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To: Board Members

Subject: Agenda Item XIV. Executive Officer's Report

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a. Biannual Report of the Examination Statistics for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacist Licensure Examination (NAPLEX)

Attachment 1

Examination scores for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and North American Pharmacist Licensure Examination (NAPLEX) are released twice a year, generally in spring and fall.

The Semi-Annual CPJE statistical report for April 2018 through September 2018 reflects that the overall pass rate for the CPJE is 78.2 percent. The pass rate for graduates from the California schools of pharmacy is 89.7 percent. The overall pass rate for the NAPLEX is 93.9 percent. A copy of the Semi-Annual CPJE Statistical Report is provided in **Attachment 1**.

CPJE: Overall Pass Rates		
	Frequency	**Percent**
Fail	465	21.8
Pass	1,664	78.2
Total	2,129	100

NAPLEX: Overall Pass Rates		
	Frequency	**Percent**
Fail	95	6.1
Pass	1,461	93.9
Total	1,556	100

5 – Year Comparison of CPJE and NAPLEX Pass Rates (Percentage)					
	CPJE			**NAPLEX**	
	Fail	**Pass**		**Fail**	**Pass**
April 2013 – Mar. 2014	19.9	80.1		4.5	95.5
April 2014 – Mar. 2015	21.3	78.7		4.3	95.7
April 2015 – Mar. 2016	21.6	78.4		5.8	94.2
*April 2016 – Mar. 2017	34.6	65.4		10.1	89.9
April 2017 – Mar. 2018	29.7	70.3		7.9	92.1

***New content outline in effect**

b. Update on the 2018 Intergovernmental Working Meeting on Drug Compounding

On September 24 and 25, the FDA convened its annual meeting with state boards of pharmacy and in some cases the state offices of the department of public health. I

attended on behalf of California and the board.

The FDA has been convening these meetings since the DQSA was enacted in late 2013. Approximately 30 to 40 states were present. The purpose of the meeting was to share information about the status of sterile and nonsterile compounding, and outsourcing operations in various states and the emerging policies of the FDA in these areas.

The board was specifically asked to speak in two areas:

1. On a proposed memorandum of understanding between each board and the FDA that would allow a pharmacy to ship 50 percent of its compounded products across state lines instead of the current limit of 5 percent (discussed in item e below).
2. On the board's activities to regulate outsourcers in CA or doing business into CA.

The board's compounding and outsourcing staff often work closely with the FDA on common interests and inspection issues. This meeting offers the opportunity to liaise and share information with FDA staff from across the US. Both board programs are strong in comparison with activities of other state boards.

c. Update on the National Association of Boards of Pharmacy Executive Officers' Meeting

The board's executive officer attended the annual meeting of executive officers of boards of pharmacy on October 1-4, which is convened by the National Association of Boards of Pharmacy. I provided a presentation on state efforts to secure from wholesalers copies of suspicious orders involving controlled substances sales to pharmacies and other wholesalers that under federal law, must be reported to the Drug Enforcement Administration. California is one of several states that recently added similar requirements for reporting to state law.

I also attended the annual in person meeting of the .Pharmacy executive committee following the executive officers forum while at NABP.

d. Update on the California Society of Health Systems Pharmacists Annual Meeting

From October 5-7, I attended the CSHP annual meeting in San Diego. Board Members Schaad and Serpa both attended in their private roles.

During this meeting, which is focused on diverse continuing education topics, the board provided a presentation to a standing room audience of at least 300 people on newly enacted 2019 laws coupled with a question and answer session with me, Christine Acosta and Tom Lenox. The three of us also staffed a booth in the exhibit area for three hours on Friday and Saturday to respond to questions from meeting attendees. There were over 2,100 attendees at this meeting.

While in attendance, the three of us attended various educational sessions including multiple sessions dealing with compounding matters and opioid issues.

Additionally, I was honored by CSHP with CSHP's 2018 Lifetime Honorary Membership Award.

e. Discussion and Consideration of the FDA's Memorandum of Understanding Relating to the Regulation of Pharmacy Compounding

Attachment 2

On September 7, 2018, the FDA released a revised *draft* memorandum of understanding. If approved and signed by a state, it would allow compounding pharmacies in the state to ship up to 50 percent of their compounded drug products across state lines – as an alternative to the current limit of 5 percent of such shipments. The state would be required to identify to the FDA which pharmacies are compounding and shipping more than 5 percent of their compounded drug products outside the state. A month by month calculation would need to be part of the evaluation.

