American College of Physicians
Leading Internal Medicine, Improving Lives

February 16, 2018

The Honorable Orrin Hatch
Chairman
Senate Finance Committee
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
Washington, DC 20510

Dear Senators Hatch and Wyden:

On behalf of the American College of Physicians (ACP), I appreciate this opportunity to respond to your questions regarding the need to improve treatment for individuals with opioid and substance use disorders. These disorders impose a devastating and deadly impact on individuals and families and we look forward to working with you to help ensure that these individuals have access to the care they need. ACP has published several position papers on this topic and we hope that our expertise will guide you as you work toward reforming Medicare and Medicaid to enhance treatment for these patients.

ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 152,000 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.

Internists are uniquely suited to treat individuals with opioid and substance use disorders as they are often the first point of contact into the health system for patients with chronic pain. Our physicians have an ethical obligation to manage and relieve pain in a manner that reflects the best available clinical evidence. The challenge for physicians and public policymakers is how to deter prescription drug abuse while maintaining patient access to appropriate treatment.

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 inform some of the answers to your questions below and provide a resource for you as you examine policies on this topic.

We believe that Congress can enact measures to improve the treatment of our patients with opioid use disorders and substance use disorders (OUDs, SUDs) by reforming Medicare and Medicaid to incentivize the integration of behavioral health into primary care. Our policies also support the treatment of patients with opioid use disorders with non-pharmaceutical therapies when clinically appropriate, as well as additional education for physicians concerning the risk and benefits of treatment of pain with opioids, and reducing administrative burdens associated with the use of prescription drug monitoring programs (PDMPs).

Our feedback on your questions below provide additional guidance and detail about our policies regarding OUDs and SUDs and we look forward to working with you to enact these measures as Congress considers ways to stem the rising tide of opioid use.

1. ***How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUDs?***

Physicians are obligated by the standards of medical ethics and professionalism to practice evidence-based, conscientious pain management that prevents illness, reduces patient risk, and promotes health. 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 non-opioid pharmacologics and non-pharmacologic interventions. Payment policies should align to encourage evidence-based pain management that includes non-opioid pharmacologics and non-pharmacologic interventions.

The College strongly supports reforming Medicare and Medicaid payment policies designed to better integrate behavioral health, including screening, referral and treatment of opioid and substance use disorders, into the primary care setting. 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 these disorders. Many patients with chronic pain present co-morbid behavioral health conditions, including anxiety and depression, that can have an effect on pain management.

Unfortunately, many barriers to the seamless integration of behavioral and primary care exist in the physician payment structures of Medicare and Medicaid. Behavioral and physical health care providers have a long history of operating in different care silos and reimbursement policies have not always incentivized integrated, team-based care. Recently, Medicare has developed new payment codes for certain integration models, such as the Psychiatric Collaborative Care Model (CoCM).

We are pleased that in 2017, the Centers for Medicare and Medicaid Services (CMS) began to pay physicians separately for behavior integration services they provide to Medicare beneficiaries. Four new codes were added to the Medicare Physician Fee Schedule that provide payment for behavior health services such as counseling or other non-pharmological interventions for patients with substance abuse disorders.

While the CoCM model is well-established, there are many other integration models and approaches that may be more scalable and appropriate for different practice settings and capabilities. 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. Its bundled monthly pay components also provide a means to financially support the required infrastructure and clinical resources necessary for effective integration. Team-based care is especially necessary when caring for patients who have or are recovering from substance use disorders. CMS should continue to test team-based, coordinated care models that are designed to treat the whole patient, including the patient's pain management needs, in a manner that emphasizes use of evidence-based non-opioid pharmacologic and non-pharmacologic pain management interventions.

One model of care that provides additional Medicare payment for non-pharmological interventions is the Medicare Diabetes Prevention Program (MDPP). In this care setting, rather than treating patients at risk for type two diabetes with prescription drugs, Medicare provides beneficiaries with an approved Centers for Disease Control and Prevention (CDC) curriculum of classes that provide practical training in long-term dietary change, increased physical activities, and behavior changes in weight control. A study of MDPP found that behavior changes resulting in modest weight loss sharply reduced the development of type 2 diabetes.

