INTRODUCTION

At the 2017 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) adopted Policy D-120.935, “Evaluating Actions by Pharmacy Benefit Manager and Payer Policies on Patient Care,” which directed the AMA to:

1. Take steps to implement AMA Policies H-120.947 and D-35.981 that prescriptions must be filled as ordered by physicians or other duly authorized/licensed persons, including the quantity ordered.

2. Work with pharmacy benefit managers, payers, relevant pharmacy associations, and stakeholders to:
   a. Identify the impact on patients of policies that restrict prescriptions to ensure access to care and urge that these policies receive the same notice and public comment as any other significant policy affecting the practice of pharmacy and medicine, and
   b. Prohibit pharmacy actions that are unilateral medical decisions; and

3. Report back at the 2018 Annual Meeting on actions taken to preserve the purview of physicians in prescription origination.

This report summarizes actions that the AMA has taken to preserve physician autonomy, highlights relevant AMA policy, and presents policy recommendations. Because the intent of the resolution and reference committee testimony primarily focused on situations related to the prescribing and dispensing of opioid analgesics, this report will similarly focus on that issue.

DISCUSSION

The AMA has been working closely with the nation’s leading pharmacy and pharmacist organizations for years in support of the therapeutic triad, that is, working to enhance the collaborative roles of physicians, pharmacists and patients to help ensure safe and appropriate medication use. With respect to prescriptions for opioid analgesics, the AMA began receiving increasing reports about pharmacists contacting physicians to request additional information about patient prescriptions for controlled substances (before they would authorize dispensing) as far back as 2013. In response, the AMA and the National Association of Boards of Pharmacy organized a
series of discussions with multiple stakeholders designed to increase awareness of factors contributing to these types of requests and to improve communication channels. Participating organizations included:

- American Academy of Family Physicians
- American College of Emergency Physicians
- American Medical Association
- American Osteopathic Association
- American Pharmacists Association
- American Society of Anesthesiologists
- American Society of Health-System Pharmacists
- Cardinal Health
- CVS Health
- Drug Enforcement Administration
- Federation of State Medical Boards
- Healthcare Distribution Management Association
- National Association of Boards of Pharmacy
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- Pharmaceutical Care Management Association
- Rite Aid
- Walgreen Co.

The stakeholders initially met in October 2013, and subsequently met numerous times over the course of 2013 and 2014 to better understand the shared responsibilities of physicians and pharmacists to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose. The stakeholders’ focus began with a review of a key provision within the Controlled Substances Act, which provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.¹ (emphasis added)

Participants engaged in a constructive dialogue and ultimately agreed and released a consensus statement (signed by nearly all of the organizations) about the challenges that physicians and pharmacists face in trying to understand and resolve “red flags” that may be apparent, and a broader array of aberrant behaviors that may manifest and raise concerns among physicians. Commonly agreed upon “red flags” have been constructed out of U.S. Drug Enforcement Administration (DEA) administrative actions and most are obvious, such as a clearly forged prescription or multiple people from out-of-state presenting prescriptions for large quantities of high-dose opioid analgesics. However, some behaviors (e.g., slurred speech, exhibiting signs of intoxication) or specific features of the prescription including drug combinations may raise questions for the pharmacist that may be unresolvable without obtaining further information from
the prescribing physician. In these cases, the organizations agreed that inter-professional dialogue was essential to resolve questions to the patient’s benefit. Stakeholders shared the consensus statement widely with the intent of increasing understanding of the shared legal responsibilities of physicians and pharmacists for controlled substance prescriptions. Subsequently, when the AMA received complaints from state medical societies or individual physicians, staff have enabled on multiple occasions direct collaboration between a retail pharmacy and the state medical society to investigate and intercede with the individual pharmacist or prescriber when necessary. An overarching goal is to ensure that legitimate inquiries by a pharmacist about a patient’s diagnosis or medical history that are necessary to fulfill their corresponding legal responsibility are not perceived as intrusive or unnecessary, and to foster communications that can help resolve potential contraindications and/or provide physicians with relevant information in a patient’s prescription history about which the physician may not be aware. Without question, such discussions can sometimes be challenging.

