AMA
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David E. Brown, DC
Director, Department of Health Professions
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Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Dr. Brown:

On behalf of the American Medical Association (AMA) and our physician and student members, I am writing to provide a brief analysis of the relationship between the most common legislative policy interventions of the nation's opioid overdose and death epidemic and key measures. Specifically, this letter will discuss opioid prescribing restrictions, mandates to use state prescription drug monitoring programs (PDMPs) and mandates for continuing medical education. Furthermore, this letter will highlight state and national trends for physicians' use of PDMPs, opioid prescribing, and mortality data related to prescription opioids, heroin and illicit fentanyl. Data specific to Virginia will be included throughout this letter.

As you review this letter and the attached information, there are a few overarching considerations:

- Nearly all policy interventions have occurred in the past 1-3 state legislative cycles, but physicians' and other health care professionals' actions to increase use of PDMPs and make more judicious prescribing decisions began 3-4 years ago;
- The nature of the opioid epidemic is changing. While death due to prescription opioids remains unacceptably high, death due to heroin and illicit fentanyl are now the main drivers of opioid-related mortality; and
- States with and without PDMP use mandates and prescribing restrictions have each seen increases and decreases, respectively.

In other words, while there may be some who attempt to directly correlate state legislative interventions with reductions in opioid-related harms, based on the available data, the AMA does not believe that correlation—let alone direct causation—can be made at this time.

<u>What is the current landscape of PDMP mandates?</u>

At least 32 states, including Virginia, have enacted a mandate.[1] The circumstances vary considerably, however. In New York, for example, prescribers of controlled substances must check the state PDMP each and every time a prescription is written for Schedule II, III or IV Controlled Substances. In Tennessee, a prescriber must check the state PDMP prior to a prescription for an opioid analgesic or benzodiazepine and once per year thereafter for continuing prescriptions. Many other states have enacted mandates that focus mainly on the initial opioid prescription.

[1] A detailed state laws chart is attached for your use.

The key question, however, is whether the mandate—or other factors—have caused physicians to use the PDMP tool. We are continuing our research and analysis for all 50 states, but we have identified a representative sample of 22 states to highlight the relationship between physician and other health care professionals' use of PDMPs and their respective legislative mandates to use them. As you can see from Table 1, PDMP use began to increase—significantly in many cases—prior to the legislative enactment and/or implementation date.[2] In Virginia, for example, high PDMP usage began well before the 2016 enactment of the Commonwealth's new mandate.

Our research also shows that the key determining factor in the state increases was how well the PDMP was integrated into the physician's workflow, ease of use, delegate access and other factors that helped incorporate the PDMP into clinical practice rather than become an administrative exercise. While the mandate will certainly further increase use of the PDMP, it is the *quality* of the Commonwealth system that is responsible for the strong uptake in use and as a result—as you can attest—Virginia's PDMP is among the nations' most successful.

Table 1: PDMP queries by health care professionals

State	2014	2015	2016	Mandate to Query	Year
Arizona		1,548,774	3,975,220	Yes	2017
Arkansas	555,240	734,625	2,536,448	Yes	2017
California	3,553,551	6,174,394	9,581,280	Yes	2017
Colorado	682,600	898,000	1,515,839	Yes (limited)	2015
Florida	1,549,916	4,105,915	8,454,622	No	N/A
Georgia			1,139,116	Yes	2018
Kentucky	4,991,810	5,498,298	5,500,000	Yes	2013
Massachusetts	860,260	1,467,392	2,768,130	Yes	10/15/2016
New Hampshire			320,683	Yes	2016
New Jersey	1,404,614	2,077,870	2,486,000	Yes	2015
New Mexico	368,283	487,844	938,940	Yes	2017
New York	16,811,126	18,145,982	18,365,222	Yes	2013
Ohio	7,500,000	10,500,000	24,094,984	Yes	4/1/2015
Oklahoma	1,141,029	2,898,085	5,478,498	Yes	12/1/2015
Pennsylvania		65,831	2,345,018	Yes	2017
Rhode Island	226,453	386,222	405,060	Yes	2016
Tennessee	5,062,732	6,442,965	7,071,199	Yes	2012
Texas	867,879	1,130,400	1,086,373	Yes	2019
Vermont	103,330	125,553	167,000	Yes	2017
Virginia	**1,870,196**	**4,860,636**	**5,400,000**	**Yes**	**2016**
Washington	522,872	958,246	3,880,532	Yes	2012
West Virginia	840,557	909,508	1,010,753	Yes	2016
TOTAL (all U.S.)	**61,462,376**	**86,096,259**	**136,095,271**		