Although patients with type 2 diabetes face different challenges on the path to wellness than those with chronic pain or OUDs and SUDs, it may be beneficial for CMS to consider additional Medicare payment for non-pharmological interventions for evidence-based treatment programs such as cognitive behavior therapy, acupuncture, and physical therapies that treat these disorders.

2. ***What barriers to non-pharmaceutical therapies for chronic pain currently exist in Medicare and Medicaid? How can those barriers be addressed to increase utilization of those non-pharmaceutical therapies when clinically appropriate?***

ACP supports removing barriers to evidence-based non-opioid and non-pharmacologic pain management services that do not involve potentially addictive medications. The CDC Guideline for Prescribing Opioids for Chronic Pain states, "Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate." The guideline lists several interventions, such as cognitive behavioral therapy, physical therapy, and weight loss for knee osteoarthritis, that may alleviate chronic pain. A clinical practice guideline issued by ACP recommends noninvasive treatments for acute, sub-acute, and chronic low back pain.

However, Medicare and Medicaid often limit coverage of non-pharmacologic or non-opioid pain management services. For example, Congress only recently approved legislation to

permanently remove Medicare caps on physical therapy and does not cover massage therapy, acupuncture, or other services mentioned in the CDC guideline on chronic pain and other clinical guidelines. A growing number of state Medicaid programs are electing to cover non-opioid pain management services but few encourage their use. Some insurance plans establish step therapy (or "fail-first") policies that require alternative treatment approaches be proven ineffective before another intervention is covered. The evidence base to support non-pharmacologic and non-opioid pain management interventions should be expanded, and as the effectiveness of interventions is determined, Medicare and Medicaid must cover them so that the lowest-risk, most effective approach is accessible to the patient.

3. ***How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?***

ACP is supportive of lifting barriers to ensure that our patients receive access to medications to treat opioid use disorders and to reverse overdoses. Medicare and Medicaid benefits should be strengthened to improve access to evidence-based medication-assisted treatment (MAT). According to the Kaiser Family Foundation, 14 state Medicaid programs do not cover the full array of MAT, buprenorphine (including the buprenorphine/naloxone formulation), naltrexone and methadone.

We are pleased that President Trump's 2019 budget includes a provision that would allow CMS to conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. Under this program, Medicare would cover methadone treatment or similar medication assisted therapy for beneficiaries with OUDs. A corresponding expansion of medication assisted treatment is also proposed for Medicaid beneficiaries, who struggle with addiction to opioids and other substance use disorders. If these programs are successful in key metrics, such as reducing deaths, hospitalizations, and emergency room visits for these beneficiaries who receive these treatments, the demonstration could be expanded nationwide.

The federal government should consider lifting the cap on the number of patients who can receive buprenorphine if a physician has been trained in proper prescribing practices. Medicare and Medicaid should cover and remove onerous limits on medications for overdose prevention and MAT, including burdensome prior authorization rules or lifetime limits on buprenorphine that prevent medically necessary care. Oversight and enforcement efforts should be strengthened to protect against misuse, diversion, and illegal sale of buprenorphine and other opioid treatment drugs. Evidence suggests that prescribers may be reluctant to obtain a buprenorphine waiver or to increase their capacity to provide buprenorphine treatment because they do not have time to care for additional patients. This issue may be addressed by expanding team-based care models to allow for efficient care delivery as well as reducing the growing administrative and paperwork burden on physicians and staff to allow more time to care for patients.

ACP recommends that Medicare and Medicaid facilitate use of physician support initiatives such as mentor programs, shadowing experienced providers, and telemedicine, that can help improve education and support efforts around substance use treatment. Professional support resources, such as Providers' Clinical Support System, and hub-and-spoke programs, such as Project Extension for Community Healthcare Outcome for Opioid Therapies, can link primary care physicians to health care professionals experienced in substance use disorder treatment and can improve physician confidence in buprenorphine prescribing practices and other areas of substance use disorder treatment.