Compounding for animals or by outsourcers is not included in the calculation.

Attachment 2 contains the revised MOU.

The MOU provides generally that pharmacies and physicians would be subject to the parameters, but the FDA's focus is principally on state regulators of pharmacies to enforce the provisions. By signing the MOU, a state board of pharmacy would:

- Agree to investigate complaints about compounded drugs in the state, including public safety concerns
- Agree to take appropriate action against pharmacies with complaints filed against them
- Notify the FDA within 3 business days of any complaint involving serious product quality or adverse drug effects
- Share results of any investigation with the FDA
- Any compounded drug shipped must be patient-specific
- If complaint involves a physician, the pharmacy board is to notify the regulator, and if serious adverse effects are involved, notify the FDA within 3 business days
- Inordinate amounts would trigger notification to the FDA by the state board of pharmacy and are defined as:
    - If the number of prescription orders for compounded drug products distributed interstate by a compounder during any calendar month is > 50 percent of the number of prescription orders for compounded drug products distributed or dispensed both intrastate and interstate by the compounder. The data would be collected for a year but would involve a month by month accounting reported to the FDA.

- States that sign the MOU agree to:
  - Identify pharmacies annually that distribute inordinate amounts of compounded drug product, labelled for specific patients, and shipped across state lines
  - Notify FDA if the state becomes aware of physicians distributing inordinate amounts
- States will collect information regarding and notify the FDA within 30 days of:
  - Total number of prescriptions for sterile compounded drugs distributed out of state
  - Total number of states in which the compounder is licensed or ships into
  - Results of the last state inspection of the entity

Comments on the draft MOU are due by December 10.

During the FDA meeting and the following week at an executive officers meeting convened by the National Association of Boards of Pharmacy, not one state indicated a willingness to sign the MOU. California submitted comments to a prior iteration of the MOU several years ago whereby 30 percent of the product would be allowed to cross state lines, which was also not supported by other states.

Concerns expressed by the states include:

- this is a great deal of effort for the states to perform which while it may be a priority for the FDA, is not necessarily that of the boards
- physicians that compound and ship across state lines should be subject to the same requirements
- efforts to compile such a list at the pharmacy level would come at the expense of other board priorities (investigating complaints, performing compliance inspections). In the case of California, this workload would not be absorbable, even if a survey of California's 7,100 pharmacies were done annually instead of inspections to calculate this information.

The National Association of Boards of Pharmacy plans to work with the FDA on identifying a possible alternative approach. The board will be advised what alternative solutions are developed.

f. Update on the Implementation of the Acceptance of Credit Cards for Renewal Payments

The board has been working with the Department of Consumer Affairs to secure the ability to use credit cards by the end of 2018. The department advises that there may be a delay because of a change in the credit card contract regarding business requirements.

The Board, working with the DCA Office of Information Services, is now advising that there will likely be a delay of up to 60 days.

The following is an overview provided by DCA about status of this project:

1. All activities the board needs to perform are still scheduled for a completion date of December 2018.
2. DCA will exert pressure on the involved agencies to secure the credit card clearinghouse contract process completed expeditiously.
3. Contract, business and technical requirements are being developed in concurrently to avoid additional delays.

One component we are requiring is that a convenience fee will be paid by the licensee, not absorbed by the board.

This remains a board priority and we will continue to engage with senior DCA officials to secure this service.

g. Personnel Update

The board is currently recruiting staff for the following positions:

- One Inspector on the Drug Diversion & Fraud team.
- One AGPA in the Enforcement unit.
- One SSA in the Enforcement unit.
- Two AGPA's in the Licensing unit.
- One SSA in the Licensing unit.
- One Program Technician in the Licensing unit.
- One Office Assistant (General) in Licensing unit.
- One Office Technician in the Administration unit.

h. Update on the Relocation of the Board's Office

Background

For the past year board staff has been working with DCA and the Department of General Services to locate new office space that can accommodate the board's significant growth.

The board signed a lease for new office space located at 2720 Gateway Oaks Drive Suite, approximately three miles from our current location. The tentative start date of the lease is February 1, 2019.