[2] For a 50-state review of all states' PDMP use, see: AMA Fact Sheet: PDMP use more than doubles from 2014 to 2016, available at https://www.end-opioid-epidemic.org/wp-content/uploads/2017/06/AMA-fact-sheet-PDMP-use-more-than-doubles-2014-2016.pdf

<u>What is the current landscape of opioid prescribing restrictions?</u>

More than 20 states thus far have enacted some type of restriction or limit on the amount of opioids prescribed to a patient. Typically, these limits are focused on the “initial prescription” for an opioid analgesic and/or benzodiazepine. In reviewing a representative sample (Table 2) of states with and without restrictions on prescribing, three clear conclusions can be drawn. First, states with and without restrictions on prescribing, all saw decreases in total opioid prescriptions from 2013 to 2016. Second, there does not appear to be any correlation between the restriction and amount of decrease. And third, *the decreases all began prior to the enactment of legislation designed to reduce opioid supply*. This includes Virginia, which had reductions above the national average as well as a per capita prescribing rate below the national average.

Table 2: State and National Totals of Filled Prescriptions - All Opioid Analgesics

State	2013	2014	2015	2016	Rx per capita 2016	Rate of change 2013-2016	Restriction on Prescribing?	Date Implemented
Arizona	5,050,348	5,038,497	4,813,236	4,549,927	0.7	9.9%	Yes	2017
California	21,047,372	20,561,933	18,666,608	17,441,819	0.4	17.1%	No	N/A
Colorado	3,678,624	3,637,189	3,471,691	3,191,200	0.6	13.3%	No	N/A
Florida	13,636,391	13,413,544	12,708,441	12,750,684	0.6	6.5%	No	N/A
Georgia	8,643,869	8,305,929	7,880,524	7,856,894	0.8	9.1%	No	N/A
Kentucky	4,997,389	4,900,964	4,471,521	4,178,616	0.9	16.4%	Yes	2017
Maine	1,105,502	1,060,604	985,562	867,776	0.7	21.5%	Yes	2016
Massachusetts	4,584,487	4,431,390	4,066,743	3,551,098	0.5	22.5%	Yes	2016
Nebraska	1,497,183	1,470,605	1,378,816	1,325,382	0.7	11.5%	Yes	2016
New Hampshire	970,834	937,024	886,243	764,009	0.6	21.3%	No	N/A
New Jersey	5,160,965	5,082,090	4,917,404	4,593,494	0.5	11.0%	Yes	2017
New Mexico	1,422,434	1,436,906	1,409,482	1,299,762	0.6	8.6%	No	N/A
New York	10,957,729	10,450,786	10,164,060	9,534,858	0.5	13.0%	Yes	2016
Ohio	11,261,528	10,794,842	9,955,858	9,057,498	0.8	19.6%	Yes	2017
Pennsylvania	11,330,259	11,031,159	10,394,466	9,496,052	0.7	16.2%	Yes	2017
Rhode Island	871,892	823,219	732,367	655,736	0.6	24.8%	Yes	2016
Tennessee	8,525,017	8,239,110	7,800,947	7,366,191	1.1	13.6%	No	N/A
Texas	18,569,734	17,959,748	15,903,061	15,444,180	0.6	16.8%	No	N/A
Utah	2,364,661	2,308,830	2,186,792	2,107,481	0.7	10.9%	Yes	2017
Vermont	418,161	415,687	388,108	348,511	0.6	16.7%	Yes	2017
Virginia	**6,346,359**	**6,047,580**	**5,608,460**	**5,240,314**	**0.6**	**17.4%**	**Yes**	**2017**
Washington	5,163,236	5,121,469	4,881,633	4,607,428	0.6	10.8%	Yes	2012
West Virginia	2,420,990	2,389,802	2,076,883	1,752,690	1.0	27.6%	No	n/a
All States	**143,678,605**	**139,811,327**	**130,140,446**	**122,741,287**	**0.7**	**14.6%**		

