American Society of Anesthesiologists™

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June 16, 2020

Robert R. Redfield, M.D.
Director
Centers for Disease Control and Prevention
Department of Health and Human Services
1600 Clifton Road, NE
Atlanta, GA 30329

Re: ASA Response to **Docket CDC-2020-0029**: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS); Request for Comment

Dear Dr. Redfield:

On behalf of the American Society of Anesthesiologists (ASA)® and our 54,000 members, we are writing in response to the Centers for Disease Control and Prevention (CDC) request for comment concerning perspectives on and experiences with pain and pain management. ASA provides this feedback from the viewpoint of physicians specializing in managing and treating patients with pain, touching upon many of the topics suggested by the agency.

As pain impacts millions of Americans and interferes with the daily lives of individuals— including professional, social and family activities, it is important to address pain with a national approach. While there have been multiple efforts by the federal government to address pain,[1] including the recent *Health and Human Services (HHS) Pain Management Best Practices Interagency Task Force report*, ASA supports revisiting priorities frequently to improve the quality of pain care for patients.

ASA was involved in the development and review of the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain (Guideline), supporting its use as guidance for primary care providers. However, witnessing significant misinterpretation and misapplication, **ASA supports recommendations to refine or expand the Guideline; we hope the CDC will consider these comments as the agency continues to assess the need for updating/expanding on the Guideline.**

Experience Managing Pain

Physician anesthesiologists treat acute and chronic pain. They are responsible for preparing the patient for surgery, administering anesthesia to relieve pain, and managing vital life functions. After surgery, they maintain the patient in a comfortable state during the recovery period and are involved in providing critical care medicine in the intensive care unit. Physician anesthesiologists are not only experts in managing post-operative pain, they may also specialize in pain medicine, a separate medical subspecialty, and treat patients outside of the perioperative or other acute care settings, such as those suffering from chronic pain disorders.

A great deal of evidence for effective pain treatments currently exists and research is ongoing to better understand the complex mechanisms of pain. Our physicians have seen this research grow over time and have taken part in many of the studies, but we also recognize that the causality of pain can be clear and predictable or totally obscure.

[1] 2011 Institute of Medicine's (IOM; now the National Academy of Medicine) *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research* and the *2016 National Pain Strategy*

Acute Pain
Research has demonstrated that patients can become at risk of becoming chronic opioid users in the post-surgical setting. In fact, studies find that prescription of an opioid at discharge is an independent risk factor for chronic opioid use one year later.[2] As the opioid crisis became a well-recognized epidemic plaguing Americans, physicians acknowledged that more had to be done to protect patients and the public. Reduction in opioid prescriptions was just the beginning.

Because the surgical experience can often be a patient's first exposure to opioids, for some patients that exposure can ultimately lead to opioid misuse and abuse. Physician anesthesiologists have played a unique role in preventing opioid use disorder (OUD), as they have experience implementing best practices for surgical acute pain management, such as opioid sparing techniques that are based on the foundation of multimodal analgesia. Models like the Perioperative Surgical Home (PSH), an ASA-developed model of standardized coordinated care that spans the entire surgical experience, and Enhanced Recovery After Surgery (ERAS) protocols, are incorporating these opioid sparing techniques and key patient education into perioperative planning. We are now seeing that more patients know to ask about alternatives to opioids when preparing for surgery and anesthesiologists are a resource for these discussions.

The severity of surgical post-operative pain is varied, and an integrated multidisciplinary pain discharge planning is crucial for high-quality patient care. Physician anesthesiologists work with surgeons to provide pain control that uses alternative opioid pain relief techniques and protocols such as regional anesthesia and other analgesics as part of a multimodal approach to reduce the use of, and reliance on, opioids during a procedure or surgery and ultimately, at discharge. During surgery, anesthesiologists use regional anesthesia and analgesia to numb a precise part of the body having surgery, with injections utilizing ultrasound, such as nerve blocks. Current literature provides evidence that utilizing multimodal analgesia with non-opioids decreases opioid use post-operatively up to 30-40%.[3]

Additional data is necessary to establish best practices across the entire care continuum. **ASA supports clinical trials in acute surgical pain which can provide the necessary data and evidence to ensure these practices are carried out in hospitals throughout the nation**— a very important tool to continue addressing the opioid crisis. Clinical trials on acute pain should aim to not only decrease opioid utilization during surgery, but also examine opioid utilization after discharge and examine the long-term outcomes of these patients.

