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 EMERGENCY MEETING
8	
9	August 27 – 28, 2020 Videoconference
10	
11 12 13 14 15 16	By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on August 27 – 28, 2020. Due to the COVID-19 pandemic, in-person attendance was not available.
17 18 19	Agenda Item 1Call to Order/Roll CallTime: 9:06 a.m.
20 21	The day 1, August 27, 2020 videoconference was called to order by Chair, Rich Holt at 9:06 a.m.
22	Board members present, constituting a quorum:
23	
24	Richard Holt, PharmD #PHAP2008, MBA – Chair
25	Leif Holm, PharmD #PHAP1606 – Vice Chair
26	James Henderson, RPh #PHAP1683
27	Lana Bell, RPh #PHAP893
28	Tammy Lindemuth, Public Member
29	Sharon Long, Public Member
30	Justin Ruffridge, #PHAP1787
31	
32	Division staff present:
33	
34	Laura Carrillo, Executive Administrator
35	Lisa Sherrell, PDMP Manager
36	Heather Noe, Occupational Licensing Examiner (Board of Pharmacy)
37	Ilsa Lund, Occupational Licensing Examiner (Board of Veterinary Examiners)
38	Carl Jacobs, Investigator
39	Greg Francois, Chief Investigator
40	Sonia Lipker, Lead Investigator
41	Harriet Dinegar-Milks (Department of Law)
42	

43 44	Members from the	<u>public present:</u>				
44 45	Coleman Cutchins, AK DHSS					
46	Heidi Lengdorfer, DHSS					
47	Daniel Nelson, TCC					
48		, CVS Health				
49	Charles Semling, AK DHSS					
50		0.	cists Associatio	on/Alaska Native Tr	ibal Health Consortium	
51	Lorri Walms	sley, Walgreens				
52	David Levy,	HCS				
53	Caren Robin	nson, Alaska Pharm	acists Associati	on		
54	.	laska Division of P	ublic Health			
55	5	ns, TelePharm				
56		Alaska Pharmacists				
57		vorth, UAA/ISU D	octor of Pharn	nacy Program		
58	CJ Kim, AK					
59 60		AK DHSS/HCS	and ation			
60 61	Gail Elliott,	ton, Southcentral F	oundation			
62	Gan Emoti,	NP				
63	Agenda Item 2	Review/Approv	ve Agenda		Time: 9:09 a.m.	
64	8					
65	Sharon Walsh joined t	the room at 9:12 a.m.				
66	U U					
67	The board reviewed	l the agenda for da	y 1.			
68						
69	•	• •			ing agenda, seconded	
70	by James Henders	son, and approved	l unanimously	, it was:		
71	DECOLVE		· 07 0000	· · 1	•	
72 72	RESULVE	D to accept the A	ugust 27, 2020) meeting agenda a	as written.	
73 74		APPROVE	DENY	ABSTAIN	ABSENT	
75	Leif Holm	X	DLIT			
76	Richard Holt	X				
77	Justin Ruffridge	Х				
78	Lana Bell	X				
79	Tammy Lindemut	th x				
80	James Henderson	X				
81	C1 T					
	Sharon Long				X	
82 83	Sharon Long The motion passed				X	

85	Agenda Item 3	Ethics

Time: 9:10 a.m.

- 86 87
 - Τŀ thic discl to

Agenda Item 4	Review/Approv	e Meeting Minu	<u>ites</u>	Time: 9:11 a.m.
	0		•	pointed to the appended
0			· ·	line 591 of the May 28 th
6	· ·	*		ication if the original
		•		ew subsection but was
previously listed as (b), but was re-alph	abetized during t	he board's emerge	ency regulation project.
Chair Holt further a	dded the limitation	s on COT were r	removed due to st	affing issues. Mr.
Ruffridge commente		•	· ·	
				ting to keep the previous
prescription is a little				
	1 ·		0	e original written date
	0	0	1 1	y to written dates and
could be interpreted		T		01
Ruffridge added he l	hadn't applied this	regulation yet, bu	it was thinking of	how it would be used.
				1 11 1 17 1 1
1	ited to line 548 of	the May /-8 meet	ing minutes, whic	h misspelled Katholyn
Runnels name.				
Task 1				
Ms. Carrillo will corr	ect Katholvn Run	nels' name on Ma	v 7-8 of the meet	ing minutes.
(Completed 09/09/20.	•			
	_ *)*			
Task 2				
Ms. Carrillo will send	d the May 7-8 and	May 28 meeting	minutes to Chair I	Holt for signature before
posting to the meeting	ng minutes page.			
(Completed 09/11/20.	20).			
•	•		e meeting minut	es, seconded Sharon
Long, and approve	d uponimously			
Long, and approve	u unanniousiy, i	t was:		
0. 11			eeting minutes	as amended and the
0. 11) to accept the M		eeting minutes	as amended and the
RESOLVEI) to accept the M		eeting minutes	as amended and the ABSENT
RESOLVEI) to accept the M 0 as written.	ay 7 – 8, 2020 m DENY		
RESOLVEI May 28, 2020) to accept the M 0 as written. APPROVE	ay 7 – 8, 2020 m DENY	ABSTAIN	

128	Lana Bell	X		
129	Tammy Lindemuth	X		
130	James Henderson	Х		
131	Sharon Long	Х		
132				
133	The motion passed with	n no further discus	sion.	
134				_
135	Agenda Item 5 <u>Pl</u>	DMP Update		Time: 9:28 a.m.
136				
137 129	Board Letter	homeoll manage of the	he board's latest activity on informin	a licensees of
138 139	0 .	· 11	he board's latest activity on informing luded a letter to all licensees affected	0
139			led that this letter included a one-page	
141	- ·	•	otion data, and how to report prescri	-
142	zero reports.	eer, review preserip		p
143	1			
144	License Integration			
145	Ms. Sherrell also provid	led a status on the	license integration project update, w	hich is slated to go
146	• •	÷ ,	sn't an enhancement for the user, bu	
147	8	1	gistration and more accurately assess	ē
148	-	. /	grate the division's licensing databas	e with the PDMP,
149	deactivating users whose	e professional licer	nse status has lapsed or expired.	
150				
151 152	Missed Reporting Notic		an alort patification to inform provi	iders of when they
152	2 /		an alert notification to inform provi irement is to report prescriptions da	
154	1 0 .	1	on pursuing this, but is also taking it	•
155		~	inched this feature before further pu	
156			F.	
157	<u>BJA Grant</u>			
158	Ms. Sherrell informed th	he board that we as	re still waiting on the Bureau of Justi	ce Assistance (BJA)
159	PDMP grant award not	ice, which can be a	announced as early as next week or a	s late as the end of
160	September.			
161				
162	Data			
163	0 1		nformed the board that out of the b	-
164 165	-		with the PDMP, which was a 4% de	-
165 166	•		the board being in renewal season w ue to no longer living or dispensing i	1
167	1 0	0	which is the highest among all boar	
168	<u> </u>		or Military Dispenser), the compliance	6
169	90%.	,,	, spender, die compliant	
170				

171 On reporting compliance, Ms. Sherrell reported that there were 232 delinquent reporters. This

- 172 could include pharmacies and practitioners who are also required to report. Ms. Carrillo added that
- the delinquent submitters data only includes providers who have either been manually added to
- the compliance function in AWARxE or who have reported at least once; the numbers do not
- 175 reflect practitioners who have never been added to this function or have never reported; so non-
- 176 compliance is much higher. Ms. Carrillo stated that they are working with division staff to update
- applications to gather provider dispensing status to track who may be required to report.
- 178
- 179 Ms. Sherrell stated that delegates currently have a limit of no more than 5 supervisors and
- 180 delegates. This was based on feedback from questionnaire that was launched from February to181 March; the limitation was set lower to align with the legislative intent to provide delegates access in
- a meaningful way. Ms. Carrillo added that some providers have requested for delegates to have
- 183 more than 20 delegates so the delegate can monitor the prescribers' practices "quality monitoring"
- and ensure they align with the healthcare practices' or institutions prescriptive guidelines, which
- isn't the intent of this type of access.
- 186

