AMDG
agency medical directors' group

A collaboration of state agencies, working together to improve health care quality for Washington State citizens.

March 18, 2019

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
200 Independence Avenue, S.W., Room 736E
Washington, DC 20201
Attn: Alicia Richmond Scott, Task Force Designated Federal Officer

Dear Ms. Scott:

The Washington State Agency Medical Directors' Group (AMDG) believes that there are three principal strategies to reverse the prescription opioid epidemic:

1. Prevent unnecessary or inappropriate acute prescribing so that the next cohort of our citizens is not exposed or placed at risk for transition to chronic opioid use and risk associated harms, including dependence, opioid use disorder, morbidity and mortality;
2. Deliver evidence-based multimodal care to address acute and chronic pain on a community-wide basis; and
3. Reduce long-term harms for the 7-10 million patients on chronic opioids in a patient-centered way. This includes the delivery of effective treatment pathways, such as tapering and treating opioid use disorder, and support services such as care coordination and behavioral therapies.

The HHS draft report substantially addresses strategy 2, but does not adequately address strategy 1 and 3. The following are specific comments on the draft:

- Under section 2 (Clinical Best Practices), we are pleased to see the emphasis on the biopsychosocial model and multidisciplinary pain management and recommendations to address psychosocial barriers to recovery of patients in acute and chronic pain. The AMDG agrees with the need to have more robust insurance coverage for these health care services. We also agree with the emphasis on collaborative, stepped-care management, similar to services provided to patients with chronic diseases such as diabetes. Please see the work on this done in Washington State (The Robert Bree Collaborative. Collaborative Care for Chronic Pain. URL: http://www.breecollaborative.org/topic-areas/previous-topics/chronic-pain/. Accessed 2/28/2019). While there is an emphasis on innovative means of delivering these services, we suggest **additional areas for research**:

    - Determine how health systems could most efficiently and effectively deliver multimodal, collaborative care for acute and chronic pain and how care coordination could be used to support this type of effort.
    - Determine how such delivery models could effectively support primary care providers in continuing to care for patients with chronic pain.
    - Investigate financial and non-financial incentives to implement these delivery models.

  - Address the needs of providers in continuing to care for patients with chronic pain and to avoid patient abandonment.
  - Evaluate the "hub and spoke" model to deliver collaborative care to patients both at risk of addiction and meeting the DSM-V case definition of opioid use disorder.

- Under section 2.2.1 (Risk Assessment), we agree with the emphasis on the use of prescription drug monitoring programs and on broader assessment of biopsychosocial and family factors to help assess risk. However, there is no substantial evidence that risk assessment, per se, a central tenet of this report, is effective in avoiding harms related to opioid use. A systematic review of two of the most widely used risk assessment tools, treatment agreements and urine drug testing, have shown only weak evidence of effectiveness in reducing opioid misuse (Starrels et al. Systematic review: Treatment agreements and urine drug testing to reduce opioid misuse in patients with chronic pain. Ann Int Med 2010; 152: 712-720). In addition, evidence is limited for the use of instruments, such as the Opioid Risk Tool, to screen for risk of aberrant drug-related behaviors (Chou R, et al. Opioids for chronic non-cancer pain: prediction and identification of aberrant drug-related behaviors: a review of the evidence for an American Pain Society and American Academy of Pain Medicine clinical practice guideline. J Pain 2009; 10: 131-46). There is little to no acknowledgement in this report that rapid development of dependence is a sure path to subsequent harm and risk of addiction. It is very likely that a large majority of patients receiving moderate to high opioid doses for 3 months or more are dependent, and differentiating dependence from addiction by use of current instruments is insufficient. (Ballantyne JC et al. Opioid dependence vs addiction. A distinction without a difference. Arch Int Med 2012; 172: 1342-43). Therefore, we recommend the following research area:

  - Develop instruments sufficient to differentiate dependence from addiction among patients receiving opioid prescriptions for chronic non-cancer pain.

