion on a proposed new regulation for national certified pharmacy
931 technicians.

932 (a)(1): Reword to read, “A pharmacy technician who holds a national certification, working under
933 the direct supervision of a pharmacist, may perform a final check and dispense a non-controlled
934 substance prescription...”

935 (a)(2): Chair Holt inquired whether Mr. Sanders had input on the ability for these nationally
936 certified technicians to clarify certain details of a prescription order. Ms. Carrillo inquired whether
937 the Department of Law has provided feedback on whether the board could regulate nationally
938 certified technicians? The reason Ms. Carrillo asked is because the medical board had to go
939 through legislative efforts to regulate nationally certified medical assistance, and the bill didn’t
940 pass. Chair Holt stated this was initiated in 2016 and that the initial thought process is that the
941 proposal isn’t to regulate a new licensing category as they’re already regulated as pharmacy
942 technicians, but the board just wants to propose what they are able to do once licensed. Mr.
943 Sanders inquired whether it would be clearer for Department of Law to use the term, “licensed
944 pharmacy technician who is a nationally certified technician,” that way it’s not perceived as a new
945 licensing class. Mr. Holm expressed his opposition to allowing these technicians to clarify all
946 details, including performing the final check, adding it makes little sense

947 (a)(4): Mr. Holm inquired why they would be able to transfer a prescription drug order but not
948 receive it, to which Chair Holt referred to the definition of “dispenser” under AS 08.80.480(8),
949 suggesting it provides the authority to only prepare and deliver a prescription drug order, not
950 receive it. Chair Holt stated the board would return to this discussion after lunch.

951 (b): No proposed changes or discussion.

952 (c): Chair Holt stated that this section mirrors the intern regulations. No proposed changes or
953 discussion.

954 (d): Ms. Carrillo, Phil Sanders, and Chair Holt discussed rewording this to read, “A nationally
955 certified pharmacy technician may perform all the duties of a pharmacy technician. A pharmacy
956 technician who does not hold a national certification may not perform the duties in (a) and (b)
957 above.”

958
959 Chair holt called for lunch at 12:32 p.m. and asked to return from lunch at 1:30 p.m.

960
961 *Off record at 12:32 p.m. for lunch.*

962 *Back on record at 1:32 p.m.*

963
964 Upon return from lunch, the board again addressed the proposed changes to 12 AAC 52.235,
965 specifically subsection (4).

966

967 12 AAC 52.235(a)(4) – Approved nationally certified pharmacy technician functions (new section)
 968 Mr. Holm stated he didn't understand why the board would be amenable to allowing nationally
 969 certified pharmacy technicians to transfer a prescription to another pharmacy but won't allow
 970 them receive a transfer. Mr. Henderson stated that at least one pharmacist must be involved in the
 971 transfer. Chair Holt addressed concerns about writing the prescription order details down
 972 incorrectly, but Mr. Holm stated the most negative consequence and issue to consider is that we're
 973 placing confidence in them to review and ultimately dispense a prescription but are not confident
 974 in their ability receive the prescription. The board continued to discuss this topic before making a
 975 motion.

976
 977 **TASK 17**

978 Ms. Carrillo will add a new FAQ to the website addressing the delegation of sending and receiving
 979 a non-controlled substance prescription drug order, citing the board's intent to establish a new
 980 section for nationally certified technicians and participating in the transfer of prescription drug
 981 orders.

982 *(Complete; Ms. Carrillo forwarded the verbiage for this new FAQ to the publications specialist on 11/21/19).*
 983

984 12 AAC 52.210 – Pharmacist duties

985 (6): This section is proposed to strike, “making a final check on all aspects of a completed
 986 prescription...” leaving only, “assuming the responsibility for a filled prescription. This change in
 987 effect would allow delegation of duties associated with some aspects of checking prescription
 988 orders to nationally certified technicians. Ms. Bell commented she would not feel comfortable
 989 taking responsibility for prescriptions checked and ultimately filled by a technician. Mr. Holm
 990 commented again on the logic as to why we would allow these technicians to perform the final
 991 check but not receive a transferred prescription order. Chair Holt agreed.