Chronic Pain
Chronic pain does not always have a discernable or objective medical cause because mental and social health factors can influence its impact. ASA recognizes a biopsychosocial approach to pain assessment and treatment is necessary to ensure individualized care.

Anesthesiologists, and others specializing in pain medicine, have a separate board certification, with additional training and education, including a one-year fellowship in pain, which makes them uniquely qualified to manage those suffering from chronic pain— an especially complicated subset of patients. Pain medicine specialists acknowledge individualized patient care and safety is the utmost priority when treating chronic pain. The treatment plan and modality should always be the decision of the treating

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[2] Hah, Jennifer M.; Bateman, Brian T.; Ratliff, John; Curtin, Catherine; Sun, Eric. Chronic Opioid Use After Surgery. Anesthesia & Analgesia 2017; 125(5):1733–1740.
[3] Wick EC, Grant MC, Wu CL. Postoperative Multimodal Analgesia Pain Management with Nonopioid Analgesics and Techniques: A Review. JAMA Surg. 2017;152(7):691–697. doi:10.1001/jamasurg.2017.0898.

physician and the patient after jointly discussing options, weighing benefits and risks, as well as expectations.

For a small percentage of patients, opioids can be an appropriate treatment option to manage chronic pain. These patients should be closely monitored by a physician that specializes in pain and be educated of the risks associated with opioid medications, as well as how to properly store and dispose of the medications. Co-prescribing of naloxone can also be an important tool for physicians prescribing opioids to chronic pain patients and ASA supports providing naloxone to patients and their families if they are on high-dose opioids. Frequent, in-person visits for these patients are also important to ensure nothing has changed with their pain and to ensure opioid medications are still the best treatment option.

The importance of pain specialists to patients taking opioids is demonstrated by a study that examined potential opioid overprescribing.[4] The study compared prescribing patterns of primary care physicians (MDs), nurse practitioners (NPs), and physician assistants (PAs). The findings revealed that while most NPs/PAs prescribed opioids in a pattern similar to MDs, NPs/PAs had more outliers who prescribed high-frequency, high-dose opioids than MDs. Authors of the study recommended that efforts to reduce opioid overprescribing should include targeted provider education and risk stratification. ASA is in agreement and also believes that these results highlight the continued need for provider education and training on pain management, including opioid prescribing, substance abuse, treatment and prevention, as well as non-opioid treatment options.

Our physicians have also found that mental health can play an incredibly important role in treating chronic pain patients. Screening for anxiety and depression for any patient is necessary to ensure they receive comprehensive treatment, which may include behavioral therapy or counseling. Screening tools are important for acute pain as well and are typically used prior to performing surgical procedures and prescribing post-operative opioids.

Non-opioid treatments should be a primary component of recommendations for treating pain; the CDC must include detailed options for any update or revision of the Guideline. Pain specialists have found that non-opioid medications used along with physical therapy or acupuncture can be effective for some patients. Injections or nerve blocks, with local anesthetics or other medications, can also be used for muscle spasms or nerve pain. In addition, interventional pain medicine has brought several effective treatment options to patients— with utilization of diagnostic imaging and focused injection or procedures. For example, epidural steroid injections, radiofrequency ablation, sympathetic blocks, spinal cord stimulation, and neurolytic blocks have shown positive outcomes. However, these procedures are far from routine and often require fluoroscopic, CT, or ultrasound guidance to facilitate the precise and proper placement of the medication. The HHS Task Force recognized that there is a trend of inadequately trained providers performing interventional procedures and this is very concerning to ASA. As these procedures are very invasive and complex, it is imperative that they only be performed by physicians. Performance of these potentially dangerous and highly invasive procedures requires significant training and skill. More importantly, the diagnosis and decision-making around the use of these modalities requires the medical education and training received by physicians.

Our physicians frequently face challenges related to inadequate coverage by payers of interventional techniques. Existing research and evidence base must be acknowledged by payers, including the

[4] Lozada MJ, Raji MA, Goodwin JS, Kuo YF. Opioid Prescribing by Primary Care Providers: A Cross-Sectional Analysis of Nurse Practitioner, Physician Assistant, and Physician Prescribing Patterns [published online ahead of print, 2020 Apr 24]. J Gen Intern Med. 2020;10.1007/s11606-020-05823-0. doi:10.1007/s11606-020-05823-0

measurement of patient improvements in function and quality life as a factor for making coverage decisions. Payers often fail to update their policies in timely fashion to include available evidence supporting the use of high impact pain treatments labeling them as investigational or experimental long after randomized controlled trials establish high levels of evidence. Without access to these interventions, patients suffer or are exposed to lesser treatments which may include opioids. Additionally, payers often require patients fail a trial of opioids prior to having access to interventional treatments.