Update

Board staff was recently advised that there may be a delay in the approval of the floor plans by the fire marshal. This will likely require that the February 1, 2019, move date be delayed. Board staff will continue to work with DCA and the Department of General Services and will provide updates to Organizational Development committee as more

information becomes available.

i. Update on the Controlled Substance Utilization Review and Evaluation System (CURES)

Attachment 3

Provided in **Attachment 3** are tables outlining the CURES data released from the Department of Justice for January through September 2018

Attachment 1

California State Board of Pharmacy
CPJE Statistics
April 2018 – September 2018

The charts below display data for all candidates who took the CPJE examination between April 2018 to September 2018, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period noted above). Typically, the board reports CPJE performance data at six-month intervals.

Overall Pass Rates

CJPE P/F		Frequency	Percent
Valid	F	465	21.8
	P	1664	78.2
	Total	2129	100.0

NAPLEX P/F		Frequency	Percent
Valid	F	95	6.1
	P	1461	93.9
	Total	1556	100.0

Location of School

			CJPE P/F		
			F	P	Total
	California	Count	111	965	1076
		% within school	10.3%	89.7%	100.0%
	Other US	Count	310	628	938
		% within school	33.0%	67.0%	100.0%
	Foreign	Count	44	71	115
		% within school	38.3%	61.7%	100.0%
Total		Count	465	1664	2129
		% within school	21.8%	78.2%	100.0%

			NAPLEX P/F		
			F	P	Total
	California	Count	27	678	705
		% within school	3.8%	96.2%	100.0%
	Other US	Count	55	695	750
		% within school	7.3%	92.7%	100.0%
	Foreign	Count	13	88	101
		% within school	12.9%	87.1%	100.0%
Total		Count	95	1461	1556
		% within school	6.1%	93.9%	100.0%

Gender

			CJPE P/F		
			F	P	Total
gender	F	Count	274	1072	1346
		% within gender	20.4%	79.6%	100.0%
	M	Count	191	592	783
		% within gender	24.4%	75.6%	100.0%
Total		Count	465	1664	2129
		% within gender	21.8%	78.2%	100.0%

			NAPLEX P/F		
			F	P	Total
gender	F	Count	67	911	978
		% within gender	6.9%	93.1%	100.0%
	M	Count	28	550	578
		% within gender	4.8%	95.2%	100.0%
Total		Count	95	1461	1556
		% within gender	6.1%	93.9%	100.0%

California Schools

			CJPE P/F		
			F	P	Total
school	UCSF	Count	17	87	104
		% within school	16.3%	83.7%	100.0%
	UOP	Count	25	164	189
		% within school	13.2%	86.8%	100.0%
	USC	Count	4	172	176
		% within school	2.3%	97.7%	100.0%
	Western	Count	11	106	117
		% within school	9.4%	90.6%	100.0%
	Loma Linda	Count	13	55	68
		% within school	19.1%	80.9%	100.0%
	UCSD	Count	5	57	62
		% within school	8.1%	91.9%	100.0%
	Touro U	Count	8	86	94
		% within school	8.5%	91.5%	100.0%
	Cal Northstate	Count	9	104	113
		% within school	8.0%	92.0%	100.0%
	Keck	Count	2	45	47
		% within school	4.3%	95.7%	100.0%
	West Coast U	Count	4	15	19
		% within school	21.1%	78.9%	100.0%
	Chapman	Count	8	42	50
		% within school	16.0%	84.0%	100.0%
	CA Health Sci U	Count	5	32	37
		% within school	13.5%	86.5%	100.0%
Total		Count	111	965	1076
		% within school	10.3%	89.7%	100.0%

California Schools (continued)

			NAPLEX P/F		
			F	P	Total
school	UCSF	Count	7	80	87
		% within school	8.0%	92.0%	100.0%
	UOP	Count	2	130	132
		% within school	1.5%	98.5%	100.0%
	USC	Count	0	114	114
		% within school	0.0%	100.0%	100.0%
	Western	Count	1	75	76
		% within school	1.3%	98.7%	100.0%
	Loma Linda	Count	2	47	49
		% within school	4.1%	95.9%	100.0%
	UCSD	Count	0	49	49
		% within school	0.0%	100.0%	100.0%
	Touro U	Count	1	57	58
		% within school	1.7%	98.3%	100.0%
	Cal Northstate	Count	6	52	58
		% within school	10.3%	89.7%	100.0%
	Keck	Count	2	13	15
		% within school	13.3%	86.7%	100.0%
	West Coast U	Count	4	11	15
		% within school	26.7%	73.3%	100.0%
	Chapman	Count	1	24	25
		% within school	4.0%	96.0%	100.0%
	CA Health Sci U	Count	1	26	27
		% within school	3.7%	96.3%	100.0%
Total		Count	27	678	705
		% within school	3.8%	96.2%	100.0%