992
 993 12 AAC 52.235(a)(4) – Approved nationally certified pharmacy technician functions (new section)

994 The board then returned to the proposed change to 12 AAC 52.235(a)(4).
 995

996 **On a motion duly made by Lana Bell, seconded by Tammy Lindemuth, and approved**
 997 **unanimously to ascertain the board's position on moving forward with addressing non-**
 998 **controlled substances under the proposed new section, 12 AAC 52.235(a)(4), it was:**
 999

1000 **RESOLVED to propose a new subsection, 12 AAC 52.235(a)(4) addressing the**
 1001 **transfer of non-controlled substances for nationally certified technicians.**
 1002

	APPROVE	DENY	ABSTAIN	ABSENT
1004 Leif Holm	x			
1005 Richard Holt	x			
1006 Phil Sanders	x			
1007 Lana Bell	x			
1008 Tammy Lindemuth	x			

1009	James Henderson	x		
1010	Sharon Long			x

1011
1012 No further discussion.

1013
1014 **On a motion duly made by Rich Holt and seconded by Tammy Lindemuth to accept the**
1015 **proposed changes to the new subsection 12 AAC 52.235(a)(4) to read, “Transfer a non-**
1016 **controlled substance prescription drug order in accordance with 12 AAC 52.500.” it was:**

1017
1018 **RESOLVED to propose a new subsection, 12 AAC 52.235(a)(4).**

	APPROVE	DENY	ABSTAIN	ABSENT
1021	Leif Holm	x		
1022	Richard Holt	x		
1023	Phil Sanders		x	
1024	Lana Bell		x	
1025	Tammy Lindemuth	x		
1026	James Henderson	x		
1027	Sharon Long			x

1028
1029 Further discussion: Mr. Holm indicated that the participation should be on both sides, and
1030 expressed the board address the ability for nationally certified technicians to also receive
1031 prescription transfers. Chair Holt clarified that this section is to be interpreted as allowing
1032 participating in all aspects, sending and receiving, of a transfer. Ms. Lindemuth inquired as to what
1033 the difference is between the transfer of controlled vs. non-controlled substances, to which Chair
1034 Holt indicated it ultimately comes down to diversion. Chair Holt commented that states vary in
1035 their scope and limitations for allowing nationally certified technicians to participate in all aspects
1036 of transferring prescription drug order.

1037
1038 12 AAC 52.210 – Pharmacist duties

1039 The board then returned to discussion the proposed changes to pharmacist duties.
1040 (7): This section is proposed to strike, “consulting with a patient or a patient’s agent regarding a
1041 prescription or information contained in the patient medication record system.” There was no
1042 opposition to this proposal.

1043
1044 **On a motion duly made by Rich Holt and seconded by Tammy Lindemuth to accept the**
1045 **proposed changes to 12 AAC 52.210 to read, “...Except as provided in 12 AAC 52.220 and**
1046 **12 AAC 52.235, the following duties may be performed only by a pharmacist: (1) receiving**
1047 **an oral prescription drug order from a practitioner or authorized agent of a practitioner;**
1048 **(2) consulting with a patient in accordance with 12 AAC 52.585; (3) independent**
1049 **prescribing of a prescription drug order for vaccines, related emergency medications, or**
1050 **opioid overdose drugs in accordance with 12 AAC 52.992 and 12 AAC 52.994; (4)**

1051 determining the product substitution required for a prescription in accordance with 12
 1052 AAC 52.510; (5) interpreting drug regimen review data in accordance with 12 AAC 52.570;
 1053 and (6) assuming the responsibility for a filled prescription.” it was:
 1054

1055 **RESOLVED** to accept the proposed amendments to 12 AAC 52.210.
 1056

	APPROVE	DENY	ABSTAIN	ABSENT
1057 Leif Holm	x			
1058 Richard Holt	x			
1059 Phil Sanders		x		
1060 Lana Bell		x		
1061 Tammy Lindemuth	x			
1062 James Henderson	x			
1063 Sharon Long				x

1064
 1065
 1066 No further discussion.
 1067

1068 **TASK 18**

1069 Ms. Carrillo complete the regulation FAQs document for all proposed amendments and will
 1070 submit the regulation project to the regulations specialist for cursory review by law.
 1071 *(Complete; the regulation packet was sent to Department of Law on 01/22/2020)*
 1072