- Under section 4, we disagree with a number of the critiques of the 2016 CDC opioid guidelines.

  - Review of the CDC guideline. The evidence for the following statement is mostly anecdotal: "An unintended consequence of the [CDC] guideline is the forced tapering or patient abandonment that many patients with chronic pain on stable long-term doses of opioids have experienced." Forced tapering and patient abandonment are already prevalent in the chronic opioid therapy patient population, with or without the CDC guideline, due to the complexity of these patients and the time necessary for their care, as well as their poor outcomes. Research in Washington State has shown that first year medical students report overwhelming negative perceptions regarding the difficulty of caring for chronic pain patients during their first year of primary care experience in the field (Corrigan et al. What can we learn from first-year medical students' perceptions of pain in the primary care setting? Pain Medicine 2011; 12: 1216-1222). A survey of primary care clinicians practicing in safety net and private clinics revealed one-third reported a death or life-threatening event in a chronic pain patient to whom they had prescribed opioids. Clinicians' narrative comments on factors that affect chronic pain management include barriers to and uncertainties in optimal management; the complex biopsychosocial nature of chronic pain; seriousness of prescription opioid abuse; effort and burden required to properly manage chronic pain; and clinician commitment to provide care for chronic pain patients and benefits of expanded care model for chronic pain (Leverence RR, et al. Chronic non-cancer pain: A siren for primary care—a report from the PRImary Care MultiEthnic Network (PRIME Net) J Am Board Fam Med 2011; 24: 551-61). We agree that patient abandonment should strongly be discouraged and that population-based support and insurance payment for appropriate alternatives to treat pain would allow more primary care providers (PCPs) to continue to care for chronic pain patients on opioids.

The AMDG and Bree Collaborative are focused on the strategic goal to systematically address patients on chronic opioid therapy. A recent systematic review suggested that tapering may be an effective means to reduce or discontinue chronic opioid therapy, and that pain, function and quality of life may improve with such an approach (Frank JW, et al, Patient outcomes in dose reduction or discontinuation of long-term opioid therapy: A systematic review. Ann Int Med 2017; 167: 181-191). However, the evidence is low quality, and additional development of clinical practice guidelines and further research is important. The Patients Centered Outcomes Research Institute has projects like this underway.

- Review of the CDC guideline. We also have concerns about the following statement: "The CDC guideline was not intended to be model legislation for state legislator to enact." While this may not have been the intent of the authors of the CDC guideline, if states wish to incorporate the evidence-based recommendations in legislation to curb the opioid epidemic, this is preferable to basing legislation on anecdotal evidence that resulted in the current crisis. It was exactly such "model legislation" promulgated by the Federation of State Medical Boards and other surrogates funded by drug companies in approximately 1999-2001 that led more than 20 states to pass new rules, often at the level of the state medical boards, to make opioid prescribing much more permissive. With such language and principles as: "No ceiling on dose", "the way to treat tolerance is to keep increasing the dose", and "No disciplinary action will be taken against a practitioner based solely on the quantity and/or frequency of opioids prescribed" (Washington administrative Code 246-919-830, 12/1999). Opioid dosing and mortality rose dramatically in Washington State. Our state promulgated new laws and regulations based on the AMDG's evidence-based guideline in 2009-2011, which repealed these "model guidelines". We have subsequently seen a significant statewide decrease in prescription opioid related deaths (42% decrease from 2008 – 2017).

- Recommendation 7b. "Additional factors influence risk and benefit that should be considered; therefore, guidance regarding dose should not be applied as strict limits." This recommendation implies that there is no firm dosing threshold that should be used. However, with the exception of the North Carolina study cited in this report (Dasgupta et al, Ref 108), most of the population-based studies have related opioid dose to overdose morbidity and mortality. These studies, across multiple populations, have consistently found increased risk at doses above 90-100 mg/day MED in the range of a two-nine fold increase (Dunn KM, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Int Med 2010; 152: 85-92; Gomes T, et al. Opioid dose and drug-related mortality in patients with nonmalignant pain. Arch Int Med 2011; 171: 686-691; Bohnert AS, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. JAMA 2011; 305: 1315-1321; Zedler B, et al. Risk factors for serious prescription opioid-related toxicity or overdose among Veterans Health Administration patients. Pain Med 2014; 15: 1911-1929; Garg RK, et al. Patterns of opioid use and risk of opioid overdose death among Medicaid patients. Med Care 2017; 55: 661-668). In addition, the Garg et al study found an increased risk for opioid-related mortality of 2.3-fold, even in the dose range of 50-89 mg/day MED, consistent with the CDC opioid guidelines.