US Schools of Pharmacy

		CJPE P/F		
		F	P	Total
school graduated	Auburn	0	2	2
from	Samford	1	0	1
	U of AZ	3	8	11
	U of AR	2	2	4
	UCSF	17	87	104
	U of Pacific	25	164	189
	USC	4	172	176
	U of CO	4	36	40
	U of Conn	1	7	8
	Howard DC	2	6	8
	FL A&M	1	1	2
	U of FL	2	8	10
	Mercer	3	7	10
	U of GA	0	1	1
	Idaho SU	1	2	3
	U of IL Chi	6	15	21
	Butler U	0	3	3
	Purdue	1	6	7
	Drake	0	2	2
	U of IA	2	3	5
	U of KY	3	4	7
	NE LA U	0	1	1
	Xavier	4	3	7
	U of MD	3	10	13
	MA Col Pharm	10	21	31
	NE-MA	4	19	23
	Ferris	0	2	2
	U of MI	3	7	10
	Wayne SU	4	0	4
	U of MN	4	7	11
	U of MS	2	1	3
	St. Louis Col of PH	3	8	11
	UMKC	1	0	1
	U of MT	0	6	6

Creighton	5	13	18
U of NE	0	1	1
Rutgers	2	7	9
U of NM	5	4	9
Western	11	106	117
Midwstern U Chicago	10	15	25
A&M Schwartz	4	1	5
St. Johns	10	8	18
SUNY-Buff	3	4	7
Union U	1	10	11
UNC	0	3	3
ND SU	1	1	2
OH State U	2	5	7
U of Cinn	0	2	2
U of Toledo	3	4	7
SW OK State	1	1	2
U of OK	0	4	4
OR State U	3	7	10
Duquesne	1	7	8
Phl C of Pharm	3	8	11
Temple	3	7	10
U of Pitt	3	7	10
U of PR	2	0	2
U of RI	2	8	10
Med U of SC	1	1	2
U of SC	1	0	1
SD SU	1	0	1
U of TN	1	2	3
TX SO U	1	3	4
U of Hous	4	2	6
U of TX	3	3	6
U of UT	3	1	4
Med C of VA	2	4	6
U of WA	5	9	14
WA State U	1	5	6
WV U	1	0	1
U of WI-Mad	0	5	5

U of WY	3	1	4
Campbell U	1	2	3
Nova Southeastern	4	8	12
Wilkes University	1	0	1
Texas Tech	3	2	5
Bernard J Dunn	4	6	10
Midwestern AZ	7	33	40
Nevada College of Pharm	15	54	69
Loma Linda U	13	55	68
UCSD	5	57	62
MA School of Pharm - Worcester	19	22	41
Palm Beach Atlantic University	2	2	4
Lake Erie Col	9	14	23
Touro U	8	86	94
U of Charleston	4	4	8
South U School of Pharm	2	4	6
Hampton U (VA)	2	1	3
Pac U of Or	3	15	18
Wingate U	0	4	4
U of Findlay	1	0	1
U of Incarnate Word	0	2	2
Sullivan U	3	0	3
Cal Northstate	9	104	113
Other/FG	44	71	115
U of HI - Hilo	11	22	33
NE Ohio Universities	0	2	2
Texas A&M	0	3	3
Thomas Jefferson U	3	2	5
Belmont U	1	2	3
Harding U	1	4	5
Husson U	1	1	2

	Appalachian College of Pharm	3	3	6
	Lipscomb U	2	4	6
	Chicago St U	4	5	9
	U of New England	9	9	18
	Regis University	1	9	10
	Notre Dame of MD	4	1	5
	Union U	0	2	2
	St. John Fisher	0	4	4
	Concordia U Coll Pharm	2	0	2
	Rosalind Franklin U	2	2	4
	Western NE U	0	1	1
	U of Saint Joseph	2	5	7
	Roosevelt U	1	1	2
	D'Youville	1	1	2
	Touro New York	6	2	8
	South College	7	1	8
	Manchester U	1	1	2
	SIUE	0	1	1
	U of South Florida	1	0	1
	KECK GRAD INST SCHL PHARM	2	45	47
	CA Health Sci U	5	32	37
	Fairleigh Dickinson	0	2	2
	Cedarville U	0	1	1
	U of the Sciences	6	1	7
	UNTX Col of Pharm	0	1	1
	WEST CST UNIV COL PHARM	4	15	19
	CHAPMAN U SCHL PHARM	8	42	50
	U MD Eastern Shore	0	1	1
Total		465	1664	2129