ASA urges the CDC to help ensure consistent and timely coverage, as well as reimbursement for these procedures by recommending interventional procedures performed by adequately trained and experienced physicians, as important treatment options for pain patients.

Another theme that ASA would like to highlight gained from our physicians' experiences treating pain is the **importance of continued clinical research for chronic pain**. There is a lack of large scale randomized controlled trials (RCTs) in support of interventional procedures. More research is also needed in areas such as cellular and molecular pain mechanisms.

Experience Choosing Among Pain Management Options— Physician Barriers

As mentioned above, there are various options for treating pain and individualized care should drive the decision for which treatments are most appropriate. Unfortunately, there are multiple barriers that impact both the practice and delivery of effective, high quality, evidence-based pain care.

ASA physicians have described that one of the most frustrating barriers to treating patients are payer issues such as prior authorization and the associated administrative burdens. There is variability in coverage determinations, as well as the multitude of issues surrounding prior authorization: delayed care for patients, administrative burdens, i.e. forms, phone calls and "paperwork," as well as the increased staff time battling payers. So much manpower is spent in obtaining prior authorization for non-opioid sparing treatments and interventions on the front end and then again, on the back in trying to be appropriately reimbursed.

These barriers can influence the course of treatment and treatment decisions are often made by physicians performing peer-to-peer case evaluations without expertise or board-certification in pain medicine. For example, one pain medicine specialist described a patient that was the perfect candidate for a spinal cord stimulator (SCS). Even after she had successfully stopped taking opioids, participated in an effective trial period with the SCS, prior authorization for the permanent placement of her SCS amounted in a nine-month delay in care. The patient required resumption of prescription opioid medications to maintain her function while waiting for the necessary approvals to obtain the SCS.

Another outcome of disparate coverage policies is that because certain treatment options are not covered, opioids become a first line of therapy when another treatment might be more appropriate. We must improve insurance coverage and reimbursement for evidence-based medical, behavioral and complementary pain services in continuing to make headway against the opioid crisis. **Payers need to place greater emphasis on outcomes measured by the functional improvement and quality of life for patients in making coverage decisions. The CDC can play a role by ensuring non-opioid therapies are recommended as effective treatment options in its guidance.**

The HHS Task Force identified many of these challenges facing providers and ASA agrees that there are key areas to be addressed related to both acute and chronic pain, such as:

- The need to provide for appropriate screening and risk assessment of patients through an examination of additional payment mechanisms for proper evaluation by trained physicians.
- The importance of opioid treatment discussions, increased education between providers, patients, and payers, about evidenced-based care and treatment plans.
- The lack of alignment of payment guidelines and policies as it relates to the development and implementation of proper treatment and on-going care for patients needing pain management.

ASA has also identified opportunities and policy recommendations related to payment and coverage policies for acute and chronic pain. While not directly in CDC's purview, as the agency continues to work with other stakeholders, including CMS, we ask that you consider these points. They center upon expanding patient access to pre-operative consultation related to pain care and opioid misuse and abuse prevention; coverage of non-opioid alternatives for acute pain relief; and coverage of new chronic pain technologies. A communication to HHS/CMS outlining these recommendations is attached.

Barriers to high-quality pain care go beyond policy and payer issues, however. There are also challenges related to the initial CDC Guideline and other legal implications, as well as the physician workforce and education, and patient expectations. These issues are highlighted below.

CDC Guideline & Legal Issues
While ASA understands the importance of the CDC Guideline as a clinical tool for primary care physicians, it has had a rippling effect of unintended consequences. ASA sent a formal communication to the agency last year, outlining concerns and that communication is attached to these comments as reference. We are pleased to see that the CDC acknowledged the misapplication of the Guideline.