187 Pharmacists make up about 11% of all registered users, but that we'd get a more accurate picture 188 of registration composition after renewal. Ms. Sherrell then pointed to the table listed on the last 189 page of the report, which was included in all board reports in response to their requests to see 190 how their professions' prescribing patterns compares to other professions. This table included 191 data from October 2019 to March 2020 and shows the number of providers who prescribed at 192 least once, the number who viewed no patients at all, prescribers who prescribed over a certain

- 193 MME, and those who prescribed dangerous combinations, such as benzodiazepines and opioids.
- 194
- 195 <u>Guidance to other boards</u>
- Ms. Sherrell stated that in reports for the other affected boards, a new recommendation sectionwas added encouraging boards to give licensees guidance on registration and use, encouraging
- 198 delegate use to improve the clinical reviewing workflow, and facilitating/continuing discussions on
- 199 prescribing thresholds by MME. Ms. Carrillo added that she and Ms. Sherrell have recently met
- with the Board of Dental Examiners, the State Medical Board, and the Board of Nursing to
- 201 provide their PDMP updates and to discuss salient issues such as use data, dangerous
- 202 combinations, and timeframes to register. Ms. Carrillo noted these discussions were very fruitful
- and that they are looking forward to continued efforts to collaborate.
- 204
- 205 Chair Holt acknowledged that Ms. Sherrell and Ms. Carrillo have been very instrumental in
- 206 providing education to boards on how to register with and use the database. Chair Holt added that
- 207 reviewing data specifically has been explained and is simplistic; there are no barriers in terms of
- 208 entering the information needed to review, which is three fields (first name, last name, and date of
- 209 birth).
- 210 Chair Holt thanked Ilsa Lund, who was on the line and is the licensing examiner for the Board of
- 211 Veterinary Examiners, and who has also been instrumental in assisting this board to improve their
- understanding of the PDMP. Ms. Lund, in collaboration with Ms. Carrillo, Ms. Sherrell, Chair
- 213 Holt, and the Department of Law, have created a number of guidance documents to facilitate

improved compliance, including a template Chair Holt created for the Veterinary Board's use in 214 sending it out to their veterinarians. Ms. Lindemuth also offered her thanks to staff on their

- 215 efforts.
- 216
- 217
- 218 Intrastate Integration

219 Ms. Carrillo informed the board that integrating PDMP data with healthcare practices and 220 instructions in the state can be a prolonged process due to the need to sign MOUs; it is not a simple click to approve. Ms. Carrillo added the screening process entails ensuring each practices' 221 providers have proper credentials to access the PDMP and that they've paid all required fees. This 222 223 can be labor-intensive and time consuming, particularly with institutions with hundreds of 224 providers. According to Appriss, it is possible providers accessing the PDMP through their 225 existing system's electronic health record system can bypass the state's registration process 226 altogether due to the ability to use the practice's medical director's credentials and not sign into 227 the database directly. In a legal opinion provided to Ms. Carrillo on July 30, 2020, the Department of Law indicated the process of ensuring proper credentials prior to approving integration is 228 229 appropriate and needed. Ms. Carrillo added that Appriss' Provider Authorization feature will 230 check credentials behind the scenes and eliminate the manual review process, which will be a 231 relief; however, MOUs would still be needed, also per the legal opinion.

232

233 Notice on Assessment of Civil Fine

234 A notice was sent out to all pharmacists with Alaska addresses informing them of the board's

- 235 intent to pursue a fine for no or delayed registration. Ms. Sherrell indicated the letter generated
- 236 some confused responses as some providers interpreted the letter as indicating they were in non-
- 237 compliance when it was a general notice. Chair Holt added that the fine letter was voted on as a
- result of discussion on disciplinary matrix during the board's May 7 8 meeting. 238
- 239
- 240 Disciplinary Matrix
- 241 Chair Holt addressed the disciplinary matrix and Ms. Carrillo inquired about whether the board 242 wanted to discuss adding non-compliance with reporting to the matrix as the board had previously only addressed registration. Mr. Ruffridge expressed his interest in discussion this, stating that it 243 244 seems the PDMP is the board on record around the PDMP; it's not just pharmacists reaching out, 245 but potential disciplinary action from other boards. Chair Holt clarified that the board doesn't 246 discipline other boards; the State Medical Board has their own disciplinary matrix and other
- 247 boards have been encouraged to establish their own.
- 248
- 249 Carl Jacobs joined the room at 9:58 a.m.
- 250 AAG Harriet Dinegar-Milks joined the room at 10:00 a.m.
- 251
- 252
- 253 Renewal
- 254 Mr. Ruffridge commented on the renewal process, stating the application currently doesn't allow
- pharmacists to proceed with renewing online if they don't have to register. Mr. Ruffridge added 255
- there may be pharmacists who aren't required to register at the time due to not dispensing, but 256

257 258 259 260	may need to be registered because they may eventually need to dispense or work per diem as a temporary. Ms. Carrillo commented she could speak to this during Agenda Item #13 for renewal updates scheduled the next day.				
261 262	Agenda Item 6	Investigative Uj	<u>pdate</u>		Time: 10:07 a.m.
263	Investigative Report				
264	Investigator Jacobs p	resented the boar	d's report, which	ch included activity fr	om April 18, 2020 to
265	0 5 1		1 ·	-	ssion recommended for
266	executive session. Ch				
267					intake of a case prior to
268	that case moving to the	he complaint stati	us where a noti	ice is sent to the indiv	idual indicating they
269	have sufficient eviden	ice to pursue the	matter.		
270					
271	Investigator Jacobs tu			1	
272	included in the board	's confidential bo	ard packet. The	e board reviewed the	documents.
273	0		CC . 1 		H2010 001474
274 275	•		0	▲	case #2019 – 001474,
275	seconded Tammy I	indemum, and	approved una	minously, it was:	
277	RESOLVED	to adopt the im	position of civ	vil fine for case #201	19 - 001474
278	RECOLUED	to adopt the fill			
279		APPROVE	DENY	ABSTAIN	ABSENT
280	Leif Holm	Х			
281	Richard Holt	Х			
282	Justin Ruffridge	Х			
283	Lana Bell	Х			
284	Tammy Lindemuth	X			
285	James Henderson	X			
286	Sharon Long	Х			

287

The motion passed with no further discussion. 288

289

290 Subpoena Process

291 AAG Harriet Dinegar-Milks from the Department of Law was present to speak generally to the 292 subpoena process. AAG Milks informed the board that the subpoena is used as a tool to gather 293 information, that it's the legal instrument that tells one entity what documents are being sought in order to complete an investigation. AAG Milks added this includes no fact-finding or disciplinary 294 295 authority; it is simply a tool used to gather information. It was further added that an investigation cannot be completed without that information, and not until the investigation is completed will a 296 297 matter ever come before the board. Chair Holt likened this permission to giving a hall pass to the 298 students who want to use the restroom.

- 300 Mr. Ruffridge stated his interest in understanding the process was less to do with the legal 301 definition and process of a subpoena, but more so to be certain that the board had a discussion 302 regarding the fact that they are under debate on what is happening with the Board of Veterinary Examiners' compliance with the PDMP. Mr. Ruffridge added it's concerning the board would 303 304 start the investigative processes when veterinarians have expressed multiple times some issues with 305 PDMP usage. Mr. Ruffridge then added it is more about whether it is the right time to pursuing investigations. AAG Milks asserted that the Board of Pharmacy isn't the Board of Veterinary 306 307 Examiners; it's not the Board of Pharmacy's problem. AAG Milks stated the current law directs 308 subpoenas to the Board of Pharmacy because they are the holders of the information, but it is the 309 respective licensing board, e.g.: Board of Veterinary Examiners, who makes the ultimate decision to discipline their licensees. Mr. Holm appreciated this clarification from AAG Milks. 310
- 311

312 Chair Holt stated he had attended the last Veterinary Board of Examiners meeting as an invited

313 guest along with AAG Milks. Chair Holt informed the board that they have ample PDMP

314 information, not only regarding the statutes and regulations, but also legal interpretations, adding 315 he has personally drafted a response to their questions and concerns and provided them exact

he has personally drafted a response to their questions and concerns and provided them exactdirection on how to solve their concerns, including template letter they could modify to

317 communicate with their licensees what the requirements are. AAG Milks indicated this board is 318 subject to statutory schemes, professionally and culturally, and that it takes some time to get used 319 to. AAG Milks stated the PDMP requirements they have to follow are also still relatively new, but 320 that she is confident that board is getting there.