Country

		CJPE P/F		
		F	P	Total
country	Brazil	1	1	2
	China	0	2	2
	Costa Rica	1	0	1
	E&W Germany	1	1	2
	Egypt	11	21	32
	France	1	0	1
	United Kingdom	1	2	3
	India	6	9	15
	Iraq	2	3	5
	Iran	0	7	7
	Japan	0	1	1
	Jordan	2	3	5
	Lebanon	2	0	2
	Morocco	1	0	1
	Nigeria/New Guinea	1	1	2
	Philippines	10	10	20
	Pakistan	0	3	3
	Poland	1	0	1
	Puerto Rico	1	0	1
	Portugal	0	1	1
	Saudi Arabia	0	1	1
	Syria	2	3	5
	USA	421	1595	2016
Total		465	1664	2129

Attachment 2

DRAFT MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED DRUG PRODUCTS BETWEEN THE STATE OF [insert STATE] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the State of [insert State] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the State of [insert State] of complaints relating to human drug products compounded in such State and distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

   1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

   2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

   3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

b. To qualify for these exemptions, among other things, a compounded drug product must meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

   1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts[1] of compounded drug products interstate and

[1]The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i). The content of this MOU conforms to the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Drug Products Distributed Outside the State

1. Appropriate agencies of the State of [insert State] will investigate complaints received relating to drug products compounded by a pharmacist and distributed outside the State by a pharmacy. Primary responsibility for investigating complaints involving drug products compounded by a pharmacist will generally lie with the [insert State Board of Pharmacy or other appropriate State agency].

2. Complaints relating to compounded drug products distributed outside the State that will be investigated include reports received by the State concerning adverse drug experiences or product quality issues associated with drugs compounded by a pharmacist. See Appendix A for definitions of *adverse drug experiences* and *product quality issues*.

3. Any investigations performed by the State of [insert State] under this MOU will include, but are not limited to, taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

4. Based on findings from an investigation of a complaint about drug products compounded by a pharmacist and distributed outside the State, if the complaint is found to be valid, the State of [insert State], in accordance with and as permitted by State law, will take the action that the State considers to be appropriate and warranted to ensure that the relevant compounding pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient

corrective action to address any identified public health risk relating to the complaint, including the risk that future similar complaints may occur.

5. The State of [insert State] will notify FDA by sending an email to StateMOU@fda.hhs.gov with the information described in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days after receiving any complaint relating to a drug product compounded by a pharmacist and distributed outside the State involving a serious adverse drug experience or serious product quality issue. After this notification, the State will share with FDA the results of the investigation that it conducted. See Appendix A for definitions of *serious adverse drug experience* and *serious product quality issue*.

6. If the State of [insert State] receives a complaint involving an adverse experience or product quality issue relating to a drug compounded by a physician and distributed outside the State, the State will notify the appropriate regulator of physician compounding within the State. If the complaint involves a serious adverse drug experience or serious product quality issue, the State will also notify FDA by sending an email to StateMOU@fda.hhs.gov with the information in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days, after receiving the complaint.

7. The State of [insert State] will maintain records of the complaint, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The State will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

b. Distribution of Inordinate Amounts of Compounded Drug Products Interstate

1. For purposes of this MOU, a pharmacy or physician has distributed an inordinate amount of compounded drug products interstate if the number of prescription orders for compounded drug products distributed interstate during any calendar month is greater than 50 percent of the number of prescription orders for compounded drug products distributed or dispensed both intrastate and interstate by such pharmacy or physician during that month.

2. On an annual basis (at minimum), the State of [insert State] will identify, using surveys, reviews of records during inspections, or other mechanisms available to the State, compounding pharmacies that distribute inordinate amounts of compounded drug products interstate by collecting information regarding the total number of prescription orders for compounded drug products distributed or dispensed

intrastate and the total number of prescription orders for compounded drug products distributed interstate.

3. If the State of [insert State] becomes aware of a physician who is distributing compounded drug products interstate, the State will coordinate with the appropriate regulator of physician compounding within the State to determine, using surveys, reviews of records during inspections, or other mechanisms available to the State, whether the physician distributes inordinate amounts of compounded drug products interstate by collecting information regarding the total number of prescription orders for compounded drug products distributed or dispensed intrastate and the total number of prescription orders for compounded drug products distributed interstate.