Efforts should also be made to prevent overdoses. Medicaid programs should cover take-home naloxone and should not institute any barriers, such as prior authorization requirement, that may hinder distribution. In general, funding should 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. Legal protections (that is, Good Samaritan laws) should be established to encourage use of naloxone and the reporting of opioid overdoses in instances where an individual's life is in danger. Physician standing orders to permit pharmacies to provide naloxone to eligible individuals without a prescription should be explored and physicians should be reimbursed for services to educate patients about naloxone, by, for example, billing Medicaid through the Screening, Brief Intervention Referral and Treatment benefit.

4. ***Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?***

One way that Medicare can minimize the risk of seniors developing OUDs and SUDs is through strong oversight of the program to ensure that our seniors are not being prescribed inappropriate doses of prescription drugs.

ACP offered input on and ultimately expressed support for the CDC Guideline for Prescribing Opioids for Chronic Pain. The CDC's guideline helps inform physicians of when opioids are appropriate for a typical patient with chronic pain; however, patients have individual care needs that may not reflect the recommendations presented in the guidelines and it is imperative that these and other guidelines not be used to make coverage decisions that may impair access for those with legitimate indications. The College is concerned that recent proposals would direct Medicare Advantage and Part D programs use the morphine milligram equivalents dosage and 7-day supply limits described in the CDC guideline as a threshold to trigger case management, point-of-sale safety edits and other activities. ACP cautions that such thresholds should not be rigidly applied and there must be some flexibility to allow adjustments in determining dosages reflecting physician judgment. If overutilization controls are to be implemented, they must be done in a way that provides ample flexibility to deliver the appropriate care for patients with complex care needs and does not create an undue burden on prescribers.

5. ***How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?***

ACP supports efforts to educate physicians on the appropriate medical uses of controlled drugs and the dangers of both medical and nonmedical use of opioids.

The College has organized a collection of resources under the featured heading "Opioid Epidemic" as part of our Online Learning Center, aimed at helping physicians to better treat patients with pain and/or opioid use disorder. The resources cover opioid therapy, pain management, behavioral health, and substance use disorder. Since 2015, over 2,000 physicians have attended live seminars provided by ACP at regional and national meetings. ACP's online Safe Opioid Prescribing educational modules have been accessed by over 30,000 unique viewers, and hundreds have viewed our patient education support resources for management of chronic pain and opioids. Continuing medical education (CME) can broaden awareness and understanding of evidence-based prescribing practices. The Safe and Competent Opioid Prescribing Education (SCOPE of Pain) program can improve prescriber attitudes and knowledge about safe opioid prescribing and increase confidence in assessing pain in a new patient, communicating and collaborating with patients around opioid initiation, and assessing the potential benefit and risk of opioids for chronic pain in a new patient, among other competencies. However, a substantial number of physicians report that mandatory education would discourage them from prescribing opioids, potentially limiting access for patients for which opioids are medically necessary.

To encourage physicians to participate in CME related to pain management or proper prescribing of opioids, ACP has recommended that the DEA registration fee be waived for those who complete voluntary courses on pain management and substance use disorders. This policy will ensure that providers have the flexibility to engage with educational topics and materials that best suit their learning needs, including in-depth courses relating to specific areas of clinical practice. Generally, ACP policy opposes any legislation and/or regulation that mandate continuing medical education (CME) as a condition of licensure or re-licensure to practice medicine, regardless of subject or content.

A number of states require prescribers to complete CME related to pain management, controlled substances, and substance use disorders. ACP encourages federal stakeholders to review the evidence of the effect of such state mandatory education laws on access to pain medication and whether enhancements in prescriber knowledge, awareness, and confidence about safe prescribing have been achieved.