There are many reasons why opioid prescribing has decreased in every state in the nation, including physicians and other health care professionals making more judicious prescribing decisions. As the Commonwealth's new prescribing guidelines are implemented in daily practice, it is clear that there likely will be further reductions in opioid supply. We understand why policymakers and payers have focused on limiting opioid prescribing, but we urge an equal focus on improving the quality of care for patients with pain. We believe that the objective should be to improve the number of pain patients whose pain is well controlled without needing high doses of opioids for lengthy periods of time. Achieving that would be true quality improvement, and it is a mistake to approach a reduction in opioid prescribing alone as the goal. Finally, it is the AMA's position that the policy objective should focus both on how well patients' pain is controlled and what therapies are being used to manage pain. It is not acceptable to focus all the attention on reducing opioid prescribing if the result is to increase patient suffering.

What is the current landscape of CME requirements?

The third main type of policy intervention introduced by state legislators focuses on mandatory education requirements on opioid use. At least 25 states have enacted some type of continuing medical education (CME) requirement for physicians and other health care professionals concerning topics relating to opioids, prescribing, pain management, substance use disorders and other areas. Similar to PDMP mandates and prescribing restrictions, however, there does not appear to be a consistent theme across these requirements. The AMA strongly supports enhancing physicians' education, but believes that the education should be meaningful and relevant to a physician's practice and patient population. The mandates may do that in some cases, but not in others. This is why the AMA Opioid Task Force created a new website that houses more than 300 state and specialty specific resources, including multiple Virginia-specific resources: https://www.end-opioid-epidemic.org/virginia/

Table 3: State CME mandates

State	**Summary of mandate/requirement**[3]
Alabama	Two hours on "prescribing" goes into effect January 2018
Arkansas	Prescribers are required to obtain at least two hours of CME on prescribing (emphasis on Schedule II Controlled Substances)
California	All physicians (except pathologists and radiologists), as a one-time requirement, must take 12 units on pain management and the appropriate care and treatment of the terminally ill. This must be completed by the physician's 2nd license renewal date or within four years, whichever comes first
Florida	Requirement limited to physicians prescribing or dispensing controlled substances in registered pain management clinics
Georgia	One-time three hour course designed specifically to address controlled substance prescribing practices. Goes into effect January 2018.
Iowa	For primary care physicians who treat chronic pain, two hours every five years
Kentucky	At least 4.5 hours relating to the use of KASPER (the state PDMP), pain management, addiction disorders, or a combination of two or more of those subjects for licensees who are authorized to prescribe or dispense controlled substances within the Commonwealth
Maine	Three hours every two years as a condition of prescribing opioid medication

[3] This is not meant to provide legal advice or the specific legal description of the state requirement. The AMA recommends reviewing the full statutory and/or regulatory requirement in the states.

Table 3: State CME mandates (cont'd)

Maryland	One hour on opioid prescribing
Massachusetts	Three hours of pain management training and opioid education per the Commonwealth's two-year licensing cycle
Mississippi	Five hours must be related to the prescribing of medications with an emphasis on controlled substances.
New Hampshire	Three hours of NH Board of Medicine approved CME required every two years relating to opioid prescribing, including medication-assisted treatment
New Jersey	One credit on topics concerning opioid analgesics, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction and diversion
New Mexico	Five hours in appropriate courses, including pharmacology, basic awareness, state and federal regulations, pain management and treatment, and other courses subject to medical board approval
New York	All prescribers who hold a DEA license must take a three hour course on pain management, palliative care and addiction
North Carolina	One hour course on controlled substance prescribing – as of July 1, 2017
Ohio	Limited to pain management clinics; the physician owner/operator must complete at least 20 hours in pain medicine every two years, to include one or more courses addressing the potential for addiction; part of the state requirement for a certificate of registration renewal
Oklahoma	One hour every other year on prescribing, dispensing, and administering controlled substances
Oregon	One hour pain management course; a minimum of six CME credit hours in the subject of pain management and/or the treatment of terminally ill and dying patients
Pennsylvania	For initial license applicants, at least two hours of education in pain management or identification of addiction and at least two hours of education in the practices of prescribing opioids. For license renewals, at least two hours of CME in pain management, identification of addiction or the practices of prescribing of opioids
Tennessee	At least one hour on prescribing practices; providers of intractable pain treatment must have specialized CME in pain management
Vermont	At least two of the hours must be on the topics of hospice, palliative care or pain management services. All licensees who are required to certify completion of CME and who prescribe controlled substances shall certify at the time of each renewal that at least one of the hours of qualifying CME activity is related to the topic of safe and effective prescribing of controlled substances
West Virginia	Three hours of drug diversion training and best practice prescribing of controlled substances training as a condition of licensure renewal
Wisconsin	Two hours on a Wisconsin State Medical Examining Board-approved course on the MEB's opioid prescribing guideline.