321

322 AAG Harriet Dinegar-Milks left the room at 10:28.

323

326

324 <u>Consent Agreements</u>

325 The board acknowledged they had a consent agreement matter to discuss confidentially.

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

331

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

334		APPROVE	DENY	ABSTAIN	ABSENT	
335	Leif Holm	X				
336	Richard Holt	X				
337	Justin Ruffridge	X				
338	Lana Bell	X				
339	Tammy Lindemutl	n x				
340	James Henderson	Х				

341	Sharon Long	X			
342 343 344	The motion passed wit	h no further dis	cussion.		
345 346 347	Staff members, Laura C Sherrell were authorize	, ,	· 1	ker, Greg Francois, H	eather Noe, and Lisa
348	Off record at 10:30 a.m.				
349	On record at 11:16 a.m.				
350					
351	2	•			0(c)(2), and seconded
352	by Justin Ruffridge, t		•		
353 354	purpose of discussing person, provided the		- /	-	and character of any
355	person, provided the	person may re-	quest a public	uiscussion.	
356	AND Rich Holt moti	oned to take n	o action on th	e consent agreemer	t matter; with
357	unanimous approval			8	,
358			-		
359			C	reement, but to ent	er back into executive
360	session in accordance	e with AS 44.62	.310(c)(2).		
361					
362		APPROVE	DENY	ABSTAIN	ABSENT
363	Leif Holm	X			
364	Richard Holt	X			
365	Justin Ruffridge	X			
366	Lana Bell	X			
367	Tammy Lindemuth	Х			
368	James Henderson	X			
369	Sharon Long	X			
370 371 372	The motion passed wit				
373 374 375	Staff members, Laura (Sherrell were authorize	•	*	ker, Greg Francois, H	eather Noe, and Lisa
376	Off record at 11:18 a.m.				
377	On record at 12:35 p.m.				
378	1 0	back on record,	Chair Holt clar	ified no motions were	e made during executive
379	session.				
380 381 382	On a motion duly ma Dominique Brown, a	• •		-	agreement for

384 **RESOLVED** to reject the consent agreement for Dominque Brown.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm		X		
Richard Holt		X		
Justin Ruffridge		X		
Lana Bell		X		
Tammy Lindemu	th	X		
James Henderson	l	X		
Sharon Long		X		
The motion failed; discussion.	the board did not a	dopt the conser	nt agreement. There	was no further
Agenda Item 9	Lunch			Time: 12:37 p.m
Chair Holt called fo	or lunch.			
Off record for lunch at	12:37 р.т.			
Back on record from h	unch at 1:19 p.m.			
Agenda Item 10	Work Groups/S	ubcommittee	Updates	Time: 1:22 p.m.
COVID-19 Board	Chairs Meeting			
	0	the last several 1	months and is comp	rised of healthcare-
related board chairs	. This group meets	biweekly.	_	
<u>Healthcare Work G</u>	1		1.C	
				t away from Mandate own work group, while
1	0		•	d that guidelines woul
1				which board member
		-		Ruffridge volunteered
Task 3	1 . e			
Ms. Carrillo will ser		0 1	ll for availability and	an invitation to begin
Ms. Carrillo will sen discussions on mov	ving away from Mar	ndate 15.	·	
Ms. Carrillo will sen discussions on mov	ving away from Mar	ndate 15.	oll for availability and <i>met on 10/01/2020)</i> .	an invitation to begin

Alaska Pharmacists Association (AKPhA) 425

- Molly Gray provided an update on their Fall CE conference, town hall in October, and its vaccine 426
- 427 work group, which is being put together with funding by the CDC. Ms. Gray also updated the
- 428 board on the AKPhA's efforts to mentor student pharmacists as they enter the profession,
- including CV review services, as well as an update on the annual convention planned for February 429
- 430 and potential legislation to allow technicians to provide immunizations. Ashley Schaber provided
- 431 an update on prescriptive authority for pharmacists, MAT therapy, and Healthy Alaskans 2030.
- 432
- 433 Department of Health and Social Services (DHSS)
- 434 Coleman Cutchins informed the board they're looking at public health and access to care,
- 435 particularly access to care issues in chronic disease management. On a national level, Dr. Cutchins
- commented they are seeing a lot of pharmacists filling in that role and he encourages the Alaska 436
- 437 Board of Pharmacy to support efforts in that direction. On testing, Dr. Cutchins stated that if you
- 438 look at this on a national level, pharmacists engaged in this early on; however, in Alaska, we don't
- have a clearly defined scope allowing pharmacists to provide medical care, and it continues to be a 439
- 440 barrier in pharmacists not having the ability to perform these tests as a medical procedure and be
- reimbursed for them. Dr. Cutchins also informed the board they are continuing to look at 441
- prophylaxis and are monitoring updates with a trial biosimilar; if it hits market, it is the hope there 442
- won't be a barrier to prescribing and administering it, adding the FDA clarified pharmacists can 443 444 prescribe controlled substances as long as pharmacists have their own personal DEA. Giving
- Idaho as an example, Dr. Cutchins stated the federal government actually encourages pharmacists 445
- 446 to become licensed in Idaho for two reasons: they can prescribe and they don't require the MPJE.
- 447
- 448 Chair Holt commented to Dr. Cutchins that legislation is needed to be changed to allow
- 449 technicians to provide immunizations and for pharmacists to prescribe.
- 450

451 Erin Narus provided an update on the Medicaid Pharmacy & Therapeutics Committee meeting on

- 452 September 18, and will convene to discuss the preferred drug list. Dr. Narus also provided an 453
- update on the drug utilization review committee meeting, also scheduled for that day. The division's Medicaid pharmacist and professional group training opportunities for pharmacist 454
- 455 billing are also slated for two dates in August. Dr. Narus also provided an update on Medicaid
- 456 enrollment for pharmacies; pharmacies may enroll into the Pharmacy Professional Group or they
- 457 can continue to administer vaccinations through a collaborative plan with the State Medical Board.
- 458 Dr. Narus worked with the AKPhA to compress what would have taken 9 months into a 3 - 4
- 459 month period to ensure expediting enrollment. These efforts also aimed to and reimburse pharmacists for COVID-19-related services, specifically testing and administration. Dr. Narus also 460
- commented that they were keeping a pulse on decreases in availability of home infusion therapy 461 462 services.
- 463 464 Agenda Item 10 Work Groups/Subcommittee Updates Time: 2:10 p.m. 465 Controlled Substances Advisory Subcommittee (CSAC) 466

Ms. Lindemuth informed the board the CSAC has met for the first meeting of the year and that a
second meeting is scheduled soon. Ms. Lindemuth commented that Derek Walton from the state
crime lab joined the meeting and educated them on Kratom. Also in attendance were Katholyn
Runnels and Dr. Anne Zink. The committee looked at trends that are going on with different
designer drugs, specifically new synthetics that are being created. On kratom, Ms. Lindemuth

472 explained it's a naturally-producing compound that comes from a tropical tree native to southeast

473 Asia. It is said kratom helps improve work productivity, but more recently it has become used as a

474 novel psychoactive substance. Ms. Lindemuth added that it's becoming increasingly used in

- western Alaska, especially over the last 3-4 years. The FDA is concerned that kratom can pose arisk of abuse and dependence as it works on the same receptors as opioids.
- 477

Ms. Lindemuth also informed the board that access to meth and heroin has decreased, but what
they've found is that they can mail Krtaom through USPS, so that has increased. In October, they
had \$18,00 worth of packages that are coming from St. Lawrence Island. All different ages have
been using Kratoms but it is used especially among youth and homeless, and there's no social

482 stigma. Ms. Lindemuth also commented on medical providers having to obtain clearance from
483 kratom. Of interest is that there's a correctional center; requiring medical providers to have

484 clearance from Kratom. Active

485

486 Ms. Lindemuth also commented that while tramadol is scheduled, there is some abuse of
487 gabapentin, which isn't yet scheduled. There are also issues with stocking, especially in rural areas,
488 and also instances of medivacs due to overdose events. The CSAC is also looking at dangerous
489 combination prescribing.