6. ***What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?***

One of the obstacles to data sharing and coordination is that each of the 50 states has their own Prescription Drug Monitoring Program which makes it difficult for physicians to track their prescriptions of their patients who obtain opioids in other states. We are pleased that the

Comprehensive Addiction and Recovery Act (CARA) that was signed into law includes a section to provide funding to states to maintain, improve or establish a comprehensive Prescription Drug Monitoring Program (PDMP) to track the dispensing of controlled substances that will be accessible to all doctors who wish to review a patients prior usage of opioids.

ACP supports the establishment of a national PDMP that would analyze and collect data related to the prescribing of controlled substances. Until such a program is implemented, ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting program. ACP strongly recommends that prescribers and dispensers check PDMPs in their own and neighboring states (as permitted) prior to writing and filling prescriptions for medications containing controlled substances. All PDMPs should maintain strong protections to assure confidentiality and privacy.

Although PDMPs have been an effective tool in reducing the rate of unnecessary opioid prescriptions and have reduced opioid-related overdose deaths, the usage of PDMPs has also been linked to increased administrative burdens for physicians. Several policies must be pursued to reduce administrative burdens associated with PDMPs, including ensuring interoperability with electronic health record systems. According to a recent report from the Pew Charitable Trust, the integration of PDMP data into a patient's health IT record would save the physician time and reduce administrative hassle associated with this task. The report notes that "integration with health IT makes PDMP data available to prescribers as part of their workflow without the need for multiple user accounts, log-ons, or user interfaces, thus saving prescribers time and effort. One study, involving focus groups of 35 prescribers from nine states, identified time spent accessing a report as a barrier to PDMP use and recommended integration with health IT as part of the solution."

Another solution would be to allow health care team members other than the physician to consult PDMPs. This would allow the physician to have a record of patient usage of opioids readily available to him or her before a decision is made on the type of medication to prescribe to the patient.

SAMHSA and other federal agencies have initiated pilot projects and provided funding to states to encourage interoperability and interoperability of PDMPs, but more needs to be done to enhance user friendliness.

7. ***What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?***

According to the National Conference of State Legislatures, many states have established prescription drug monitoring programs to track controlled substance prescriptions, have sought to regulate pain management clinics, developed prescribing guidelines, enacted drug overdose immunity (Good Samaritan) laws or broadened access to naloxone, and have initiated public education and awareness campaigns. Florida saw a 50% decline in opioid overdose deaths after

enacting a law that regulated pain clinics (so-called pill mills) and prohibited health professionals from dispensing such drugs from their offices. A Kentucky law required licensure of pain clinics and created stringent recordkeeping and education requirements for physicians and other health professionals who prescribe controlled substances. The law increased the number of physicians using the state's prescription drug monitoring system and reduced the rate of individuals receiving prescriptions from multiple providers.

8. ***What human services efforts (including specific programs or funding design models) appear to be effective in preventing or mitigating adverse impacts from OUD or SUD on children and families?***

Congress may also look to the states for examples of how the criminal justice system may be reformed to offer treatment rather than jail time for individuals with substance use disorders to help keep families together. Several states have revised sentencing laws for nonviolent drug offenses. In 2009, New York rewrote its mandatory minimum sentencing mandates for certain nonviolent drug offenders and expanded policies that provided access to substance use disorder treatment before incarceration. New Hampshire, Mississippi, and California also expanded or established treatment as alternatives to jail time for certain drug use offenses.

Components of comprehensive drug addiction treatment should also be extended to those in need, including medical services, mental health services, educational services, HIV/AIDS services, legal services, family services, and vocational services.

We hope that our answers to your questions will provide you guidance on policies to address the significant human and financial cost related to OUDs and SUDs. We hope that the Senate Finance Committee will continue to stay engaged on this topic by hosting meetings with stakeholders to solicit our ideas on ways to curb SUDs, hosting hearings that provide expert testimony on treating patients with chronic pain, and developing legislation that would enact policies to relieve the suffering of our patients with OUDs and SUDs. We appreciate the opportunity to provide our views on this topic and, if you have additional questions regarding our policies or this letter, please do not hesitate to contact Brian Buckley at bbuckley@acponline.org or by phone at 202-261-4543.

Sincerely,

Jack Ende, MD, MACP
President