Do PDMP mandates and prescribing restrictions have a direct impact on opioid-related mortality?

In the AMA's state and national advocacy, we urge policymakers to focus on legislative interventions that will lead to two primary outcomes regarding the nation's opioid overdose and death epidemic: (1) reducing opioid-related harms—particularly overdose and death; and (2) improving access to treatment.

Generally, a review of representative states (Table 4) shows a continuing increase of rates of mortality across the three major opioid categories—regardless of PDMP mandates and prescribing restrictions. And while the chart below only shows a limited number of states, it is representative of the fact that the nature of the epidemic is changing from one driven by prescription opioids to one driven by illicit fentanyl and heroin. Prescription opioid mortality remains unacceptably high, but other than a few, limited examples (e.g. California, New Hampshire, New Mexico and Virginia) mortality continues to rise in this category. It is not clear why these states have seen slight decreases and other variations in prescription opioid-related mortality, but they, too, have seen increases in illicit fentanyl and heroin-related death.

Table 4: Opioid-related mortality[4] and relationship with PDMP mandates and prescribing restrictions

	Natural and Semisynthetic Opioids (e.g. oxycodone, hydrocodone)				Synthetic Opioids, other than Methadone (e.g. fentanyl)				Heroin				PDMP Mandate	Date	Prescribing Restriction	Date
	2012	2013	2014	2015	2012	2013	2014	2015	2012	2013	2014	2015				
Arizona	326	253	290	298	36	52	57	72	101	146	197	247	Yes	2017	Yes	2017
California	965	1039	1047	1019	146	176	194	229	362	486	561	593	Yes	2017	No	n/a
Colorado	223	221	259	259	52	67	80	64	91	120	156	159	Yes	2015	No	n/a
Florida	850	751	697	789	162	200	343	610	101	181	344	567	No	N/A	No	n/a
Georgia	300	309	388	435	61	80	174	284	40	67	153	222	Yes	2018	No	n/a
Kentucky	391	349	344	382	70	76	179	323	143	215	228	310	Yes	2013	Yes	2017
Maine	61	64	80	102	15	23	62	116	12	16	38	52	Yes	2017	Yes	2016
Mass.	171	179	178	225	67	98	453	949	246	288	469	634	Yes	2016	Yes	2016
N.H.	56	62	81	63	24	30	151	285	39	67	98	78	Yes		No	n/a
N.J.	217	231	245	237	38	57	111	243	304	383	424	508	Yes	2015	Yes	2017
N.M.	179	209	223	160	37	23	66	42	104	89	139	156	Yes	2017	No	n/a
New York	616	644	608	705	164	210	294	668	516	666	825	1058	Yes	2013	Yes	2016
Ohio	499	518	618	690	139	167	590	1234	696	998	1208	1444	Yes	2015	Yes	2017
Penn.	358	406	411	460	99	108	217	429	323	409	503	663	Yes	2017	Yes	2017
R.I.	72	80	70	95	12	32	82	137	30	65	66	45	Yes	2016	Yes	2016
Tenn.	491	524	554	643	77	99	132	251	50	68	148	205	Yes	2012	No	n/a
Texas	480	452	471	473	121	112	157	186	367	369	425	523	Yes	2019	No	n/a
Utah	328	358	367	357	59	58	68	62	84	122	110	127	Yes		Yes	2017
Vermont	27	37	21	25	NSD	17	21	33	10	20	33	33	Yes	2017	Yes	2017
Virginia	**276**	**297**	**323**	**276**	**89**	**125**	**176**	**270**	**121**	**206**	**253**	**353**	**Yes**	**2016**	**Yes**	**2017**
Wash.	332	269	288	261	59	59	62	65	177	205	289	303	Yes	2012	Yes	2012
W.V.	348	341	363	356	89	98	122	217	63	144	163	194	Yes		No	n/a
U.S.	**11134**	**11342**	**12159**	**12728**	**2628**	**3105**	**5544**	**9549**	**5925**	**8257**	**10574**	**12957**				

