

REPORT OF THE BOARD OF TRUSTEES

B of T Report 22-A-19

**Subject:** Inappropriate Use of CDC Guidelines for Prescribing Opioids  
(Resolution 235-I-18)

**Presented by:** Jack Resneck, Jr., MD, Chair

**Referred to:** Reference Committee B  
(Charles Rothberg, MD, Chair)

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1 INTRODUCTION

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3 At the 2018 Annual Meeting, the House of Delegates (HOD) referred the second resolve of  
4 alternate Resolution 235, “Inappropriate Use of CDC Guidelines for Prescribing Opioids.” The  
5 second resolve in the alternate resolution asked:

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7 [T]hat our AMA actively continue to communicate and engage with the nation’s largest  
8 pharmacy chains, pharmacy benefit managers, National Association of Insurance  
9 Commissioners, Federation of State Medical Boards, and National Association of Boards of  
10 Pharmacy in opposition to communications being sent to physicians that include a blanket  
11 proscription against filing prescriptions for opioids that exceed numerical thresholds without  
12 taking into account the diagnosis and previous response to treatment for a patient and any  
13 clinical nuances that would support such prescribing as falling within standards of good quality  
14 patient care.

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16 This report provides an update on those communications, highlights complementary AMA  
17 advocacy and provides recommendations.

18  
19 DISCUSSION

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21 The nation’s opioid epidemic has led to extensive policy development in multiple areas—from  
22 several hundred new state laws and regulations to hundreds of millions of dollars earmarked by  
23 federal legislation for treatment of opioid use disorder, harm reduction efforts and other initiatives.  
24 Debating the merits of the new laws and regulations would go beyond the scope of this report, but  
25 it should be noted that each new law or regulation occurred within a notice and comment period as  
26 well as extensive public debate informed by stakeholder advocacy that underpins the lawmaking  
27 process. Medical societies may not have supported each piece of legislation or agreed with the  
28 regulatory agencies charged with rulemaking, but organized medicine has been an active  
29 participant in every state, in Congress and with the relevant federal agencies.

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31 That is not, however, the only type of policymaking that has occurred. Health insurance companies,  
32 national pharmacy chains and pharmacy benefit management companies (PBMs) all have—to  
33 varying degrees—implemented their own policies governing physician prescribing of controlled  
34 substances as well as patients’ abilities to have a controlled substance prescription dispensed to  
35 them. The result of this type of quasi-regulation is incredibly difficult to quantify on a large scale  
36 basis due to the lack of transparency in the public sphere, but the AMA and many medical societies

1 continue to receive concerns from physicians and patients as to the disruptive nature of health plan,  
2 pharmacy chain or PBM interference in the patient-physician relationship. The concern and/or  
3 perceived interference has included pharmacists calling to ask about a patient's diagnosis or request  
4 patient records, a pharmacist asking for clarification about a prescription or alerting the physician to  
5 red flags, a pharmacist recommending a different medication strategy, and in some cases, a  
6 pharmacist informing the physician that the prescription will not be filled. This concern and/or  
7 interference has even gone so far as a pharmacist demanding patients taper their opioid  
8 prescriptions, telling them that the U. S. Drug Enforcement Administration (DEA) identified the  
9 patient's prescription as "exceeding the maximum Morphine Milligram Equivalents (MME) as  
10 defined by the Centers for Disease Control and Prevention (CDC)." In response to this last  
11 incident, the DEA and CDC, among others, stated to the AMA (and the Medical Association of  
12 Georgia) that the pharmacist's actions and interpretation of CDC and DEA rules and guidelines  
13 were incorrect and inappropriate. MAG informed the AMA of this situation, and the AMA, in turn,  
14 reached out to the DEA, CDC, National Association of Boards of Pharmacy and others—all of  
15 whom quickly engaged with the AMA to register their disapproval of the pharmacy action and state  
16 that they would take all relevant actions in Georgia. Your Board appreciates the fact that DEA,  
17 CDC, NABP and others took action to support the concerns of MAG and the AMA.