1073 Ownership percentage

1074 Ms. Carrillo commented that the board receives frequent questions relating to what constitutes an
 1075 ownership change. Chair Holt informed the board of a scenario in which an individual was
 1076 gradually purchasing a percentage of the company stock over a period of years until 100% of the
 1077 company was acquired. Ms. Lindemuth suggested it would be once there’s 100% acquired. Ms.
 1078 Carrillo inquired to the board whether they should define “pharmacy ownership” under 12 AAC
 1079 52.995, then accordingly update the change of ownership section, 12 AAC 52.40 to specify what
 1080 constitutes majority ownership. Chair Holt stated it doesn’t make sense for an individual, who for
 1081 example, is acquiring 10% of the facility every year, to submit the change of ownership paperwork
 1082 at each percentage of additional acquisition, which requires a brand-new application. Mr. Sanders
 1083 suggested defining ownership as acquisition of more than 50% of the company, which he stated is
 1084 consistent with corporation tax law, and makes sense when there are multiple owners involved.
 1085 Ms. Bell commented that ownership changes may be most appropriately addressed by a legal
 1086 opinion. Ms. Carrillo commented that the topic of ownership changes has been discussed and
 1087 determined at the division level previously with the corporations and business licensing section,
 1088 such as whether a change of ownership occurring at the tertiary or grandparent level constitutes a
 1089 change.
 1090

1091 *James Henderson left the room at 2:26 p.m.*

1092 *James Henderson joined the room at 2:26 p.m.*

1093 On a motion duly made by Rich Holt and seconded by Tammy Lindemuth to Add a new
 1094 definition to 12 AAC 52.995 for “Pharmacy ownership,” which means the majority of
 1095 ownership, to also amend 12 AAC 52.040 by changing the title to, “Change of Pharmacy or
 1096 Facility Ownership,” and also to amend (b) to say, “a change in ownership that meets the
 1097 definition outlined in 12 AAC 52.995 requires a new and separate pharmacy or facility
 1098 license or registration in accordance with 12 AAC 52.020,” it was:

1100 **RESOLVED** to create a new definition for pharmacy ownership under 12 AAC
 1101 52.995 and amend the change of pharmacy ownership section in 12 AAC 52.040.

	APPROVE	DENY	ABSTAIN	ABSENT
1104 Leif Holm	x			
1105 Richard Holt	x			
1106 Phil Sanders	x			
1107 Lana Bell	x			
1108 Tammy Lindemuth	x			
1109 James Henderson				x
1110 Sharon Long				x

1111
 1112 No further discussion.

1113
 1114 12 AAC 52.423 – Remote pharmacy

1115 Ms. Carrillo reminded the board that the previous section (e) was repealed such that remote
 1116 pharmacies can be renewed if there is a central pharmacy operating within 10 miles, but that
 1117 subsection (b)(2) still states a remote pharmacy can’t operate if there’s an existing pharmacy within
 1118 10 miles. Citing the North Carolina Dental Board case, Ms. Carrillo described the board having
 1119 issued cease and desist letters to teeth whiteners at the mall without due process, who were then
 1120 held liable for violating anti-trust laws. Ms. Carrillo inquired whether the board might consider
 1121 how this restriction could affect other businesses. Mr. Holm commented that when the regulations
 1122 were first put in place, technology was a lot different; the restriction was more so for patient
 1123 safety, and the technology was to be put in place for areas that truly needed the services. The
 1124 board ultimately decided to table this for discussion until the next meeting.

1125
 1126 **TASK 19**

1127 Ms. Carrillo will add 12 AAC 52.423 to the agenda for the next meeting.

1128 *(Complete).*

1129
 1130 Chair Holt called at 3:07 p.m.

1131
 1132 *Off record at 3:07 p.m.*

1133 *On record at 3:15 p.m.*

1134

1135 **Agenda Item 10** **Board Business**

Time: 3:15 p.m.