490

491 Chair Holt commented that gabapentin across country is scheduled in some states and in some 492 cases is even reported to state PDMPs. Chair Holt also added that there was an instance where in 493 the past two years, a pharmacy was shipping large quantities into western Alaska that the postal 494 service came to the board to express their concerns. Ms. Carrillo commented that her 495 understanding was in order for gabapentin to be scheduled at the state level, it had to be scheduled 496 at the federal level first, to which Ms. Bell said that was correct. Ms. Long inquired as to whether 497 there was a bill introduced to schedule this, to which members of the board could not recall.

498

499 Agenda Item 12 Public Comment

Time: 2:18 p.m.

500

Daniel Nelson joined the meeting to address his concern with the board's emergency regulations,
particularly with the potential of there being big picture faults due to the seemingly rushed
process. Dr. Nelson's primary concerns were around the scope of practice expansion for
pharmacy technicians. Chair Holt thanked Dr. Nelson for his comments and recalled similar
comments submitted previously. Chair Holt indicated to Dr. Nelson that there are some legislative
changes needed that would take 1 – 2 years to address and potentially resolve those concerns.

507

508 Molly Gray commented a packet was emailed to Ms. Carrillo regarding the HSS amendment to the509 Public Readiness and Preparedness (PREP) Act, which primarily addressed allowing pharmacy

510 technicians and interns to administer vaccines. Ms. Gray's question was would the federal statutes

511 circumvent state federal statutes and regulations around this issue? Chair Holt commented that,

512 much like the issue with billing and ordering COVID-19 testing, the board took that inquiry to the

513 Department of Law. We will need some direction on how this issue intersects with state and

federal laws. Ms. Gray also inquired about age restrictions on immunizations. Chair Holt was notaware of any age restrictions in Alaska, suggesting federal laws seem more restrictive on this scope.

516

517 TASK 4

Ms. Carrillo will seek a legal opinion on whether federal requirements under the Public Readiness
and Emergency Preparedness (PREP) Act requires the board to adopt corresponding regulations
clarifying their ability to provide immunizations to individuals ages 3 through 18. There are
currently no age restrictions for pharmacists or pharmacy interns in Alaska per 12 AAC 52.992. *(Pending; Ms. Carrillo requested this on 08/31/2020).*

523

524 Agenda Item 10 <u>Work Groups/Subcommittee Updates</u> Time: 2:25 p.m.

525

526 Hearing no further public comment, the board returned to updates from work groups.

- 527
- 528 <u>Compounding Subcommittee</u>
- 529 Dr. Holm commented that he and Dr. Ruffridge met in June and are continuing to work through 530 simplifying guidelines for compounding. This committee plans to schedule another meeting soon 531 for an update at the board's next meeting.
- 532
- 533 <u>Healthcare Workgroups</u>

534 In place of Health Mandate 15, the Governor is advising boards establish their own guidelines.

535 Instruction has been given from Director Chambers for healthcare boards to convene and adopt536 guidance for their licensees. Ms. Bell and Dr. Ruffridge volunteered to represent the Board of

- 537 Pharmacy for this initiative.
- 538
- 539 PDMP Board Chairs Meeting

540 Ms. Carrillo provided the update that this meeting will be underway and is coordinating with staff 541 and their board chairs to finalize a meeting date.

- 542
- 543 <u>COVID-19 Chairs Meeting</u>

544 Chair Holt is continuing to participate in the bi-weekly (previously weekly) chairs meeting, which545 has been ongoing since March.

546

547 Agenda Item 13 <u>Work Groups/Subcommittee Updates</u> Time: 2:30 p.m.

- 548 Staff and Renewal Update
- 549 Ms. Carrillo informed the board there has been a lot of inquiries from pharmacists who may be
- 550 confused about the ability to renew their license. At present, the online profile application is not
- able to accommodate optional fees (e.g.: no PDMP fee, only the \$25.00 fee, or the \$50.00 for the
- 552 previous and current PDMP registration renewal). Pharmacists who are not up to date on their

- 553 PDMP fees or are not required to register are directed to fill out the paper application; however, 554 when they attempt to renew online and see the error message indicating them to do this, it is being
- 555 interpreted as not being able to renew at all.
- 556
- 557 Ms. Carrillo also commented that most licensees are not submitting the required documents in 558 order to renew, which is delaying the renewal process for everyone as staff must circle back to 559 these applications multiple times.
- 560
- 561 <u>Statistics</u>
- As part of a task from the previous meeting, Ms. Carrillo informed the board she had gathered
 data from the Alaska Department of Labor (DOL) on employment for pharmacists and pharmacy
 technicians. For pharmacists, DOL describes employment growth as moderate with low
 employment opportunities, but projects an 11.4% decrease of employment from 2016 to 2026,
 compared to a 5.6% increase at the national level overall. For pharmacy technicians, employment
- 567 growth is low with moderate employment, with a 7.6% increase projected through 2026, which is
- **568** lower than the national projected average at 11.8%.

Board Business

- 569
- Ms. Carrillo also provided a status update on license and renewal statistics. As of 08/19/2020, the
 board had a 3.8% increase in total applications (active and in process) since the board's last report,
 which was provided in May. Also as of this date, staff has renewed 1,770 licensees out of 4,829
- 573 (37%). There are 42 days left to renew.574

Time: 2:37 p.m.

- 575 576
- 577 <u>Reports of Theft/Loss</u>

Agenda Item 7

578 The board reviewed the report of theft/loss (DEA form 106) for Safeway Inc at 44428 Sterling579 Highway.

580

581 Chair Holt clarified acceptable CE completion dates as the order issued in April didn't explicitly 582 state CE would be extended. We reached out to AAG for clarification and the acceptable 583 completion dates are, July 1, 2018 to September 30, 2020. Ms. Carrillo commented that on the 584 application the dates don't energies this range but if a phermatist is gudited and it is found they

- application, the dates don't specify this range, but if a pharmacist is audited and it is found theycompleted their CEs during this timeframe, those will be accepted.
- 586
- 587 Agenda Item 8 <u>Correspondence</u>

Time: 2:38 p.m.

588

589 Anita Taylor submitted an inquiry to the board for clarification to practice "physician compounding". Chair Holt commented that under AS 08.80.400, the board is not able to regulate the practice of medicine. Ms. Carrillo inquired whether there was any scope of pharmacy practice restricted under to licensees or registrants under AS 08.80. Dr. Ruffridge requested for clarification and inquired whether the question is if compounding, would by statute, be considered to be exclusive to pharmaceutical care operation, to which Ms. Carrillo confirmed; whether 595 compounding is a practice of pharmacy reserved only for pharmacies/pharmacists. Dr. Ruffridge

agreed that was something worth looking into. The board agreed a legal opinion could be 596 requested as to whether, in light of AS 08.80.400, whether professionals can practice aspects of 597 598 pharmacy for any medicinal preparation, such as compounding, without obtaining a license by the Board of Pharmacy. Ms. Long commented that in her experience, naturopaths and dermatologists 599 have raised these same questions in preparing medicinal mixtures. Mr. Henderson commented 600 whether other providers are regulated by USP 797 and 800 around compounding. 601 602 603 **TASK 5** 604 Ms. Carrillo will seek a legal opinion on there are any aspects of pharmacy that are restricted only 605 to individuals who are licensed under AS 08.80, such as compounding. 606 (Pending; Ms. Carrillo requested this on 08/31/2020). 607 608 Bianca Johnson inquired about FDA drug samples. Chair Holt commented the board don't 609 regulate drug samples, to which Ms. Bell agreed, indicated it is not within the board's jurisdiction. 610 611 Agenda Item 7 **Board Business** Time: 2:47 p.m. 612 613 The board returned to discussing application review and Carl Jacobs joined the room at 2:45 p.m. to 614 be present for this discussion. 615 616 On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), and seconded 617 by Lana Bell, the board unanimously moved to enter executive session for the purpose of 618 discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion. 619 620 621 **RESOLVED** to enter into executive session in accordance with AS 44.62.310(c)(2). 622 623 APPROVE DENY ABSTAIN ABSENT Leif Holm 624 Х 625 Richard Holt х 626 Justin Ruffridge х 627 Lana Bell х Tammy Lindemuth 628 х 629 James Henderson х

630 631

632 The motion passed with no further discussion. Staff members, Laura Carrillo and Carl Jacobs were633 authorized to remain in the room.