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19 These different physician-pharmacist interactions, however, are often the inevitable result of  
20 policies mainly focused on the dose and/or number of days for a prescription for opioid analgesics.  
21 It should be noted at the outset that the AMA strongly supports physicians' efforts to ensure that if  
22 a prescription for an opioid analgesic is warranted to help treat a patient's pain, physicians should  
23 prescribe the lowest effective dose only for the shortest duration of time. The AMA also supports  
24 pharmacists as key partners in helping ensure medication safety and as part of the patient-  
25 physician-pharmacist therapeutic triad. The Board and the AMA Opioid Task Force point out that  
26 physicians' efforts to make more judicious prescribing decisions have led to a more than 22 percent  
27 reduction in retail opioid prescriptions dispensed between 2013-2017, and that these reductions  
28 began prior to nearly all legislative, regulatory and other efforts focused on reducing opioid supply.  
29

30 Concurrent with and despite this progress, national pharmacy chains, health insurance companies  
31 and PBMs have implemented their own restrictive opioid prescribing policies. This report will not  
32 detail every iteration and difference between the policies except to say that most of the policies are  
33 some variation of the "CDC Guideline for Prescribing Opioids for Chronic Pain—United States,  
34 2016" (the CDC Guideline).<sup>2</sup> In the CDC Guideline's introduction, CDC stated:

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36 [T]he recommendations in the guideline are voluntary, rather than prescriptive standards. They  
37 are based on emerging evidence, including observational studies or randomized clinical trials  
38 with notable limitations. Clinicians should consider the circumstances and unique needs of  
39 each patient when providing care.

40  
41 Yet, the CDC Guideline goes on to make two recommendations that appear in nearly all the  
42 pharmacy, payer and PBM policies:

43  
44 [Recommendation] 5. When opioids are started, clinicians should prescribe the lowest effective  
45 dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully  
46 reassess evidence of individual benefits and risks when considering increasing dosage to  $\geq 50$   
47 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to  $\geq 90$   
48 MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/day.

1 [Recommendation] 6. Long-term opioid use often begins with treatment of acute pain. When  
2 opioids are used for acute pain, clinicians should prescribe the lowest effective dose of  
3 immediate-release opioids and should prescribe no greater quantity than needed for the  
4 expected duration of pain severe enough to require opioids. Three days or less will often be  
5 sufficient; more than seven days will rarely be needed.

6  
7 The AMA is concerned by the fact that policymakers, health plans, corporate pharmacy chains and  
8 PBMs have used these recommendations to restrict or refuse patients (with few exceptions) to  
9 receive a prescription greater than 90 MME or for more than seven days. It is important to note that  
10 CDC Guideline Recommendations 5 and 6 were intended guidelines for acute pain episodes, not a  
11 hard threshold, and not intended for chronic pain patients. The U.S. Department of Health and  
12 Human Services Interagency Pain Care Task Force draft report commented:

13  
14 [A]t least 28 states have enacted legislation related to opioid prescription limits, and many  
15 states and organizations **have** implemented the guideline without recognizing that the intended  
16 audience was [primary care providers]; have used legislation for what should be medical  
17 decision making by healthcare professionals; and have applied them to all physicians, dentists,  
18 NPs, and PAs, including pain specialists. Some stakeholders have interpreted the guideline as  
19 intended to broadly reduce the amounts of opioids prescribed for treating pain; some experts  
20 have noted that the guideline emphasizes the risk of opioids while minimizing the benefit of  
21 this medication class when properly managed. The CDC guideline was not intended to be  
22 model legislation for state legislators to enact.<sup>3</sup>

23  
24 Many of the state legislative and other policies enacted and/or implemented since then, however,  
25 justify the dosage limit for acute pain based on the CDC Guideline. The HOD addressed this in  
26 Policy D-120.932, “Inappropriate Use of CDC Guidelines for Prescribing Opioids.” While it is  
27 common for state opioid prescribing restriction policies to allow for exceptions for patients with  
28 cancer, in hospice or who require palliative care, to name a few, exceptions are highly variable  
29 regarding post-operative surgical care, chronic pain, cancer remission-related pain, sickle cell or  
30 other conditions for which a patient might require a prescription for a greater dosage than a state  
31 law might allow.