4. For pharmacies or physicians that have been identified as distributing inordinate amounts of compounded drug products interstate, the State also will collect information regarding the total number of prescription orders for sterile compounded drugs distributed outside the State; the number of States in which the compounding pharmacy or physician is licensed or number of States into which the compounding pharmacy or physician distributes compounded drug products; and whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded drug products without valid prescription orders for individually identified patients.

5. The State will notify FDA by sending an email to StateMOU@fda.hhs.gov within 30 days of identifying a pharmacy or physician within its jurisdiction that has distributed inordinate amounts of compounded drug products interstate and will include the information described in section III.c.1.b of this MOU.

c. Submission and Disclosure of Information

1. When submitting information to StateMOU@fda.hhs.gov regarding complaints relating to compounded drug products distributed outside the State or regarding distribution of inordinate amounts of drugs interstate, the following minimum information will be included:

a. Complaints:

i. Name and contact information of the complainant;

ii. Name and address of the pharmacy/physician that is the subject of the complaint;

iii. Description of the complaint, including a description of any compounded drug product that is the subject of the complaint;

iv. State's initial assessment of the validity of the complaint relating to a compounded drug product distributed outside the State, if available; and

v. Description and date of any actions the State has taken to address the complaint.

b. Inordinate Amounts:

i. Name and address of the pharmacy/physician that distributed inordinate amounts of compounded drug products interstate;

ii. The total number of prescription orders for compounded drug products distributed or dispensed intrastate;

iii. The total number of prescription orders for compounded drug products distributed interstate;

iv. The total number of prescription orders for sterile compounded drug products distributed interstate;

v. The number of States in which the compounding pharmacy or physician is licensed or into which the pharmacy or physician distributes compounded drug products, and

vi. Whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded human drug products without valid prescription orders for individually identified patients.

2. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 or commissioning of officials under 21 CFR 20.84 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement, or commissioning terms, will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4

of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the State of [insert State] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including, but not limited to, the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the State of [insert State] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the State of [insert State] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert name of State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the State no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the State will notify FDA.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research

Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[State]
TBD

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 30-day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the State does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded drug products distributed outside the State, the MOU may be terminated upon 30-days' notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the State will notify all licensed pharmacists, pharmacies, and physicians within the State of the termination and advise them that as of 30 days from the date of the posting of the termination notice, compounded drug products may be distributed (or caused to be distributed) out of the State only in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR THE STATE OF [insert State]
By (Type Name)	By (Type Name)
Title	Title

Appendix A. Definition of Terms Used in the MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution:** *Distribution* means that a compounder has sent a drug product out of the facility in which the drug was compounded. Such distribution may include, but is not limited to, delivery or shipment to a physician's office, hospital, or other health care setting for administration, and dispensing the drug product by sending it to a patient for the patient's own use.

  Note: To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU will not alter this condition.

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

Attachment 3

CURES Registrants: January – September 2018	
Pharmacists	42, 005
Total Number of Individuals Registered	189, 516
Percentage of Pharmacists Registrants	22%

Patient Activity Reports Generated: January – September 2018	
By Pharmacists	6,598,299
Total Number of Reports Generated	11,824,881
Percentage Reports Generated by Pharmacists	56%

Number of Times CURES Accessed: January – September 2018	
Accessed by Pharmacists	2,976,701
Total Times Accessed by Anyone	5,172,871
Percentage of Time Pharmacists Accessed CURES	58%

Prescriptions Entered Into CURES: January – September 2018*										
	January	**February**	**March**	**April**	**May**	**June**	**July**	**August**	**September**	**Total**
Schedule II	1,726,990	1,480,870	1,588,066	1,533,991	1,667,542	1,556,515	1,591,632	1,618,469	1,489,334	14,253,409
Schedule III	310,252	264,141	288,155	282,299	305,624	295,207	300,782	305,018	279,448	2,630,926
Schedule IV	1,761,696	1,506,128	1,649,786	1,591,822	1,682,599	1,615,704	1,648,649	1,642,124	1,535,760	14,634,268
Schedule V	72,753	50,045	49,681	39,282	39,454	35,218	36,831	33,519	37,974	394,757
Total	3,871,691	3,301,184	3,575,688	3,447,394	3,695,219	3,502,644	3,577,894	3,599,130	3,342,516	31,913,360

*Includes other prescription drugs reported to CURES.