To summarize, many state medical boards have used the Guideline to discipline physicians prescribing outside of the recommendations in the CDC Guideline. Others have attempted to apply the dosing thresholds of the Guideline to all patients and to physicians beyond primary care. Patients have suffered the consequences— some individuals stable on high-dose opioids, cut-off. Forced tapering is never safe. Other unintended consequences have been both a reduction in physicians willing to treat chronic pain patients and an overwhelming flood of patients to physicians still willing to provide care to these patients and prescribe opioids. Some physicians still worry about liability when prescribing opioids for pain above mandated thresholds or state regulations.

While regulations and guidelines are important for the safe prescribing of opioids, attention should be paid to arbitrary limitations placed upon patients and physicians via the CDC Guideline, insurance reimbursement, or pharmacy dispensing. Maintaining clear carve outs are necessary. Physicians should not be subject to professional discipline, loss of board certification or clinical privileges, criminal or civil liability, or other penalties solely for prescribing opioids at a level above a certain threshold. Therefore, **ASA supports recommendations to update and emphasize/expand on the CDC Guideline and would welcome the opportunity to participate in this work.**

Physician Workforce & Education
ASA supports public, patient, and provider education, as it is essential to individuals obtaining necessary and appropriate pain care. Pain education has been a priority for anesthesiologists; ASA focuses on member education by ensuring resources and continuing medical education (CME) are available for physicians, including information on opioid prescribing, substance use disorders, and non-opioid treatments. Anesthesiologists and their surgical colleagues utilize the PSH and ERAS protocols to improve post-operative pain education by partnering with patients and families on pain management and expectations, risks of opioids, and proper storage and disposal. As previously mentioned, these **non-**

opioid treatment options need to be widely emphasized and circulated to all physicians, patients and the public.

In 2013, core competencies in pain assessment and treatment were developed, creating a foundation for developing, defining, and revising curricula and as a resource for the creation of learning activities across health professions designed to effectively advance pain care. While progress has been made in establishing pain curriculum in medical schools, more needs to be done. A study showed that almost 90% of medical schools require courses on pain, but the median number of teaching hours is only nine. Therefore, it is unclear whether residents are getting adequate training in pain.[5] **ASA supports efforts to close gaps in education and understanding and would welcome working with CDC and other stakeholders to create and disseminate materials.**

Patient Expectations about Pain
ASA members, as well as other physicians, have highlighted that a key challenge to treating pain are the expectations of patients. However, we've started to see a paradigm shift. The long-held idea that we should be pain free, even after surgery has started to wane. As physicians are talking about pain more with patients, including the risks and benefits of different treatments, as well as explaining that some pain is expected, education has improved. In turn, the beliefs and expectations of patients around pain are starting to change. A key component of this shift has been the collaborative efforts of physicians and patients to treat pain. Addressing pain with a collaborative approach involves shared decision making and realistic goal setting. The growth in resources available has also contributed to patients being more informed, preferring an approach that's patient centered and multidisciplinary, where they feel they are involved in their own care.

To ensure conversations about patient expectations about pain are a priority for physicians, ASA partnered with the American Academy of Orthopaedic Surgeons (AAOS) on a Pain Alleviation Toolkit. The toolkit provides clinicians with strategies to support that communication between physicians and patients and is a resource on decision-making to help patients get as comfortable as possible, as safely as possible. The toolkit is free and has templates that can be utilized by physicians outside of the surgical and anesthesiology specialties.

Experiences Getting Information Needed to Make Pain Management Decisions

Guidelines
One area ASA believes is an opportunity for improvement relates to practice guidelines. Greater standardization and uniformity in clinical practice guidelines would help physicians make more uniform decisions around pain management. Several medical specialty guidelines already exist, and professional societies have an interest in developing consensus best practices. Adoption of clinical best practice guidelines into medical settings and training programs is essential to standardizing pain medicine practice. **The CDC could serve as a convening body to support efforts of professional societies.**

PDMPs
Prescription drug monitoring programs (PDMPs) are an important physician tool but require additional enhancements and innovation regarding functionality and uniformity. Both use and technology vary greatly from state to state and this has resulted in challenges measuring PDMP benefits. For example, access to "real time" data is not always possible. However, ASA has long supported physician use of PDMPs, interoperability across state lines and further integration into workflow. Thus, ASA encourages

[5] Zoberi K, Everard KM. Teaching Chronic Pain in the Family Medicine Residency.

electronic health record (EHR) vendors to integrate PDMPs into their system design to enhance interoperability and continuity of care. Another challenge of PDMPs is consistent and adequate funding. ASA believes that reliable federal support to the states is important and can help address some of these challenges. The Society has also contemplated a national PDMP and would support such efforts if it were well-designed and implemented, and also addressed shortcomings of state PDMPs. Such a uniform resource could reduce gaps in care, enable prescribers to effectively monitor patients and help prevent substance use and abuse.