Publication of the Centers for Disease Control Guideline For Prescribing Opioids For Chronic Pain (CDC Guidelines) in March 2016, has changed the regulatory and clinical practice environment and led to new challenges for pain management and opioid prescribing, including the likelihood that some patients will have their prescriptions for opioid analgesics dispensed as written. Two of the CDC Guideline’s recommendations—which were developed as voluntary guidance and not a bright line threshold, according to CDC—make specific reference to prescriptions above a certain morphine milligram equivalent amount (Recommendation 5) and above a certain quantity (or days’ supply) (Recommendation 6). In comments to the CDC during the review period, the AMA expressed specific concerns about the unintended consequences of such thresholds—highlighting that future payer and legislative actions would likely align with the CDC Guidelines in ways that would not be patient centric.

Since the publication of the CDC Guidelines, more than 20 states have enacted opioid prescribing limits that include specific dose and/or quantity thresholds. What is notable is that nearly every state prescribing restriction is different, although most purport to have exceptions for patients with cancer; those who are in hospice or receiving palliative care; at end of life; or when the opioid is part of a treatment regimen for a substance use disorder. Furthermore, it is notable that opioid prescribing appears to have reached its zenith in 2012 (259 million prescriptions) with modest decreases every year since yielding a cumulative 17 percent decrease, between 2012 to 2016 (215 million prescriptions). It is beyond the scope of this report to analyze the lack of correlation between decreased opioid prescribing and increased opioid-related mortality, but the AMA remains deeply concerned that policymakers’ focus continues to be on reducing opioid supplies, with little or no emphasis on increasing access to multidisciplinary pain care, including non-opioid, and non-pharmacologic alternatives.

In addition to state laws that govern prescribing behavior, there has been significant activity by payers, pharmacies, and pharmacy benefit managers (PBMs) to adopt and implement opioid prescribing restrictions based on CDC Guidelines, including new policies in 2017 from the nation’s largest PBMs, CVS Caremark, Express Scripts, and Optum. This is in addition to prescription review policies that were previously implemented by pharmacies. Many payers also have instituted new prior authorization policies based on CDC Guidelines, including many state Medicaid plans, Blue Cross Blue Shield plans, and plans sponsored by United Health Care, Anthem, Aetna, Cigna, and others. In each case, the pharmacies, PBMs, and payers affirm their commitment to ending the opioid epidemic through increased vigilance regarding opioid prescribing, and many of the plans have touted their success in reducing opioid prescribing. The Board notes that the inevitable effect of any statutory, regulatory or other policy to restrict a practice will, in fact, lead to such a
restriction. What is less clear, however, is whether the restrictive policies have had a concomitant
effect of improving patients’ pain care, or (and beyond the scope of this report) whether those
policies have helped identify patients at risk of overdose and referred them to treatment for a
potential substance use disorder.

The AMA continues to work with pharmacy associations and business entities, including asking
the central question about whether the new policies are helping patients. The actions by
pharmacies, is in addition to legislative and regulatory activity limiting quantity and dose of opioid
analgesics, and in some cases, benzodiazepines. While the AMA remains concerned by actions to
apply one-size-fits-all solutions to the opioid epidemic, we are cognizant that many state medical
societies have been deeply engaged in the legislative process to help craft the resulting laws.
Pharmacy, PBM, and payer policies, however, have not received the benefit of public notice or
comment.

When comment is sought—such as through the federal government—the AMA makes its concerns
clear. One of the most recent examples was in response to the Centers for Medicare & Medicaid
Services (CMS) request for comment on a new electronic quality measure (eCQM) focused on the
degree of potential opioid overuse, and using 90 morphine milligram equivalents as the quality
measure standard, the AMA on February 9, 2018 emphasized:

Identifying those patients for whom opioid prescriptions exceed => 90 morphine milligram
equivalents (MME)/day may serve as an indicator of whether a patient is at risk of overdose
and should be co-prescribed naloxone, but the AMA believes that significant revisions and
testing are required prior to implementing this measure in any federal program. The measure
as constructed implies that patients who do not receive => 90 MME/day over a 90-day period
receive higher quality care. We do not believe that the measure, with its broad denominator
population and limited exclusions, adequately captures the recommendations from the
CDC. The recommendations allow for physicians to document a clinical rationale or
justification when 90 MME/day is exceeded; yet, the measure does not capture if a
justification exists nor does it provide a well-defined and targeted denominator.

