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)

INTRODUCTION

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

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

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

DISCUSSION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AMA POLICY

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

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) support balanced opioid-sparing policies that are not based on hard thresholds, but on patient individuality, and help ensure safe prescribing practices, minimize workflow disruption, and ensure patients have access to their medications in a timely manner, without additional, cumbersome documentation requirements. (New HOD Policy)

2. That our AMA oppose the use of "high prescriber" lists used by national pharmacy chains, pharmacy benefit management companies or health insurance companies when those lists do not provide due process and are used to blacklist physicians from writing prescriptions for controlled substances and preventing patients from having the prescription filled at their pharmacy of choice. (New HOD Policy)

Fiscal Note: Less than $500.

REFERENCES

[1] Undated letter from Lakeside Pharmacy, "Opioid Therapy Above the MME." On file with author.
[2] 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
[3] 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
[4] See, for example, CVS Caremark® Opioid Quantity Limits Pharmacy Reference Guide. Available at https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf
[5] 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
[6] 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
[7] Physicians and patients can learn more about American Medical Association advocacy to broadly address prior authorization issues at www.FixPriorAuth.org
[8] 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/
[9] 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
[10] 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
[11] 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
[12] "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
[13] 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
[14] 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