Thus, while the AMA hopes that the positive trend in prescription-related opioid mortality in Virginia will continue, it cannot be said that the Commonwealth's new policies have had a direct effect without further data showing continued decreases. At the same time, we recognize the suggestions that the increased pressure on physicians to restrict prescribing opioids has caused some physicians to stop prescribing opioids altogether, including no longer treating patients on chronic, long-term opioid therapy. The argument follows that those patients often turn to diverted medications for pain relief, and data does show that nearly 60 percent of patients who misuse opioid analgesics do so for pain relief.

What is challenging to understand, however, is whether patients who cannot obtain prescription opioids through legitimate means turn to illicit fentanyl and heroin. Many claim that 70 to 80 percent of heroin users started on a prescription opioid. It is not clear, however, how many of those heroin users first used a prescription opioid prescribed to them by a physician or other health care professional, how many became dependent through repeated prescriptions and whether there were other factors involved. Without question, further analysis here is needed to best identify how to reduce opioid misuse as well as successful programs to reduce exposure to heroin and illicit fentanyl.

<u>What does the AMA recommend?</u>

One very promising initiative is occurring within Virginia. Your state's Medicaid 1115 waiver to increase access to treatment for substance use disorders as well as improve access to comprehensive, multidisciplinary pain care—including non-opioid pain care—is by recent accounts, a great success. In data shared with the AMA by the Virginia Department of Medical Assistance Services, it is clear that the

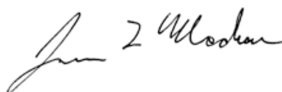
[4] See "Opioid Overdose Deaths by Type of Opioid" available at http://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-type-of-opioid/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Virginia waiver is a model that other states would do well to consider. Without detailing all of the outcomes, we were particularly impressed by the comprehensive nature of efforts to increase the number of physicians treating patients with substance use disorders; incentives to support the increase in treatment; and changes to treatment for pain that emphasize multidisciplinary pain care. Notably, the AMA shares the Commonwealth's goals of removing prior authorization hurdles for medication assisted treatment (MAT) for substance use disorders as well as prior authorization for certain non-opioid pain care. We strongly urge that this combination of statewide support for increasing access to care combined with the removal of administrative barriers be carried over to legislative and other policy discussions in Virginia.

We would also like to point out that in January 2017, the New York Attorney General announced settlements with Anthem, CIGNA and Blue Cross Blue Shield to remove barriers and expand access to life-saving treatment for opioid use disorders. Generally, the agreement provides that these payers will no longer require prior authorization for treating patients with MAT for the treatment of a substance use disorder. The agreement is supposed to cover all commercial plans in all states where the payers do business.[5] As Virginia moves forward with potential solutions to the epidemic, we would like to believe that other payers would willingly undertake measures to remove barriers to MAT. Short of that, however, the AMA strongly supports state legislatures taking action to prohibit prior authorization for MAT—as well as urging the state attorney general and bureaus (or departments) of insurance to determine whether payers in the Commonwealth are in compliance with the agreements.

In closing, please accept this letter and its analysis as a starting point for further discussions. By looking at the three most common forms of legislative intervention, and comparing those to opioid-related mortality, this letter hopes to clarify the tenuous nature of making any type of definitive correlative or causational statement between them. Even as the AMA continues to urge physicians to take action with respect to PDMPs, prescribing and education, we simultaneously urge increased emphasis on removing barriers to evidence-based, multimodal pain care and comprehensive treatment for substance use disorders. Unless and until these occur, we are very concerned that opioid-related overdose and death will continue to rise. If you have any questions, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, Advocacy Resource Center at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Sincerely,



James L. Madara, MD

cc: Medical Society of Virginia

[5] Anthem and Empire Blue Cross agreement: https://ag.ny.gov/sites/default/files/final_letter_agreement_anthem-empire_mat_010117.pdf; Cigna agreement: https://ag.ny.gov/sites/default/files/ny_oag-cigna_mat_letter_agreement_101916.pdf