While it is not yet known when CMS will publish the final measure, the AMA has and will
continue to stress the need for clinical decisions to have a clear rationale informed by the best
available evidence. Furthermore, use of the CDC Guidelines in this manner is also inconsistent
with the intended use of the Guidelines.

For example, the CDC Guidelines states:

Clinical decision making should be based on a relationship between the clinician and patient,
and an understanding of the patient’s clinical situation, functioning, and life context. The
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.

Additionally, the AMA has actively engaged with multiple pharmacies, public health, and other
organizations to advance policies increasing access to naloxone. It should be noted that the Board
and AMA Council on Legislation first approved AMA model state legislation, the Help Save Lives
from Overdose Act, in 2013, and revised and updated the model bill in subsequent years. In
partnership with more than two dozen state medical societies, pharmacy associations, and other
stakeholders ranging from the Federation of State Medical Boards, National Association of Boards
of Pharmacy, Walgreens, CVS, National Governors Association, and many others, the AMA model bill—or similar versions—are now law in every state in the nation. This type of collaborative effort has undoubtedly saved tens of thousands of lives. At the same time, the AMA continues to hear reports that some patients may not be able to afford naloxone due to the cost, lack of awareness of patient assistance programs or the ongoing stigma associated with naloxone. The AMA will continue to work to address these barriers to care so that when a patient needs access to naloxone, it will be available.

The AMA also has engaged in efforts by the National Association of Insurance Commissioners (NAIC) to revise their model legislation on the pharmacy benefit. AMA staff worked closely with other stakeholders, including many consumer and patient organizations, to advocate for the need to regulate utilization review (e.g. pharmacy benefit managers) that delay or decrease access to patient care and stand in the middle of the patient-physician decision making process. Additionally, AMA staff sought provisions that prevented continual formulary changes and other cost-saving tactics by payers that undercut physicians’ ability to ensure patients receive appropriate care. While many positive provisions supported by the AMA were incorporated into the final NAIC model, much work remains to be done as state legislatures consider pharmacy benefit regulations.

As such, the AMA has developed model legislation to address the issues of prior authorization, step therapy and other utilization management programs that have regularly impeded the practice of medicine by physicians, and just this year alone, is working with nearly a dozen state medical societies on state bills.

Additionally, over the last year the AMA has assembled a multi-stakeholder group that created a set of highly cited and widely distributed principles on utilization management reforms, all aimed at right-sizing payer involvement in patient care. In addition to policy discussions and changes that these principles have informed, they also served as the basis for a recent consensus statement among the American Medical Association, Blue Cross Blue Shield Association, America’s Health Insurance Plans, American Pharmacists Association, American Hospital Association, and Medical Group Management Association on the need to reform prior authorization programs and processes.

More broadly, the AMA also has engaged with the National Association of Insurance Commissioners and others to support notification of patients and physicians before a health insurance company or PBM may change a patient’s prescription. This situation often occurs as a PBM restricts a formulary during a patient’s plan year. In 2017, two of the nation’s two largest pharmacy benefit managers – Express Scripts and CVS/Caremark, which set the coverage for many health insurers – continue to aggressively remove medications from their formularies.

When health insurers or PBMs decide to exclude certain products, or increase the patients’ cost-sharing, patients are forced to switch to a new medication, which may or may not be as effective. And if the patient wishes to continue taking the medication that he or she used to stabilize a medical condition, the off-formulary cost may not be affordable – and it will not count towards the patient’s deductible. These types of forced-switching and increased patient cost-sharing are associated with declines in medication adherence, which in turn can lead to poorer patient health outcomes. In some cases, patients are forced to choose between necessary treatments and decisions such as expenses for food or shelter.

For physicians and patients, when a prescription for an opioid analgesic—or any other medication—is denied at the pharmacy counter, there may be multiple reasons. In some cases, as described above, the health insurance company or the PBM may be applying a hard edit associated with limits based on the CDC Guidelines. In other cases, it may be the pharmacy chain policy that
determines what the pharmacist may dispense. In these situations, the pharmacist is placed in the
difficult position of having to inform the patient, and often, the physician, that the original
prescription will not be filled. In other cases, also described above, the pharmacist may
determine—per his or her lawful exercise of the pharmacist’s corresponding responsibility—that
the prescription was not issued for a legitimate purpose in the usual course of professional practice.

