April 1, 2019

Vanila M. Singh
Chief Medical Officer
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

RE: Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Dear Dr. Singh,

The American College of Physicians (ACP) commends the work of the Pain Management Best Practices Inter-Agency Task Force (Task Force) in preparing this vital draft report and appreciates the opportunity to comment. ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. The Task Force has developed a draft report that strikes a crucial balance by offering recommendations that seek to end the nation's opioid epidemic while recognizing the need to support patient-focused, multidisciplinary, multimodal pain management. Over the last several years, ACP has published a series of policy papers on this topic that provide our prescription for policy reforms to curb the abuse of prescription drugs including: The Integration of Care for Mental Health, Substance Abuse, and other Behavioral Health Conditions into Primary Care; Prescription Drug Abuse; and Health and Public Policy to Facilitate Effective Prevention and Treatment of Substance Use Disorders Involving Illicit and Prescription Drugs. These policy papers can serve as a resource for you as you examine policies on this topic.

Specific Comments:

Introduction: ACP appreciates the acknowledgement that "multidisciplinary, multimodal approaches to acute and chronic pain are often not supported in time and resources, leaving clinicians with few options to treat often challenging and complex underlying conditions." ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain. This "toolkit" starts with strong patient–physician relationships and supportive systems of care, and further can include nonaddictive medications, controlled medications, and other evidence-based interventions. Insufficient insurance coverage and other barriers have discouraged comprehensive

interventions, including nonpharmaceutical pain management. Further, physicians may not have adequate time to thoroughly counsel patients about medication safety.

Approaches to Pain Management (2.1)

We support recommendation 1a and request the final report include examples of collaborative pain care models that could be adopted by physicians and other health care professionals working outside of the VA and DoD systems. Potential examples include the Comprehensive Primary Care Plus, which emphasizes whole-person, collaborative care focused on shared decision-making. Further, we strongly support adopting approaches to integrate behavioral health into primary care as a way to address physical and behavioral comorbidities. Payment incentives in Medicare and Medicaid can be designed to continue to support the Patient Centered Medical Home, with its emphasis on whole person primary care, care coordination, and delivery of care by a team of professionals, as an excellent foundation for the integration of behavioral and primary care to manage pain and treat patients with OUD or SUDs

Medications (2.2) General comments: ACP strongly believes that physicians must become familiar with, and follow as appropriate, clinical guidelines related to pain management and controlled substances, such as prescription opioids, as well as nonopioid pharmacologics and nonpharmacologic interventions. Physician support initiatives, such as mentor programs, shadowing experienced providers, and telemedicine, can help improve education and support efforts around pain management.

We appreciate the acknowledgment that "The idea of a ceiling dose of opioids has been put forward, but establishing such a ceiling is difficult, and the precise level for such a ceiling has not been established. The risk of overdose increases with the dose, but the therapeutic window is highly variable." We raised similar concerns about draft language in the CDC's Draft Guideline for the Use of Opioids for Chronic Pain:

> The College fully supports the first section of recommendation that "[when opioids are started] providers should prescribe the lowest effective dosage." While not apparently the intent, we are concerned that the remainder of the recommendation (e.g. morphine milligram equivalent maximum dosage of 90 MME) can too easily be misused (too rigidly applied) by payers and others in a manner that will decrease access to appropriate and effective pain medication for specific patients… Physicians must be responsive to the specific and unique needs of their patients. They must be able to adjust medication dosages according to individual needs that may vary over time and are not the same for all patients. Consequently, ACP opposes arbitrary maximum dosages by payers and health plans. These guidelines are instructive, but like any guidelines, they should not be rigidly applied and there must be some flexibility to allow adjustments in determining dosages reflecting physician judgment.

ACP recognizes that defined maximum dosage (i.e., morphine equivalent) and duration of therapy limitations are not applicable to every clinical encounter. We favor establishment of evidence-based, nonbinding guidelines regarding recommended maximum dosage and duration of therapy that a patient taking controlled substance medications may receive. However, guidelines should not be used as standards that may affect patient access to medically-necessary care.

Prescription Drug Monitoring Programs (PDMP) (2.2.1.1.)

General comments: PDMPs are not a panacea to the opioid epidemic. However, some evidence shows use of PDMPs reduces the number of patients receiving prescriptions from multiple providers and helps to ensure that pain medications are not diverted.

Recommendations 1d, 1e, and 1f: We strongly agree that physicians and other health care providers should determine when to use PDMP data and that use should not be mandated without proper clinical indications. PDMPs can be difficult and time-consuming to use. ACP recommends ensuring interoperability with electronic health record systems and permitting other health care team members to consult programs to encourage PDMP use. It should be noted that even if different PDMP programs agreed to use the same health IT standards (the specific technical standards that would allow PDMPs and EHRs to communicate, exchange, and extract data), there is still so much variation in state laws, funding, and PDMP access procedures that the experience of clinicians attempting to use the PDMPs will continue to vary significantly across the country.