х

634 Off record at 2:48 p.m.

Sharon Long

635 On record at 3:46 p.m.

637 Upon return from executive session, Chair Holt clarified that no motions were made in executive638 session.

639 On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), and seconded

by Justin Ruffridge, the board intends to pursue a consent agreement with the pharmacist

641 applicant under case #2017-000092 as a condition for licensure due to violations related to

- AS 08.80.261(a)(7) and (c)(d)(e). This agreement will outline probation for five years, drug and alcohol testing, marijuana testing, AA/NA meetings, counseling reports, employer
- 644 reports, and supervision, and restrictions on remote employment.
- 645

646 **RESOLVED** to pursue a consent agreement with the applicant under 2017-000092 as a 647 condition for licensure as a pharmacist.

APPROVE 649 DENY ABSTAIN ABSENT 650 Leif Holm х 651 Richard Holt х 652 Justin Ruffridge х 653 Lana Bell х 654 Tammy Lindemuth х 655 James Henderson х 656 Sharon Long х

657

648

658 The motion passed with no further discussion.

659 660 On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), and seconded by Justin Ruffridge, the board intends to pursue a consent agreement with the pharmacist 661 applicant under case # 2017-000557 as a condition for licensure due to violations related to 662 663 12 AAC 52.920(a)(4) and AS 08.80.261(a)(2), (a)(9), (a)(11), and (a)(14). This agreement will outline probation for five years, drug and alcohol testing, marijuana testing, AA/NA 664 665 meetings, counseling reports, employer reports, and supervision, restrictions on remote 666 employment, and no access to controlled substances while in the workplace. 667

668 **RESOLVED** to pursue a consent agreement with the applicant under 2017-000557 as a 669 condition for licensure as a pharmacist.

671		APPROVE	DENY	ABSTAIN	ABSENT	
672	Leif Holm	X				
673	Richard Holt	X				
674	Justin Ruffridge	X				
675	Lana Bell	X				
676	Tammy Lindemut	h x				
677	James Henderson	х				

_	Sharon Long	x	
	<u> </u>		
Т	The motion passed	l with no further discussion.	
	*		
1	ГASK 6		
Ν	Ms. Carrillo will for	rward the motion language to Inve	estigator Jacobs on the matters for cases
2	2017-000092 and 2	2017-00057.	
(.	Submitted 10/02/2	2020).	
1	Task 7		
C	Chair Holt will sign ⁻	the adoption order for case #2019-	001474 and provide it back to the division.
((Completed 08/31/2	2020).	
A	Agenda Item 8	<u>Correspondence</u>	Time: 3:54 p.m.
Λ	Ms. Long left the mee	ting at 4:00 p.m.	
Т	The board returned	d back to correspondence.	
			UAA pharmacy program wrote to the board
			ne National Precursor Log Exchange
			ng system to track Sudafed sales for
-	· ·	PSE). PSE can be manufacture rec	
	*	*	Alaska do not have free access to this
			en beholden to know they've only purchased
			Chair Holt commented that AS 17.30. Ms.
(Carrillo inquired if	Sudafed related legislation is on th	he board's or has been on the AKPhA's rada
			e board's statutes and regulations talks abou
			n required, storage, access, and log books, b
d	loesn't specify it m	nust be a manual log book.	
-	F 1 0		
	Fask 8		
			ey're aware of electronic log book for PSEs
10	• •	egislation around Sudafed.	
		zu: wis. Carrillo sent an email to Molly	
(1			Gray and Ashley Schaber with the AKPhA;
(1	AKPhA forwarded in	nquiry to legislative committee on 10/05	
() _		nquiry to legislative committee on 10/05	/ 2020).
() T	The board reviewe	<i>nquiry to legislative committee on 10/05</i> d the letter from the Office of Ma	nagement and Budget (OMB) in Washington
() T T	The board reviewed DC. from Russel V	<i>nquiry to legislative committee on 10/05</i> d the letter from the Office of Ma Jought. This letter relates to an MO	7/2020). nagement and Budget (OMB) in Washington DU to track compounding across states. Dr.
	The board reviewed DC. from Russel V Leif commented th	<i>nquiry to legislative committee on 10/05</i> d the letter from the Office of Ma Yought. This letter relates to an MO nat he is currently receiving solicita	7/2020). nagement and Budget (OMB) in Washington OU to track compounding across states. Dr. tions about how it's not good for the
L L P	The board reviewed DC. from Russel V Leif commented the profession as it put	nquiry to legislative committee on $10/05$ d the letter from the Office of Ma Vought. This letter relates to an MC nat he is currently receiving solicita ts an undue burden on monitoring	7/2020). nagement and Budget (OMB) in Washington DU to track compounding across states. Dr.

- 721 Carrillo commented she recalled similar correspondence on national tracking for 3PLs and
- 722 inquired if they were related
- 723

724 Task 9

725 Ms. Carrillo will research previous correspondence from the FDA to assess whether it is related to

- the OMB joint document from the APhA, APC, and NCPA opposing a national MOU to allowreporting and record keeping of intrastate distribution of compounded drugs.
- 728 (Completed 09/06/2020; Ms. Carrillo reviewed previous 2019 correspondence from the Drug Supply Chain
- 729 Security Act (DSCSA), which intends to build an electronic, interoperable system to identify and trace certain
- 720 procription drugs as they are distributed in the United States These appear to be related)
- **730** prescription drugs as they are distributed in the United States. These appear to be related).
- 731

732 Agenda Item 7 <u>Board Business</u>

Time: 4:08 p.m.

733

- The board reviewed task lists from the previous meetings. One of the tasks was to submit travelapproval requests for Dr. Holm and Dr. Ruffridge to attend a compounding conference, however,
- the dates and delivery of the conferences have since changed.

738 Task 10

- Ms. Carrillo will look into compounding conferences and submit travel requests for Dr. Ruffridgeand Dr. Holm accordingly.
- 741 (Completed 09/21/2020; Ms. Carrillo submitted a request for Dr. Holm to attend the virtual compounding
- **742** conference on September 21 and 22. This is the 3rd Annual Compounding Compliance conference.)
- 743
- **744** Recess at 4:20 p.m.
- 745
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- 760 761
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- 762 763

~	State of Alaska	
Department of Commerce, Community and Economic Development		
Di	vision of Corporations, Business and Pro	ofessional Licensing
	Alaska Board of Pharmac	су
1	DRAFT MINUTES OF THE EMERGE	NCY MEETING
	August 27 – 28, 2020 Videocon	ference
Article 6, a sc	of AS 08.01.070(2), and in compliance wit heduled meeting of the Board of Pharma 8, 2020. Due to the COVID-19 pandemic	acy via videoconference on
These are dra	ft minutes and have not yet been approv	red by the board.
Agenda Item 1	Call to Order/Roll Call	Time: 9:06 a.m.
The day 2, Aug	ust 28, 2020 videoconference was called to ord	er by Chair, Rich Holt at 9:06 a.r
Board members	present, constituting a quorum:	
Richard	Holt, PharmD #PHAP2008, MBA – <i>Chair</i>	
	m, PharmD #PHAP1606 – Vice Chair	
	enderson, RPh #PHAP1683	
	l, RPh #PHAP893	
	Lindemuth, Public Member	
2	Long, Public Member	
	uffridge, #PHAP1787	
-	\sim	
Division staff p	resent:	
Laura Ca	rrillo, Executive Administrator	
	rrell, PDMP Manager	
Heather	Noe, Occupational Licensing Examiner (Board	of Pharmacy)
Ilsa Lune	l, Occupational Licensing Examiner (Board of	Veterinary Examiners)
Members from	the public present:	