32  
33 AMA has consistently stated its opposition to these hard thresholds because of the potential danger  
34 they pose if a patient does not neatly fit into an exception category (e.g., hospice, cancer, palliative  
35 care). At the same time, multiple national pharmacy chains implemented some variation<sup>4</sup> of the  
36 CDC Guideline as their policy—a move the AMA warned would occur.<sup>5</sup> AMA President  
37 Barbara L. McAneny, MD, shared with the HOD at the 2018 Interim Meeting that a pharmacy  
38 denied an opioid prescription to one of her prostate cancer patients—claiming he was a drug  
39 seeker.<sup>6</sup> Additionally, the AMA “FixPriorAuth” campaign<sup>7</sup> heard from a patient’s wife that:

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41 [T]his happened to my sweetheart, changing insurance companies. He was on pain meds for an  
42 extended period and they wouldn’t authorize his meds in time so his current prescription ran  
43 out and we had to go to the hospital for pain control. They are heartless!!

44  
45 The AMA’s first engagement with this issue dates to discussions that occurred in 2013-2014 with  
46 the National Association of Boards of Pharmacy (NABP), the Federation of State Medical Boards  
47 (FSMB) and many other stakeholders. Those discussions were born from concerns physicians and  
48 others raised with respect to early precursors of opioid prescription restriction policies. The result  
49 of those discussions was not only a consensus statement highlighting the legal and professional  
50 obligations of physicians, but also the corresponding responsibility of pharmacists.<sup>8</sup>

1 The AMA’s work with the FSMB, moreover, also pre-dated the issuance of the CDC Guideline.  
2 One prominent outcome from the FSMB was adoption, in 2017, of an updated “Guidelines for the  
3 Chronic Use of Opioid Analgesics.”<sup>9</sup> The AMA was a member of the workgroup that provided  
4 input to the FSMB during its deliberations and strongly voiced its concern about “one-size-fits-all”  
5 thresholds. The FSMB, to its great credit, supported those concerns and the resulting policy reflects  
6 support for ensuring patient-focused care. For example, the FSMB states:

7  
8 [T]he “focus of the [FSMB] Guidelines that follow is on the general overall safe and evidence-  
9 based prescribing of opioids and treatment of chronic, non-cancer pain with the specific  
10 limitation and restriction that these Guidelines do not operate to create any specific standard of  
11 care, which standard must depend upon fact-specific totality of circumstances surrounding  
12 specific quality-of-care events.”

13  
14 In addition to the FSMB’s ongoing support for patient-focused care, the development of the NABP  
15 consensus statement also resulted in the development of close relationships with pharmacy  
16 counterparts at several national chain pharmacies. When issues have arisen in select states where a  
17 physician reports a concern with the dispensing decision of a pharmacy, these relationships have  
18 enabled AMA to work directly with the national chain and the state medical society to resolve the  
19 issue—a resolution based on specific facts rather than a one-size-fits-all approach. The AMA also  
20 has remained in close contact with the NABP to share information and work collaboratively where  
21 interests align, including efforts to bolster constructive relationships between physicians and  
22 pharmacists. It also is worth highlighting that some pharmacy boards are taking steps to remind  
23 their licensees about the need to ensure dispensing determinations are made on an individualized  
24 patient basis.<sup>10</sup>

25  
26 Despite continued efforts by AMA to constructively engage Walmart, Inc. (Walmart), however, the  
27 national pharmacy chain has taken a markedly different course. Specifically, Walmart has sent an  
28 unknown number of what can be considered “blacklist” letters to physicians. These unsigned letters  
29 from Walmart’s corporate headquarters have been sent in multiple states and only include a generic  
30 email address for the physician to respond to if the letter was believed to be sent in error. The letter  
31 typically states that the physician in question had his or her “prescribing patterns and practices”  
32 reviewed and as a result, “[Walmart] determined that we will not be able to continue filling your  
33 controlled substance prescriptions.” AMA has sent multiple letters, email and voice messages to  
34 Walmart opposing its policy and seeking explanation—all without meaningful response.<sup>11</sup> Others,  
35 including the Texas Medical Association, also have not received a meaningful response from  
36 Walmart.<sup>12</sup> In one instance, the overly broad and vague Walmart policy targeted a rural Idaho  
37 addiction medicine physician who prescribed buprenorphine, but did not prescribe opioid  
38 analgesics. As CDC has stated, buprenorphine for the treatment of opioid use disorder should not  
39 be used in an MME calculation,<sup>13</sup> but resolution of this matter required extensive commitment from  
40 the Idaho Medical Association and Idaho Board of Pharmacy—and resulted in patients being  
41 forced to find alternate pharmacies to continue their care.