1136

1137 Review of lost/stolen Rx

1138 The board began review of lost or stolen controlled substances on DEA form #106. Ms. Carrillo
1139 inquired what the board's purpose is of reviewing these if there are no actions taken, and the form
1140 is required to be submitted to the DEA anyway. The board expressed that if there is a pattern of
1141 losing prescriptions, this should be looked into; however, Ms. Carrillo indicated that these patterns
1142 and quantities of lost or stolen prescriptions are not tracked over time. Chair Holt indicated he
1143 doesn't recall there being an investigation as a result of concerning DEA #106 forms, but would
1144 like these matters to be pursued further.

1145

1146 **TASK 20**

1147 Ms. Carrillo will reach out to CARRS Pharmacy #1805, license #12114, for additional details
1148 relating to the three thefts/losses the facility reported on their DEA #106 form.
1149 *(Completed 01/30/2020).*

1150

1151 Review applications

1152 The board did not review or vote on approving any application during this meeting.

1153

1154 **On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), and seconded**
1155 **by James Henderson, the board unanimously moved to enter executive session for the**
1156 **purpose of discussing subjects that tend to prejudice the reputation and character of any**
1157 **person, provided the person may request a public discussion.**

1158

1159 **RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).**

1160

1161 Staff member, Laura Carrillo was authorized to remain in the room.

1162

1163 *Off record for executive session at 3:35 p.m.*

1164 *On record for public discussion at 4:05 p.m.*

1165

1166 Chair Holt clarified for the record that no motions were made during executive session.

1167

1168 USP Changes (795, 797, 800)

1169 Leif Holm reported that he attended conferences where he talked with several states regarding
1170 adoption of USP changes, indicating the consensus is that most states are not adopting 800 in part
1171 or entirely. Mr. Holm further stated that Professional Compounding Companies of America
1172 (PCCA), which is the biggest chemical compounding company in the U.S., and based out of
1173 Texas. Ultimately, USP 800 imposes an undue burden for pharmacists to install a negative
1174 pressure system that is expensive but may not necessarily contribute to increase safety for
1175 hazardous compounds. Mr. Holm added that if the board adopts 795 and 797, it will solve a lot of
1176 the concerns. He further added that he would draft regulations emulating those of Texas and
1177 would present them to the board at a later date.

1178
1179 **TASK 21**
1180 Leif Holm will continue to draft regulations addressing USP 795 and 797 for the board's
1181 consideration at their next meeting.
1182 *(Pending).*
1183
1184 Correspondence: automated dispensing cabinets
1185 The board first addressed whether the board allows automated dispensing cabinets/kiosks, and Chair
1186 Holt indicated that 12 AAC 52.420 addresses security components, which limits drugs, devices, and
1187 other items intended for sale under the direct supervision of a pharmacist must be kept in the
1188 prescription department.
1189
1190 **TASK 22**
1191 Laura Carrillo will add an FAQ addressing automated dispensing cabinets/kiosks.
1192 *(Completed; Ms. Carrillo submitted the request to the publications specialist on 11/22/19).*
1193
1194 Correspondence: equivalent drug products
1195 The board then addressed equivalent drug products in response to an inquiry from Henry Adams,
1196 who requested information on who determines equivalency. Chair Holt stated the board does not
1197 reference the orange book as a source in statute or regulation for determining equivalency. This
1198 matter is addressed in AS 08.80.294, but the decision ultimately comes down to professional
1199 judgement of pharmacist.
1200
1201 **TASK 23**
1202 Laura Carrillo will return Henry Adam's inquiry relating to how pharmacists make the equivalent
1203 drug product determination.
1204 *(Completed; Ms. Carrillo emailed Mr. Adams with this information on 11/22/19).*
1205
1206 Correspondence: rabies administration
1207 The board then reviewed correspondence from CJ Kim on drug administration for rabies, then
1208 discussed more broadly the definition of administer vs. administration. Chair Holt indicated that
1209 to his knowledge, there is no language addressing training, policies, and procedures of
1210 administration, which by letter of law, includes via injection.
1211
1212 **On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and approved**
1213 **unanimously to assess pharmacists' scope of practice when it comes to drug**
1214 **administration under AS 08.80.480(1), particularly for drugs outside of immunizations and**
1215 **their related emergency medications, including but not limited to rabies vaccinations,**
1216 **human growth hormone, and injectable testosterone), it was:**
1217
1218 **RESOLVED to request a legal opinion on pharmacists' scope of practice related to**
1219 **administering under AS 08.80.480(1).**
1220

	APPROVE	DENY	ABSTAIN	ABSENT
1221				
1222	Leif Holm	x		
1223	Richard Holt	x		
1224	Phil Sanders	x		
1225	Lana Bell	x		
1226	Tammy Lindemuth	x		
1227	James Henderson			x
1228	Sharon Long			x

1229

No further discussion.