806 807 808	Jessica Adan	per, Alaska Pharmao ns, TelePharm Alaska Pharmacists		n/Alaska Native Tril	oal Health Consortium
809 810	Agenda Item 2	Review/Approv	e Agenda		Time: 9:08 a.m.
810	Agenda Tiem 2	<u>Review/Appiov</u>	<u>e Agenua</u>		1 mile. 7.00 a.m.
812	The board reviewed	the agenda for day	2.		
813					
814	On a motion duly	made by Tammy	Lindemuth to	approve the meeting	ng agenda, seconded
815	by Rich Holt, and	approved unanim	ously, it was:		
816		_			
817	RESOLVE	D to accept the Au	igust 28, 2020	meeting agenda as	s written.
818					
819		APPROVE	DENY	ABSTAIN	ABSENT
820	Leif Holm	Х			
821	Richard Holt	Х			
822	Justin Ruffridge	X			
823	Lana Bell	Х			
824	Tammy Lindemut	ch x			
825	James Henderson	X			
826	Sharon Long	X			
827					
828	The motion passed	with no further dise	cussion.		
829		D .1.1			
830	Agenda Item 3	<u>Ethics</u>			Time: 9:16 a.m.
831 832	There were no othic	a disclosures to rep	out		
833	There were no ethic	s disclosures to rep	011.		
833	Agenda Item 4	Legal Opinion H	Reviews		Time: 9:11 a.m.
835	geniuu reenii i				
836	Ms. Carrillo remind	ed the board there l	nad been severa	al legal opinions requ	ested, five of which
837	have been returned	by the Department	of Law.		
838					
839	PDMP MOUs				
840			-	-	whether the board must
841 842					proving a PDMP data
842 843	<u> </u>	*			rstem. The legal opinion ntil a statute change can
843 844				-	ed the board that the
845				in large part driven b	
846		- ·			access the database;
847				providers at one clini	
	_		_		

- 848 The board was informed that PDMP staff were working with Appriss to turn on a provider
- 849 authorization feature that could check credentials on the backend, but it would not check whether
- 850 the fee has been received. Ms. Carrillo commented that each of the boards with PDMP
- 851 requirements are beginning to ensure their licensees are up to date on these fees. The board was
- also informed by Ms. Carrillo that there is a possibility of practices allowing providers to access
- the PDMP in their EMR via the medical directors' credentials, even if they do not have their own
- account as currently required in regulation, 12 AAC 52.855, which is problematic.
- 855
- 856 Chair Holt commented that while credentials are checked prior to approval, staff rotates; they may
- hire and fire people, and it won't be known to the board as to when these staff changes are
- 858 occurring, but that it should be up to the practice to maintain that. Ms. Carrillo agreed,
- 859 commenting this was taken into consideration when the legal opinion request was submitted;
- 860 PDMP staff will never be 100% certain who is employed at any given time at a practice and so
- questioned whether continuous follow-up was needed. Ms. Sherrell commented that provider
- authorization would validate any new credentials, which would help to an extent to automate that
- process. Chair Holt inquired whether this feature was going to turn on at the end of August, towhich Ms. Sherrell confirmed.
- 864 v 865
- 866 <u>Multiple PDMP accounts</u>
- 867 This legal opinion was around whether a provider working in multiple practices settings (e.g.:
- 868 federal IHS/VA/or military and non-federal) or had two separate professional licenses (e.g.:
- 869 dentist and pharmacist) should have two separate PDMP accounts since accounts are assigned to
- 870 emails that preferably should be issued by the provider's employer. Ms. Carrillo stated this
- 871 scenario comes up often with staff, and added that the current process is to ask the provider to set
- up multiple accounts if they are working in two separate capacities because they are accessing a
- 873 separate patient population under each account. However, the limitation is the database prevents a
- 874 provider from creating a second account if the DEA # is already taken, and the board doesn't
- have authority to require separate DEAs for each practice and there is no regulation requiringPDMP accounts to be associated with the employer.
- 876 877
- 878 AAG Dinegar-Milks at the Department of Law was not able to provide clear guidance around
- 879 practicing in multiple settings and sharing DEA numbers; however, she was able to provide
- 880 guidance that a provide clarity that a provider with two separate professional licenses should have
- two separate accounts as there are separate scope of practices for each. This will also help
- 882 distinguish, in the event there is an investigation, which board has the authority to investigate and
- 883 discipline the licensee.
- 884
- 885 <u>PDMP email accounts</u>
- 886 This topic was not a legal opinion request. Ms. Carrillo revisited the topic of email accounts and
- informed the board that if an email appears to be shared, staff will reach out to inform the licensee
- they should choose an email unique and secure to them. Chair Holt and Dr. Ruffridge
- acknowledged they had previously discussed this at the May meeting, specifically around securityconcerns with personal- versus employer-issued emails for PDMP access.

Chair Holt referred to AS 17.30.200(t), which allows issuance of prescriber report cards that must 891 be sent directly and only to the provider to which the report is concerning. These are sent via 892 893 email, and so if the email is shared, that is a breach in confidentiality. There is also unsolicited 894 notifications that are issued to the prescriber as well as patient announcements that are sent directly to emails. Ms. Carrillo commented that if it isn't explicitly stated anywhere in regulation 895 896 that emails have to be unique and non-shared, provider's may not be actively aware doing 897 otherwise could be a breach. Chair Holt added he doesn't believe there are providers nefariously 898 providing their personal email address to inappropriately share prescription information; that 899 maybe the thought process doesn't consider that potential confidentiality issue. Ms. Sherrell stated 900 there is an attestation to confidentiality when a provider creates an account, though there are many 901 instances where emails appear to be shared or belong generally to a practice.

902

903 Dr. Ruffridge commented that work addresses may have more of a potential for breaches in

904 confidentiality due to work stations becoming a little more mobile. In Dr. Ruffridge's practice,
905 they have 3 – 4 separate computers, so he created a separate, PDMP-specific email because it

906 offers the greatest confidentiality option for the work environment. Ms. Sherrell commented it

907 could be an optics issue where the employer email could appear confidential but if it's on a mobile

908 device, there is a risk of that being lost and opening up a potential for breach. Dr. Ruffridge

909 understood this generally to be the onus of the provider to determine what is most confidential in

910 their case. Chair Holt agreed with Lisa's concern around logging in to a mobile device, bringing 911 that home where a spouse, friend, or children could login.

912

913 Chair Holt requested a legal opinion from the department of law on email accounts.

914 Dr. Ruffridge requested we incorporate some sort of other security feature, like a two-factor

authentication mechanism, which is becoming mainstream because it is secure and fairly simple to

916 set up. Chair Holt agreed and Ms. Long strongly recommended there by authentication built in to917 every login.

918

919 Chair Holt added that as the body responsible for ensuring security, the Board of Pharmacy as

920 leaders will need thoroughly address this. It may come up in the board's legislative audit next year.

921

922 TASK 11

923 Ms. Carrillo will put in a legal opinion request for guidance on whether the board can require

924 employer-issued emails or if they can be personal, with examples of scenarios that might result in a

- 925 confidentiality breach, e.g.: mobile access.
- **926** (Initiated 10/06/2020).
- 927
- 928 <u>PDMP timeframe to register</u>

929 This opinion was returned in July. The Board of Pharmacy has the authority and is required under

AS 17.30.200(h) to set the timeframe to register, though other boards have established their own