42  
43 With respect to health insurance companies, the AMA has made inquiries but is not aware of any  
44 widespread action by payers to send physicians letters or other communication “that include a  
45 blanket proscription against filing prescriptions for opioids that exceed numerical thresholds  
46 without taking into account the diagnosis and previous response to treatment for a patient and any  
47 clinical nuances would support such prescribing as falling within standards of good quality patient  
48 care.” Rather, AMA is acutely aware of health insurance companies implementing hard-threshold  
49 guidelines based on the CDC guideline.

1 AMA President-elect and Chair of the AMA Opioid Task Force, Patrice A. Harris, MD, MA,  
2 raised concerns about these payer policies directly to the National Association of Insurance  
3 Commissioners (NAIC) at its Regulatory Framework Task Force hearing on Saturday, March 24,  
4 2018. AMA Chair Jack Resneck, Jr., MD, raised similar concerns about patients facing restrictions  
5 on receiving opioid analgesics without payers removing prior authorization and other restrictions  
6 on non-opioid behavioral, restorative, surgical and other non-opioid modalities at the November  
7 16, 2018 hearing of the NAIC Health Insurance and Managed Care Committee. Both Drs. Harris  
8 and Resneck highlighted patients' need for greater access to comprehensive, multidisciplinary,  
9 multimodal pain care. The AMA has continued this advocacy directly to state regulators—a  
10 primary feature of new, spotlight analyses of state responses to the opioid epidemic.<sup>14</sup>  
11

## 12 AMA POLICY

13  
14 The AMA has extensive and wide-ranging policy in support of ensuring patients receive optimal  
15 pain care and removal of arbitrary restrictions on the provision of that care. This includes having  
16 AMA “oppose legislative or other policies that arbitrarily restrict a patient's ability to receive  
17 effective, patient-specific, evidence-based, comprehensive pain care. (Policy H-95.930,  
18 “Legislative Pain Care Restrictions”). It also includes AMA’s “strong commitment to better access  
19 and delivery of quality pain care through the promotion of enhanced research, education and  
20 clinical practice in the field of pain medicine,” as well as the AMA’s “commitment to delivering  
21 compassionate and ethical pain management, promoting safe opioid prescribing, reducing opioid-  
22 related harm and the diversion of controlled substances, improving access to treatment for  
23 substance use disorders, and fostering a public health based-approach to addressing opioid-related  
24 morbidity and mortality.” (Policy D-160.981, “Promotion of Better Pain Care”). AMA policy also  
25 supports “the position that physicians who appropriately prescribe and/or administer controlled  
26 substances to relieve intractable pain should not be subject to the burdens of excessive regulatory  
27 scrutiny, inappropriate disciplinary action, or criminal prosecution.” (Policy H-120.960,  
28 “Protection for Physicians Who Prescribe Pain Medication”). As noted above, AMA policy  
29 supports ensuring that patients are not harmed by the “misapplication of the CDC Guideline for  
30 Prescribing Opioids for Chronic Pain by pharmacists, health insurers, pharmacy benefit managers,  
31 legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients’  
32 medical access to opioid analgesia.” (Policy D-120.932, “Inappropriate Use of CDC Guidelines for  
33 Prescribing Opioids”).  
34

## 35 RECOMMENDATIONS

36  
37 The Board recommends that the following recommendations be adopted in lieu of the second  
38 resolve of alternate Resolution 235-I-18, and that the remainder of the report be filed.  
39

- 40 1. That our American Medical Association (AMA) support balanced opioid-sparing policies that  
41 are not based on hard thresholds, but on patient individuality, and help ensure safe prescribing  
42 practices, minimize workflow disruption, and ensure patients have access to their medications  
43 in a timely manner, without additional, cumbersome documentation requirements. (New HOD  
44 Policy)
- 45  
46 2. That our AMA oppose the use of “high prescriber” lists used by national pharmacy chains,  
47 pharmacy benefit management companies or health insurance companies when those lists do  
48 not provide due process and are used to blacklist physicians from writing prescriptions for  
49 controlled substances and preventing patients from having the prescription filled at their  
50 pharmacy of choice. (New HOD Policy)

Fiscal Note: Less than \$500.

