

January 13, 2016

Tom Frieden, Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

***Re: Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain
(Docket Number CDC-2015-0112)***

Dear Director Frieden:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Disease Control and Prevention (CDC) for its work in developing strategies to address the growing opioid epidemic in the United States and for the opportunity to provide comments in response to the *Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain (CDC-2015-0112)*. AMCP further commends the CDC for considering the concerns raised by stakeholders, including AMCP, after the informal release of the draft guidelines in September 2015 and for formally releasing the draft guidelines for public comment. While AMCP believes the draft guidelines are a step in the right direction to ensure opioids are appropriately utilized, AMCP has several concerns with the recommendations that the CDC must consider prior to finalization and adoption to ensure that the perspective of managed care pharmacy is taken into consideration. AMCP offers comments on the following elements that it believes are either missing from the guidelines or can be improved upon:

- Core Expert Group
- Patient Risk Evaluation and Assessment
- Titration and Discontinuation of Therapy
- Lock-In Programs
- Electronic Prescribing
- Care Coordination
- Concurrent Drug Therapy
- Prescription Drug Monitoring Programs
- Opioid Overdose Antidotes
- Safe Storage and Disposal of Opioids

AMCP believes that a holistic, comprehensive, and multi-stakeholder approach among health care providers and patients is necessary to truly address the opioid epidemic. AMCP is committed to resolving issues associated with the opioid epidemic and has established an Addiction Treatment Advisory Group

which, in 2016, will evaluate current gaps and barriers to addiction treatment services and develop recommendations to improve patient care. AMCP will share the recommendations and findings from the advisory group with the CDC and other stakeholders.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Core Expert Group

In developing the draft guidelines, CDC convened a Core Expert Group to assist in interpreting the evidence and translating it into recommendations. While CDC describes the composition of the Core Expert Group, it has not identified the individuals that served on this group nor confirmed compliance with requirements under the Federal Advisory Committee Act (FACA)¹ for convening a group of this nature. The level and breadth of expertise consulted in developing the recommendations is unknown. Furthermore, the guidance is unclear whether the Core Expert Group represented a multi-stakeholder approach to the development of the guidelines, and whether pharmacy was represented. Therefore, AMCP requests that CDC publicly release the names of the individuals who served on the Core Expert Group.

Patient Risk Evaluation and Assessment

AMCP appreciates that the draft guidelines include a recommendation for providers to evaluate risk factors for opioid-related harms before beginning and periodically during continuation of opioid therapy. However, AMCP is concerned that the draft guidelines do not include a recommendation for referring patients identified as having significant risk factors for opioid-related harms (such as history of substance use disorder) to a pain specialist or addiction therapist prior to initiating opioid therapy. AMCP believes patients with a known risk of opioid-related harms require specialized care and attention to prevent unintended consequences, and therefore suggests that the draft guidelines be amended to include a recommendation for referral to a specialist when an individual is identified as high-risk for opioid-related harms.

Titration and Discontinuation of Therapy

AMCP appreciates that the draft guidelines include a recommendation that providers should not initiate opioid therapy without a plan that considers discontinuation of therapy if it is unsuccessful. While AMCP agrees that it is important to have a discontinuation plan if opioid therapy is unsuccessful, AMCP also believes it is equally as important to have a titration and discontinuation plan if opioid therapy is successful or no longer necessary. As noted by the CDC in the draft guidelines and supported in medical literature, the risk of opioid-related harms continues to increase the longer a patient remains on chronic opioid therapy and it is critical that opioid therapy be used a temporary measure while long-term non-pharmacological strategies, such as physical therapy, are implemented as appropriate for patients.^{2,3,4} Therefore, AMCP recommends that the draft guidelines be

¹ Pub. L. No. 92-463 (1972) (codified at 5 U.S.C., Appendix).

² Edlund MJ, Martin BC, Russo JE, et al. The role of opioid prescription in incident opioid abuse and dependence among individuals with chronic noncancer pain. *Clin J Pain* 2014;30:557–64.