Overdose Prevention Education and Naloxone (2.2.2)

We support co-prescribing of naloxone. ACP has recommended that funding be allocated to distribute naloxone to individuals with opioid use disorder to prevent overdose deaths and train law enforcement and emergency medical personnel in its use.

Access to Psychological Interventions (2.5.1)

We generally agree with Recommendations 1a, 1b, 1c.

Various access barriers or workforce shortages may necessitate alternative treatment delivery. We recommend that Recommendation 1a include language that care provided through alternative treatment delivery models should be coordinated with the patient's care team, including their primary care physician. ACP believes that telemedicine can be most efficient and beneficial between a patient and physician with an established, ongoing relationship. Further, hub-and-spoke models can provide support to physicians and other health care professionals delivering care in remote and/or underserved areas.

Chronic Pain Patients With Mental Health and Substance Use Comorbidities (2.5.2)

ACP supports the integration of behavioral health care into primary care and we encourage our members to address behavioral health issues within the limits of their competencies and resources. Primary care is the appropriate platform to care for these patients as it is often the first point of contact of care for patients with pain. Many patients with chronic pain present co-morbid behavioral health conditions, including anxiety and depression, that can have an effect on pain management.

Public and private health insurance payers and policymakers should work toward requiring adequate provider networks and removing payment barriers that impede behavioral health and primary care integration, and stakeholders should ensure financial resources are available to support the practice infrastructure required to effectively provide such care.

Stigma (3.1)

We generally support these recommendations and agree that "Compassionate, empathetic care in which there is a provider-patient partnership is best for countering the stigma, isolation, and psychosocial challenges of living with pain." We especially appreciate the statement that clinicians who treat pain, particularly those in primary care, experience heightened scrutiny and stigma from state medical boards, the DEA, and colleagues, that may discourage the prescribing of opioids as part of a patient's legitimate pain treatment. Burnout is a major concern for ACP and its members, and is associated with negative patient safety outcomes. ACP has acknowledged the pernicious effect that stigma can have on patients with behavioral health needs, including substance use disorder, and the problem is compounded for patients with SUD and chronic pain comorbidities. It also affects clinician willingness to treat patients with behavioral health needs and tempers workforce recruitment. ACP policy emphasizes the importance of addressing the stigma surrounding substance use disorders among the health care community and the general public.

Access to Pain Care (3.3)

We agree with the finding that "The recent advent of retail pharmacies limiting the duration of prescriptions, making changes to dosage, amounts, or placing restrictive barriers to obtaining properly prescribed pain medications has had the unintended consequence of limiting access to pain care. Without access to sufficient pain care, many patients face unnecessary medical complications, prolonged suffering, and increased risk for psychiatric conditions."

Insurance Coverage for Complex Management Situations (3.3.2)

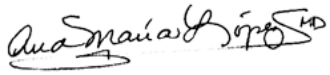
As stated elsewhere, ACP supports the consideration by physicians of the full array of treatments available for the effective treatment and management of pain. However, coverage gaps, onerous utilization management, and other barriers make pursuing a multimodal, multidisciplinary pain management strategy difficult. We appreciate the statement that "Although the HHS National Pain Strategy calls for greater access and coverage for pain management services, there is a lack of uniformity in insurance coverage and lack of coverage alignment with current practice guidelines for pain management. This is particularly true for the coverage of nonpharmacologic and behavioral health interventions." We concur with the recommendations under this heading, particularly 1a and 4a.

Review of the CDC Guideline (4)

In our 2016 comments on the draft CDC Guideline, we expressed concern that the recommendations could be used by payers, policymakers, and institutions as justification to apply prescriptive standards in a manner that would inappropriately decrease access to opioid medications for individuals for whom they serve as the most effective means of addressing pain and increasing functionality. As noted in the draft report, these concerns were founded, as insurance plans, retail pharmacies, and state and local governments adopted guideline-based acute pain opioid prescription limits and other restrictions that have had serious unintentional consequences for patients suffering from pain. We agree with the message that "clinicians should be able to use their clinical judgement to determine opioid duration for their patients" and that policies should ensure safe prescribing practices, minimize workflow disruption, and ensure timely access to medications without undue paperwork and administrative burdens.

Thank you for the opportunity to comment on this impressive draft report. Please contact Ryan Crowley, Senior Associate for Health Policy at rcrowley@acponline.org if you have additional questions.

Sincerely,



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