- 931 timeframes via motions (not regulation).
- 932

- 933 The main point is communicating to all licensees that their timeframes to register will be moot
- 934 because only the Board of Pharmacy has the authority to set the timeframe for each practitioner.
- 935 Ms. Carrillo commented that the majority of the boards developed a 30-day timeframe to register,
- such as the Medical Board and the Board of Examiners in Optometry, which the Board of
- 937 Pharmacy actually mirrored. The Board of Nursing established a 120-day timeframe and the
- **938** Veterinary Board of Examiners established a 180-day timeframe.
- 939
- 940 Chair Holt expressed his concern for these log timeframes to register and called on Ms. Lund for941 her insight with the Board of Veterinary Examiners. Ms. Lund commented that with regards to the
- 942 PDMP, seeking legislative exemption is their main priority and so the 180-day timeframe was to
- 943 wait out the legislative session.
- 944
- PDMP staff have been reminding boards and their staff of the importance to communicate that
 providers cannot be prescribing federally scheduled II III controlled substances unless they are
 registered with the PDMP. Legally, this is a requirement in order to prescribe. Ms. Sherrell started
- a recommendations section in each affected board report that providers address registering priorto prescribing. Ms. Carrillo commented that quarterly report data shows there are populations of
- 950 prescribers who are indeed prescribing these controlled substances without being registered.
- 951
- 952 On a motion duly made by Rich Holt to amend 12 AAC 52.855(a), seconded by Justin
- 953 Ruffridge, and approved unanimously to read: "a licensed pharmacist practicing in the
- state shall register with the prescription drug monitoring program's controlled substance
- 955 prescription database (PDMP). Registration must be completed within 30 days of initial 956 licensure if employment will involve dispensing a schedule II, III, or IV controlled
- substance under federal law. A prescriber shall register within 30 days after the date of
 initial licensure under AS 08 ad the date of obtaining a DEA registration, whichever date is
 later.
- 960
- 961 (1) If not dispensing in the state, a pharmacist must submit a PDMP dispensation962 exemption form provided
- 963 by the board within 30 days of initial licensure.
- 964 (2) If a pharmacist who submitted a dispensation exemption form but will have a965 change in dispensing status must register before dispensing."
- 966 967
- It was RESOLVED to amend 12 AAC 52.855(a).
- 968 969 APPROVE DENY ABSTAIN ABSENT 970 Leif Holm х 971 **Richard Holt** х 972 Justin Ruffridge х Lana Bell 973 х 974 Tammy Lindemuth х

975	James Henderson	X
976	Sharon Long	X
977		
978	The motion passed with no	o further discussion
979		
980	TASK 12	
981	Ms Carrillo will submit the	e hoard's proposed language on the timeframe to register with the

981 Ms. Carrillo will submit the board's proposed language on the timeframe to register with the982 PDMP to the regulations specialist for cursory review by the Department of Law.

- **983** (Initiated 08/28/2020).
- 984

985 Zero reporting to the PDMP

986 The board had previously attempted to adopt regulations requiring zero reporting, since it is not 987 currently clear in regulation or mentioned in statute. Department of Law returned their opinion 988 that "zero report" is not a known term amongst providers; however, Ms. Carrillo indicated it is an

industry-recognized term as it is used in the data dispenser user guide, miscellaneous letters and

990 training manuals, and in the reporting database, ClearingHouse, where these reports are submitted.

991 AAG Weaver provided alternative language to speak to the requirement to report even

992 prescriptions not dispensed that day. Chair Holt commented on AAG weaver's suggested

993 language to report on a "form", though a form is not used because it is submitted electronically.

994 The board could remove this word from the proposed zero reporting language.

995

Ms. Carrillo commented that for zero reporting, an important distinction is that providers can only
submit these to ClearingHouse. For non-zero reports, a provider can submit the data directly to
the PDMP or to ClearingHouse, but only the latter is available for zero reporting. Ms. Carrillo also
added that after discussions with the Board of Veterinary Examiners around the confusion with
reporting, she and Ms. Sherrell worked with Appriss Health to create a video for instructions on
how to do this. The video has been posted online: https://vimeo.com/454078725

- 1002
- 1003 <u>Remote order entry</u>

This legal opinion request is still pending but is around entities located outside of the state that are 1004 engaged in order entry verification of prescriptions or other pharmacy services. The question is 1005 whether pharmacies located outside of the state are able to engage in this because remote order 1006 entry currently only applies to remote pharmacies, which can only be licensed within the state. Dr. 1007 Ruffridge expressed his concern that pharmacies out of state are providing services within our 1008 1009 state remotely but expressed that perhaps during COVID-19, it may not be the most appropriate time to clamp down, although it still is restricted to in-state pharmacies because the central 1010 pharmacy must be in Alaska. Dr. Ruffridge also commented that the board does have a duty to 1011 1012 protect their job market and it could negatively affect local services if the same services are 1013 originating from out of state.

1014

1015 Chair Holt informed Dr. Ruffridge that the board had previously tried to require out-of-state1016 pharmacies to adhere to certain laws; however, the Department of Law issued guidance that this is

1017 a registration rather than a license category. The board lacks the regulatory authority for

1018 registrations as they would for licenses, and the board currently is not authorized to license non-

- 1019 resident pharmacies; it would require a statute change to enforce and discipline certain
- 1020 requirements. Chair Holt also added that the board lacks the authority to require pharmacy
- 1021 personnel, like a PIC, from non-resident pharmacies to be licensed. The recollection was that AG
- 1022 Weigand looked back to understand the legislative intent behind this restriction and reported back
- to the board that the intent was that these non-resident pharmacies operate under the jurisdiction,
- 1024 with which they're in and not under the requirements set by the Alaska Board of Pharmacy.1025

1026 Task 13

- Ms. Carrillo will follow-up on the previous task of requesting a legal opinion on remote orderentries.
- **1029** (Sent follow-up 10/06/2020).
- 1030
- 1031 Extending CE and inspection report due dates
- **1032** This was addressed during day 1 of the meeting.
- 1033
- 1034 <u>Automated drug kiosks</u>
- This was around whether the board could establish regulations are automated drug kiosks. Chair 1035 Holt drafted language to be sent to Department of Law, which was forwarded on August 10, 2020 1036 1037 with a response provided on August 19. The main takeaway from Department of Law is that a statute change is needed but that it is doable. AAG Weigand and Dinegar-Milks indicated changes 1038 1039 would need to be made, such as clear definitions around what an automated kiosk is and 1040 specifications around security and where they can be located. AAG Milks commented: physical facilities for storage and dispensing drugs must comply with the 2013 federal Drug Supply Chain 1041 Security Act (AS 08.80.030(b)(7) and (d)). 1042
- 1043

1044 Chair Holt reflected on LAW's feedback: is it a dispensing machine based on the definition of 1045 dispensing or does it eventually become a distributing mechanism? Ms. Carrillo recalled Arizona 1046 separately licenses kiosks as a distinct category. Chair Holt commented that yes, if the board 1047 wanted to license these separately, a statute change would be needed, but the board is interested in 1048 creating regulations for pharmacies within their existing authority. The board will take LAW's 1049 feedback into consideration as they further develop this new regulation section.

1050

1051 Agenda Item 5 <u>Regulations</u>

1052

Ms. Carrillo reminded the board of the regulations work flow document, which will always be
included in board packets when the board has regulations as an agenda item topic. It is not a
document the board has to routinely review but is provided only for reference. Ms. Carrillo also
commented the board's emergency regulations, which were adopted in April, become permanent
on August 30.

- 1058
- 1059
- 1060

Time: 10:28 a.m.

1061 <u>PDMP Regulations</u>

1062 The board reviewed the draft regulations included in the packet and considered changes to 12

1063 AAC 52.855 for the registration requirement. Dr. Ruffridge commented on the current renewal

1064 application, which requires the pharmacist to enter the DEA # if they want to renew online. Ms.

1065 Carrillo clarified that the online application is only for pharmacists who are required or want to

- register with the PDMP, in which case they would need to provide their employer DEA #. Notevery pharmacist works in retail, so if they do not have an employer DEA #, they would fill out
- 1067 every pharmacist works in retail, so if they do not hav 1068 the paper renewal application.
 - 1069

1070 The board discussed requiring every pharmacist to register, regardless of whether they are living in 1071 or dispensing in Alaska. Ms. Carrillo commented that it does make compliance tracking with 1072 registration tricky, because we don't always know when a pharmacist moves out of state or no 1073 longer dispenses because of changes in employment. The board had previously discussed this but 1074 there wasn't a consensus. Dr. Ruffridge expressed that he would be in favor of requiring every pharmacist to be registered just as part of being licensed in Alaska, acknowledging that 1075 requirements to register has been a burden for pharmacists because of the "policing" perspective 1076 1077 prescribers tend to have.

1078

1079 Chair Holt commented that it would improve efficiency with tracking requirements especially 1080 when there are investigative resources expended opening up a case to pursue a potential noncompliance matter with registration, which may at the end of the day end up being a non-issue 1081 1082 because that pharmacist wasn't even required to register in the first place. Chair Holt commented 1083 it should be simpler, to which the board agreed. Dr. Ruffridge added it could improve the functioning of the PDMP when resources can be efficiently directed to the program rather than 1084 tracking down who may have violated what, without having concrete certainty around a potential 1085 1086 violation.