³ Franssen M, McConnell S, Harmer Alison R, Van der Esch M, Simic M, Bennell Kim L. Exercise for osteoarthritis of the knee. *Cochrane Database Syst Rev* 2015;1:CD004376.

amended to also indicate that providers should not initiate opioid therapy without consideration of how non-pharmacological interventions will be implemented and how opioid therapy will be titrated and discontinued.

Lock-In Programs

AMCP is disappointed that the draft guidelines do not recommend the use of patient contracts or lock-in programs, also known as patient restriction and review programs. Lock-in programs, currently used in state Medicaid programs and commercial plans, allow patients identified at the highest-risk for opioid overutilization to be restricted to a single pharmacy and a single provider. Lock-in programs help to mitigate the issues associated with doctor or pharmacy poly-shopping and may reduce the number of inappropriate controlled substance prescriptions for the patients identified as being in the top percentile of risk for opioid overutilization. In 2009, the Oklahoma Medicaid department found that its lock-in program reduced doctor shopping, utilization rates of controlled substances, and emergency room visits with an average savings of \$600 per person in costs.⁵ In addition, a recent study evaluating the clinical outcomes of lock-in programs for Medicaid patients found that the proportion of stable patients increased from 31% at 6 months to 78% at 36 months.⁶ Therefore, AMCP strongly encourages the CDC to amend the draft guidelines to include a recommendation that patients identified as high-risk for opioid overutilization should be entered into a lock-in program to reduce incidence of doctor or pharmacy shopping.

As noted above, lock-in programs have successfully been used by state Medicaid programs and commercial plans for years but are currently prohibited under Medicare Part D. As the CDC notes in the draft guidelines, opioid misuse by elderly patients, the primary population covered by the Medicare Part D program, is a growing concern in the United States and it is unfortunate that lock-in programs, along with other clinical and psychosocial interventions, may not be used to allow these individuals to receive the help they need. Furthermore, Medicare beneficiaries who are disabled and under 65 are at greatest risk for overutilization or inappropriate utilization of opioids thereby strengthening the need for lock-in programs under Medicare Part D. Given the success and experience using lock-in programs, AMCP recommends that CDC incorporate the use of these programs as a guideline for certain individuals.

Electronic Prescribing

AMCP is concerned that the draft guidelines do not include a recommendation to adopt electronic prescribing for opioid medications when permissible by state law. Electronic transmission of prescription information offers benefits over written prescriptions in terms of accuracy, storage capacity, accessibility, security and productivity. Benefits of electronic prescriptions include the reduction of errors because of misinterpretation of handwritten prescriptions, confusion between similar-sounding drug names during transmission of prescription orders, and order-entry errors. Electronic prescribing systems alert prescribers to potentially harmful drug interactions, patient drug allergies, and duplicate or overlapping drug therapy, enabling the prescriber to adjust the prescription before the pharmacy dispenses the drug. Electronic prescribing systems also allow prescribers

⁴ Busch AJ, Barber KA, Overend TJ, Peloso PM, Schachter CL. Exercise for treating fibromyalgia syndrome. *Cochrane Database Syst Rev* 2007;4:CD003786.

⁵ Academy of Managed Care Pharmacy. Role of Managed Care Pharmacy in Managing Controlled Substances for Medicare Part D Beneficiaries. 2014. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18556>. (Accessed January 13, 2015).

⁶ Theresa R. F. Dreyer, Thomas Michalski, and Brent C. Williams. Patient Outcomes in a Medicaid Managed Care Lock-In Program. *Journal of Managed Care & Specialty Pharmacy* 2015 21:11, 1006-1012

to access the formulary for a patient’s prescription drug benefit, ensuring that they select a therapy for which the patient has coverage, in addition to any clinical edits that may be present.

Specifically important for opioids, electronic prescribing allows prescription information to be securely transmitted directly to the dispensing pharmacy, reducing the possibility of fraudulent prescribing. Electronic prescribing prevents patients from photocopying, altering, or otherwise tampering with written prescriptions prior to presentation to the pharmacy. Therefore, AMCP strongly encourages CDC to revise the draft guidelines to include electronic prescribing as the preferred mechanism of prescribing opioid medications to substantially reduce the prevalence of fraudulent or tampered prescriptions.