- Recommendation 8a. We oppose the conclusion that clinical judgement should solely determine opioid durations for patients. This recommendation and much of the acute pain section did not consider the large volume of studies linking duration or number of pills used for acute pain conditions to resulting harm. Brat et al. showed that for opioid naïve patients receiving opioids postoperatively, each refill and additional week of opioids were associated with an adjusted increase in the rate of misuse by 44% (Brat GA, et al. Postsurgical prescriptions for opioid naïve patients and association with overdose and misuse: retrospective cohort study. BMJ 2018; Jan 17;360:j5790. doi: 10.1136/bmj.j5790).

A CDC study has shown the risk of continued opioid use at one year increased by 1% for each day beyond the third day of the initial prescription (Shah A, et al. Characteristics of initial prescription episodes and likelihood of long-term opioid use—United States, 2006-2015. Morb Mort Wkly Rep 2017; 66: 265-269). In a study of patients 16 to 25 years, acute opioid prescription for dental procedures was substantially associated with subsequent opioid use (7-fold increase) and opioid abuse diagnosis (5.3% increased risk) (Schroeder AR, et al. Association of opioid prescriptions from dental clinicians for US adolescents and young adults with subsequent opioid use and abuse. JAMA Int Med 2019;179: 145-152).

Because of this robust evidence for harms tied to dosing and duration, the AMDG and the Dr. Robert Bree Collaborative (Bree) have developed guidelines on prescribing opioids for acute pain in dentistry (The Robert Bree Collaborative. Dental guidelines on prescribing opioids for acute pain management. Sept 2017. URL: http://www.breecollaborative.org/wp-content/uploads/Dental-Opioid-Recommendations-Final-2017.pdf. Accessed 2/18/2019) and for postoperative pain (The Robert Bree Collaborative. Prescribing opioids for postoperative pain-Supplemental Guidance. July 2018. URL: http://www.breecollaborative.org/wp-content/uploads/Final-Supplemental-Bree-AMDG-Postop-pain-091318-wcover.pdf. Accessed 2/18/2019). These guidelines were developed in collaboration with leaders from both the academic and private practice setting and professional associations in Washington. We focus on acute dental pain because dentists are proportionately the most prevalent opioid prescribers for adolescents, a particularly susceptible population regarding future misuse (Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SR. Characteristics of opioid prescriptions in 2009. JAMA 2011;305:1299-301;Miech R, Johnston L, O'Malley PM, Keyes KM, Heard K. Prescription opioids in adolescence and future opioid misuse. Pediatrics 2015:peds.2015-1364). We also focus on postoperative pain because of new emerging data on opioid prescribing and evidence that patients often receive more opioids than are necessary for pain related procedures. These guidelines, along with the 2015 AMDG and CDC guidelines, represent opioid prescribing best practices.

We are concerned with this report's overarching emphasis on the need to individualize care, based on clinicians' risk assessment and use of discretion. There also appears to be a general assumption in this report that chronic opioid therapy is effective for common non-cancer pain conditions. This is how the opioid epidemic began and was perpetuated, with the idea that most prescribers can use risk assessment and decide for themselves what patients may need regarding opioids for chronic pain. But this was based on the flawed rationale that opioids were safe and effective, and that addiction is rare. This latter trope became the mantra of the drug companies and their surrogates. Repeating the assumptions and mistakes from the past will not resolve this crisis.

Sincerely yours,

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