1230

1231 **TASK 24**

1232 Ms. Carrillo will submit a legal opinion as to whether pharmacists’ scope of practice includes their
1233 ability to administer medications outside of immunizations and emergency medications.

1234 *(Completed; Requested via deputy director on 11/22/2019; received guidance on 12/19/2019).*

1235

1236 Correspondence: Veterinary clinics/USP 800

1237 The board hasn’t adopted USP 800 and doesn’t inspect veterinary clinics.

1238

1239 Correspondence: custom flavoring

1240 Chair Holt recalled the board addressing whether flavoring considered compounding several years
1241 ago. Chair Holt added this has been a common practice for decades, but now the federal
1242 government is deciding to classify this under USP 800, which the board hasn’t adopted.

1243

1244 **Agenda Item 5 PDMP Update (from day 1 agenda) Time: 4:02 p.m.**

1245

1246 Ms. Carrillo reviewed the summary document on the National Rx Abuse and Heroin Summit and
1247 inquired to the board if any members were interested in attending next year. There was no
1248 determination on this subject.

1249

1250 Ms. Carrillo then addressed RxCheck, a PDMP interstate datasharing hub, which several states
1251 have expressed opposition to because it raises concerns about sharing PDMP data with the federal
1252 government. RxCheck is a special condition of the DOJ/BJA grant, which resulted in many states
1253 walked away from and subsequently didn’t receive the opportunity for funding because states have
1254 always owned their PDMP data. Ms. Lindemuth inquired about why this is something we have to
1255 comply with. Ms. Carrillo commented that the National Association of Boards of Pharmacy
1256 (NABP)’s datasharing hub, InterConnect, which was developed jointly with Alaska’s PDMP
1257 vendor, Appriss Health, is the preferred hub, but because we’ve received funding via the Alaska
1258 Department of Health and Social Services to launch RxCheck, we don’t have the ability to opt out.
1259 Ms. Carrillo further added that this feature must be operational by the end of November 2019, or
1260 we may be considered out-of-compliance with the grant requirement. Chair Holt inquired whether
1261 this has been looked at by the Department of Law because AS 17.30.200(d) clearly states data may
1262

1263 not be shared with the federal government. Ms. Carrillo also added that (5) of that section states
1264 the federal government may in fact receive the data if a subpoena, court order, or search warrant is
1265 submitted. Chair Holt requested a legal opinion based on the memorandum of agreement that is
1266 to be signed prior to going live.

1267

1268 **TASK 25**

1269 Ms. Carrillo will submit a legal opinion as to whether the board can legally comply with the special
1270 conditions of RxCheck given AS 17.30.200(d), which states data cannot be shared with the federal
1271 government. RxCheck is an interstate datasharing hub that was developed by and is maintained by
1272 a federal agency, the DOJ.

1273 *(Pending; Requested via deputy director and director on 11/22/2019; Ms. Carrillo provided additional*
1274 *information provided to LAQ on 01/13/2020).*

1275

1276 **Agenda Item 12 Administrative Business Time: 4:16 p.m.**

1277

1278 The board scheduled their next meeting on February 6 – 7, 2019.

1279

1280 **TASK 26**

1281 Ms. Carrillo submit a travel approval request for self and Leif Holm. Mr. Holm plans to fly in the
1282 night of the 5th and depart on the 9th as he will be attending the AkPha conference.

1283 *(Completed).*

1284


1285 **Agenda Item 13 Adjourn Time: 4:16 p.m.**

1286

1287 Ms. Lindemuth and Mr. Sanders motioned to adjourn the meeting.

1288

Laura Carrillo Digitally signed by Laura Carrillo
Date: 2020.02.15 13:54:04 -09'00' 02/15/2020
Laura Carrillo, Executive Adminsitrator Date

 02/15/2020
Rich Holt, Board of Pharmacy Chair Date