## REFERENCES

- <sup>1</sup> Undated letter from Lakeside Pharmacy, “Opioid Therapy Above the MME.” On file with author.
- <sup>2</sup> Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>
- <sup>3</sup> U.S. Department of Health and Human Services. Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. December 2018. Available at <https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html#4-review-cdc>
- <sup>4</sup> See, for example, CVS Caremark® Opioid Quantity Limits Pharmacy Reference Guide. Available at [https://www.caremark.com/portal/asset/Opioid\\_Reference\\_Guide.pdf](https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf)
- <sup>5</sup> See also AMA January 12, 2016 letter to then-CDC Director Thomas Frieden, MD. Available at <https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/cdc-opioid-guidelines-12jan2016.pdf>
- <sup>6</sup> Attacking the Dysfunction in Health Care. Barbara L. McAneny, MD, President, American Medical Association. AMA Interim Meeting, National Harbor, MD, November 10, 2018. Available at <https://www.ama-assn.org/system/files/2018-11/i18-mcaneny-speech.pdf>
- <sup>7</sup> Physicians and patients can learn more about American Medical Association advocacy to broadly address prior authorization issues at [www.FixPriorAuth.org](http://www.FixPriorAuth.org)
- <sup>8</sup> See “NABP Collaborates With Health Care Stakeholders on Ensuring Delivery of Responsible and Effective Patient Care,” February 4, 2014. Available at <https://nabp.pharmacy/nabp-collaborates-with-health-care-stakeholders-on-ensuring-delivery-of-responsible-and-effective-patient-care/>
- <sup>9</sup> Guidelines for the Chronic Use of Opioid Analgesics Adopted as policy by the Federation of State Medical Boards April 2017. Available at [https://www.fsmb.org/siteassets/advocacy/policies/opioid\\_guidelines\\_as\\_adopted\\_april-2017\\_final.pdf](https://www.fsmb.org/siteassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf)
- <sup>10</sup> See, for example, a January 23, 2019 letter from the Alaska Board of Pharmacy stressing, among other things, that “Simply refusing to fill a prescription without trying to resolve the concern may call into question the knowledge, skill or judgment of the pharmacist and may be deemed unprofessional conduct.” The full letter is available at [https://www.commerce.alaska.gov/web/portals/5/pub/pha\\_ControlledSubstanceDispensing\\_2019.01.pdf](https://www.commerce.alaska.gov/web/portals/5/pub/pha_ControlledSubstanceDispensing_2019.01.pdf)
- <sup>11</sup> See August 16, 2018 AMA letter to Walmart at <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-8-16-McMillon-Hays-Walmart-Opioid-Policy-letter.pdf>; and October 3, 2018 AMA letter to Walmart: <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-10-3-Letter-to-Walmart-FINAL.pdf>
- <sup>12</sup> “Opioid Overreach? State, Retail Pharmacy Policies Prompt Scope-of-Practice Concerns,” Texas Medicine, December 2018. Available at <https://www.texmed.org/Template.aspx?id=49157>
- <sup>13</sup> January 4, 2018 letter from Debra Houry, MD MPH Director, National Center for Injury Prevention and Control Centers for Disease Control and Prevention, to the American Society of Addiction Medicine. Available at [https://www.asam.org/docs/default-source/advocacy/letters-and-comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-\(002\).pdf?sfvrsn=7fa840c2\\_2](https://www.asam.org/docs/default-source/advocacy/letters-and-comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-(002).pdf?sfvrsn=7fa840c2_2)
- <sup>14</sup> The spotlight analyses can be found on the AMA’s opioid microsite. The Pennsylvania spotlight is available at <https://www.end-opioid-epidemic.org/wp-content/uploads/2018/12/AMA-Manatt-PAMED-spotlight-analysis-FINAL-for-release.pdf> and the Colorado spotlight is available at [https://www.end-opioid-epidemic.org/wp-content/uploads/2019/01/AMA-Paper-Spotlight-on-Colorado-January-2019\\_FOR-WEB.pdf](https://www.end-opioid-epidemic.org/wp-content/uploads/2019/01/AMA-Paper-Spotlight-on-Colorado-January-2019_FOR-WEB.pdf)