In these situations, if the pharmacist communicates with the physician to determine how to
proceed, this will take time away from the physician’s practice and the pharmacist’s ability to help
more patients. The AMA supports physician-pharmacist interactions to ensure patient safety, but
in some cases, the decision has been taken out of the pharmacist’s control—frustrating the
physician, pharmacist and likely adversely affecting the patient. And even when the
communication from the pharmacist to the physician is to resolve important questions, there still
may be frustration due to having to take time away from patient care or return a call to the
pharmacy, which may result in the physician being placed on hold for an extended period—further
delaying and impeding patient care.

AMA POLICY

The AMA supports patients having access to the medications prescribed to them by their physician
without interference into the practice of medicine (H-120.947, “Preserving Patients’ Ability to have
legally Valid Prescriptions Filled”; D-35.981, “AMA Response to Pharmacy Intrusion Into Medical
Practice”). For controlled substances, this policy must be tempered with the recognition that
pharmacists share a corresponding responsibility that carries the same legal obligations and risks
for failure to comply. In addition, AMA policy states opposition to “pharmacists being given the
authority to initiate or modify prescription drug treatment except on a case by case basis at the
specific direction of a physician” (H-160.928, “Drug Initiation or Modification by Pharmacists”).
At the same time, the AMA recognizes that “cooperative relationships with law enforcement,
regulatory agencies, pharmacists, and other professional groups” are necessary to identify
situations where a person is attempting to obtain a prescription for fraudulent or otherwise illegal
means (H-95.990, “Drug Abuse Related to Prescribing Practices”). Similarly, AMA policy
“supports legislative, regulatory, and national advocacy efforts to increase access to affordable
naloxone, including but not limited to collaborative practice agreements with pharmacists and
standing orders for pharmacies” (H-95.932, “Increasing Availability of Naloxone”). It is worth
noting that AMA advocacy, including development of model state legislation based on Policy H-
95.932, has helped lead to enactment of naloxone access laws in all 50 states. AMA policy strongly
supports “private and public payers to include all forms of naloxone on their preferred drug lists
and formularies with minimal or no cost sharing.” (H-95.932, “Increasing Availability of
Naloxone”).

AMA policy is clear that health insurance carriers and PBMs must provide accurate information to
patients at the time when plans are put forward for review by consumers. (H-125.979, “Private
Health Insurance Formulary Transparency”). Furthermore, H-125.979 clearly states that “drugs
may not be removed from the formulary nor moved to a higher cost tier within the policy term.” In
addition, AMA policy supports “forbidding insurance carriers from making formulary deletions
within the policy term.” In the event that an insurer or PBM does make a change, AMA policy calls
for “notice of covered formulary alternatives to the prescriber promptly so that appropriate
medication can be provided to the patient within 72 hours.” As directed by our HOD, the AMA has
drafted model state legislation to accomplish these goals, and the AMA strongly urges state
medical societies to work with the AMA to introduce and enact the AMA model state legislation.
RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) urge the National Association of Boards of Pharmacy and Federation of State Medical Boards to support having national pharmacy chains, health insurance companies and PBMs testify at state-level public hearings by state/pharmacy boards, respectively, on whether their policies to restrict the prescribing/dispensing of opioid analgesics are in conflict with state law governing the practice of medicine and pharmacy, respectively. (Directive to Take Action)

2. That our AMA oppose specific dose or duration limits on pharmacologic therapy that are not supported by medical evidence and clinical practice. (New HOD Policy)

3. That our AMA reaffirm Policy H-95.990, “Drug Abuse Related to Prescribing Practices,” which supports cooperative relationships with law enforcement, regulatory agencies, pharmacists and other professional groups as necessary to identify situations where a person is attempting to obtain a prescription for fraudulent or otherwise illegal means. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-95.932, “Increasing Availability of Naloxone,” which supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.
REFERENCES


4 CDC Guideline For Prescribing Opioids For Chronic Pain, March 18, 2016. Available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

5 Recommendation 5 of the CDC Guideline states: “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.”

6 Recommendation 6 of the CDC Guideline states: “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 (recommendation category).”