Care Coordination

AMCP is disappointed that the draft guidelines do not reference a team-based approach to treating patients requiring chronic therapy with opioid medications. AMCP believes that a multi-stakeholder approach to treating chronic pain, including care coordination among a patient’s various healthcare providers, is critical to ensure a patient’s pain is properly treated while minimizing the risk for opioid-related harm.⁷ Therefore, AMCP encourages the CDC to amend the draft guidelines to include a recommendation to work collaboratively and communicate effectively with the patient’s care team, including pharmacists and other health care providers who provide patient care and psychosocial services, to ensure a holistic and comprehensive approach to the patient’s individualized pain management.

Concurrent Drug Therapy

AMCP appreciates that the draft guidelines recommend the avoidance of opioid pain medications for patients receiving benzodiazepines whenever possible because concurrent therapy can exacerbate opioid-induced respiratory depression and increase risk for overdose. AMCP recommends that CDC amend the recommendation to also include the avoidance of opioid pain medications for patients receiving skeletal muscle relaxants, such as carisoprodol, as concurrent therapy with these medications can also lead to opioid-induced respiratory depression and increase risk for overdose.⁸

AMCP also recommends that the use of the language “whenever possible” be amended to further clarify that concurrent use of opioid pain medications with benzodiazepines or skeletal muscle relaxants is not a contradiction to use, but rather encourages health care providers and patients to first identify the clinical risks and benefits of using these medications concomitantly. AMCP believes it is important that a balance exists between treating patients with chronic pain and avoiding addiction or other unintended consequences, and therefore the focus should be on ensuring that patients be treated as individuals and receive access to necessary and appropriate medications.

Prescription Drug Monitoring Programs

AMCP appreciates that the draft guidelines include a recommendation that providers should review prescription drug monitoring program (PDMP) data before starting and periodically during continuation of opioid therapy. Given the need for a coordinated care approach to the management of opioid overutilization, AMCP encourages the CDC to amend the recommendation to state that not only should providers review PDMP data themselves,

⁷ Proceedings of the AMCP Partnership Forum: Breaking the Link Between Pain Management and Opioid Use Disorder. *Journal of Managed Care & Specialty Pharmacy* 2015 21:12, 1116-1122

⁸ Witenko C, Moorman-Li R, Motycka C, et al. Considerations for the Appropriate Use of Skeletal Muscle Relaxants for the Management Of Acute Low Back Pain. *Pharmacy and Therapeutics*. 2014;39(6):427-435.

but they should also work collaboratively with and react to suspicious activity alerts provided by pharmacies, health plans, law enforcement, other prescribers, and other entities that have access to PDMP data per state law.

Opioid Overdose Antidotes

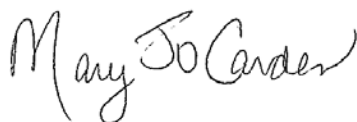
AMCP appreciates that the draft guidelines include a recommendation that providers should consider offering naloxone when factors that increase risk for opioid overdose are present. AMCP believes that engaging in awareness and advocacy initiatives to ensure that opioid overdose antidotes are readily accessible to and accepted by patients and caregivers is a critical element of reducing opioid-related deaths in the United States and commends the CDC for recognizing the importance of agents such as naloxone.

Safe Storage and Disposal of Opioids

AMCP appreciates that the draft guidelines include a recommendation for providers to discuss known risks and realistic benefits of opioid therapy before starting and periodically during opioid therapy. In addition to discussing known risks and benefits of opioid therapy, it is critical that patients are aware of how to safely store and dispose of their opioid medications to minimize the risk of theft, accidental ingestion by children, or abuse by family members/friends. Pharmacists serve a key role in educating patients in the safe storage and disposal of opioids, especially because of their accessibility to patients during person-to-person encounters, either in pharmacies or telephonically. Therefore, AMCP encourages the CDC to include the need for education, by providers and pharmacists, on the safe storage and disposal of opioids before starting and periodically during opioid therapy.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on this issue with the CDC. If you have any questions regarding AMCP's concerns or would like further information, please contact me at 703-683-8416 or mcarden@amcp.org.

Sincerely,

A handwritten signature in cursive script that reads "Mary Jo Carden".

Mary Jo Carden, RPh, JD
Vice President of Government and Pharmacy Affairs