1087

1088 Ms. Sherrell commented on how common it is to be in communication with a provider who paid 1089 the PDMP, but doesn't have to register because they don't live in Alaska or don't have a DEA, and so you have to discuss their circumstances, offer and process refunds, and document that 1090 1091 correspondence; you're consuming resources for something that could be simplified. Ms. Carrillo 1092 added pharmacists are willing to pay the extra \$25.00 PDMP fee even if they aren't required to use 1093 the database just so they can proceed with online renewals, which indicates convenience is highly 1094 valued, though it does require more time and work for staff to deal with these refunds and 1095 communication. Sharon Long also expressed her concern with the wasted resources. Ms. Lindemuth agreed it would make sense in terms of being more effective, to require everyone to 1096 register. Dr. Holm expressed concern about requiring pharmacists to pay for a system they aren't 1097 1098 required to use, recalling the significant blowback we received when we had initially proposed the 1099 fee. 1100

1101 Ms. Carrillo informed the board that on the back end, they were working on improving

- administrative processing efficiency by collecting the PDMP fee along with the professional
- 1103 license fee. In addition, PDMP staff were working with affected board staff on being sure to

capture DEA designations and dispensing designations that will allow for better tracking of who is
required to register and who is required to report. Ms. Carrillo commented that data would be
most accurate during renewals because this is the opportunity every two years to assess for
updates. While licensees are responsible for updating the details of the PDMP registration, such

- as delegate access and employment information, or whether they still hold a DEA or dispense,providers generally aren't proactive with updating their account.
- 1110

The board acknowledged Laura and Lisa's efforts to educate each prescribing board and their
licensees on how to register, but it is ultimately up to the boards to ensure their licensees comply.
Chair Holt also praised Ms. Lund for her efforts with the Board of Veterinary Examiners. Ms.
Sherrell informed the board she developed an education and outreach plan and would be

1115 progressing that priority in the weeks and months to come.

1116

1117 Agenda Item 5

Time: 11:03 a.m.

1118

1119 <u>Disciplinary Matrix</u>

1120 While on the topic of the PDMP, the board returned to discussing the disciplinary matrix for failure to

register and report. Chair Holt reminded the board that they had sent out a letter (July 7, 2020) reminding

all providers, including pharmacists and providers, of the requirement to register with and use the

- database. The board sent another letter (August 17, 2020), informing all pharmacists with Alaska addressesthat they are required to register if dispensing in the state, and that the board intends to assess a fine
- 1125 beginning October 1 for pharmacists who don't register within 30 days.

PDMP Update

- 1126
 1127 Chair Holt commented to the board that what is left for the disciplinary matrix is to determine criteria for
 1128 when a pharmacist is referred to the investigative unit for failure to report. Ms. Bell commented that we
 1129 may not have enough data to address this issue right now, adding that she believes the goal should be to
 1130 collect data over a period of time, decide what the problems are and what should be penalized and how
 1131 and when. Chair Holt stated we have the data and have a good idea of who may be delinquent, but the
- 1132 board needs to begin messaging to licensees now.
- 1133

Ms. Carrillo recalled the notification process from a few years prior where a wide net had to be cast because there are nuances and exemptions to who may not be required to report, which at the time was unknown to the board because the data on dispensing status wasn't being tracked. Chair Holt recalled it was a very manual process. Ms. Carrillo added that the letters would go to the address on file, which isn't always accurate. Dr. Ruffridge responded that it could be an area of additional discipline as we're required to keep our addresses up to date; we need to be taking notices seriously so should be keeping our addresses current in order to receive them. Ms. Bell commented that maybe by the third notice is when

- **1141** discipline should be issued.
- 1142

1143 Agenda Item 6 <u>Lunch</u> 1144

- 1145 Chair Holt called for lunch.
- 1146
- **1147** Off record for lunch at 11:49 a.m.
- **1148** Back on record from lunch at 1:07 p.m.

Time: 11:49 a.m.

1149	Agenda Item 5	PDMP Update	Time: 1:07 a.m.
1150			
1151		to discuss reporting. Ms. Carrillo indicated t	
1152		ppriss could help fill the reminder need and	
1153 1154	1	oard whether they were aware of pharmacies pharmacy software is not yet automated. Dr.	1 0 1
1154	1	ery night. Dr. Henderson also indicated he re	1 0 .
1156		board discussed repeat offenders or failing t	
1157	and there for various		o report versus rongetung to report nere
1158			
1159	The board discussed	the potential discipline occurring in three sta	iges along the lines of below:
1160			
1161	Step 1: Warning/not	ification - pharmacists will be notified of the	e board's intent to pursue disciplinary
1162	action for failure to re-	eport	
1163			
1164	A 1	tist is notified $-$ this will be the first in a regul	larly scheduled assessment for delinquent
1165	reporting. This may c	occur quarterly.	
1166 1167	Stop 3. Non complia	.nt in subsequent review of reporting status -	the pharmagist is referred to the
1168	- 1	ere a fine of \$5,000 will be assessed	the phannacist is referred to the
1169	investigative unit with	ere a fille of \$5,000 will be assessed	
1170	The board intends to	send a notice informing pharmacists this wi	ll take effect January 1, 2021.
1171		01	····· , , - · · · · · · · · · · · · · ·
1172	Agenda Item 7	Return to Regulations	Time: 2:22 p.m.
1173			
1174	<u>Refills</u>		
1175		to discussion on regulations, specifically	
1176		yond a year under 12 AAC 52.470. Chair	
1177		pensed after a year and prompted the boa	
1178		rapy. Ms. Bell stated there might be a scen	
1179	1 0	e day before, for example, and so if a pat	1 ,
1180	1 6	inuation, could the pharmacy issue it? Sha	0 0
1181		e to tide the patient over until their provi-	der is available to issue a new
1182	prescription.		
1183			
1184	0	C 52.470(g), Dr. Ruffridge recalled Dr. Ho	1 I I
1185	0	inuation of therapy would have the same	L
1186		s also Dr. Ruffridge's understanding that	
1187	-	d expire, but that there should be the opt	
1188		e an additional supply would require that	
1189		day 365, if the patient is unable to get a l	
1190		tion of therapy for 30 days to bridge ther	-
1191		ffridge's concern was around clarity arour	0
1192		terpreted as a new prescription out of no	
1193	prescription drug of	rder is defined in regulation so it can't be	broadly interpreted. If the regulation

previous date of iss	sue.			
T 1 42				
Task 13:				
		As. Sherrell on developing ure to register and report.	a draft PDMP discipli	
1		rell continuing to work on this).		
(11111111111111100/ 00/ 20.	20 by Chair 1100, Lasa Sher	reu comunaing to work on this).		
Agenda Item 8	Potential Statute Cha	anges	Time: 2:47 p	
8		_	1	
Internet pharmacie	<u>es</u>			
Ms. Carrillo inform	ned the board there has b	een inquiries about receivir	ng prescriptions online	
acknowledged the	board doesn't currently re	egulate Internet pharmacies	s but that the NABP h	
.pharmacy domain	to verify legitimate online	e pharmacies. Ms. Carrillo	was unsure of whether	
other states regulat	e Internet pharmacies, to	which Chair Holt indicated	d he could reach out to	
if any do.				
Task 15	1 1 1	1		
Chair Holt will research whether any states regulate Internet pharmacies.				
(Pending).				
The board discusse	ed next meeting dates:			
	0			
November	5 – 6 (via Zoom)			
	3 - 19 (in Juneau)			
Task 16				
	submit a travel approval 1	equest to meet in Juneau for	or the $02/2021$ meeting	
(Pending).				
Accordo Itamo O	Adiourn		Time of 2.08 m	
Agenda Item 9	<u>Adjourn</u>		Time: 3:08 p	
	· ЛЛ			
Laura Car	rillo	11/24/2020		
Laura Carrillo, Exe	cutive Administrator	Date		
V.L.OL	the second			
	. 20			
Richard Holt, Chai	*	Date		

says, "previously verified prescription drug or information" it's saying one of those things is the