Patient Education & Non-opioid Choices
As mentioned above, there has been a growth in resources available to patients, which has contributed to them being more informed. ASA has promoted resources that are easy to understand and geared at the public through its *When Seconds Count* webpage (see *asahq.org/WSC*). These materials cover multiple pain management options, including opioids and non-opioid treatment options, and these pages also include information tailored to those getting surgery, acute pain, and chronic pain. **ASA acknowledges that the CDC has contributed greatly to public education efforts and encourages the agency to continue promotion non-opioid pain treatments and medical society resources.**

Thank you for the opportunity to submit these comments. We hope the CDC will consider the observations and barriers noted by our physicians in considering updating/expanding on the 2016 Guideline. We look forward to working with the agency on future efforts to ensure high-quality, evidence-based pain care.

Sincerely,

Mary Dale Peterson, M.D., MHA, FACHE, FASA
President
American Society of Anesthesiologists

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June 26, 2019

Vanila M. Singh,M.D.
Chief Medical Officer and Chair
Pain Management Task Force
Office of the Assistant Secretary for Health.
Department of Health and Human Services

Re: Pain Management Best Practices Inter-Agency Task Force Meeting with CMS; **Docket No**. **HHS-OS-2019-0008-0001**

Dear Dr. Singh:

On behalf of the 53,000 members of the American Society of Anesthesiologists (ASA), I am writing to provide input on payment and coverage policies for acute and chronic pain as it relates to the development of an action plan by the Department of Health and Human Services (HHS) and Centers for Medicaid and Medicare Services (CMS) and stipulated by the SUPPORT Act.

ASA is pleased the HHS Pain Management Best Practices Inter-Agency Task Force (Task Force) is collaborating with CMS to develop recommendations for changes under Medicare and Medicaid to decrease opioid addiction and improve outcomes. The Society finds the Task Force final report and recommendations to be comprehensive and believes they serve as a logical next-step to ensure patients receive appropriate, high quality pain care.

The ASA appreciates the Task Force final report identifying and providing recommendations on a number of challenges currently facing providers and patients.

- The need to provide for appropriate screening and risk assessment of patients through an examination of additional payment mechanisms for proper evaluation by trained physicians.
- The importance of opioid treatment discussions, increased education between providers, patients, and payers, about evidenced-based care and treatment plans.
- The lack of alignment of payment guidelines and policies as it relates to the development and implementation of proper treatment and on-going care for patients needing pain management.

In building on the above themes identified in the Task Force final report, the ASA appreciates the opportunity to provide three additional recommendations and related actions for consideration as CMS and HHS continue to collaborate on payment and coverage policies for acute and chronic pain.

1. Expand patient access to pre-operative consultation related to pain care and opioid misuse and abuse prevention.
    - CMS should explore the creation of a HCPCS or CPT code for reporting and payment of such consultation.
2. Assure CMS covers appropriate use of non-opioid alternative acute pain relief modalities and remove barriers to access to these services.

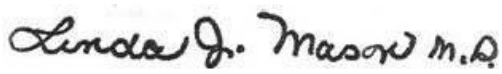
- CMS should direct Medicare Administrative Contractors (MACs) to cover non-opioid pharmacologic therapies and should ensure alignment of policies with the clinical practices that are best for patients.
- CMS should revise the requirement that the surgeon make the decision regarding the appropriateness of the use of a perioperative nerve block for postoperative pain care. The physician anesthesiologist should make the decision in consultation with the surgeon, as they are essential to post-operative pain care and have a unique and specific expertise in this perioperative treatment plan.

3. CMS should cover chronic pain relief modalities, including new technologies, and remove barriers to access to these treatments.
    - CMS should provide coverage and appropriate payment for evidence-informed interventional pain procedures when clinically appropriate.

We believe these recommendations are aligned with and build upon those contained in the Task Force final report and would also help to address existing gaps in payment and coverage policies for chronic and acute pain. Again, we appreciate the opportunity to provide input and look forward to further collaboration.

Please contact Ashley Walton, Senior Pain Medicine and Federal Affairs Manager, at 202-289-2222 or a.walton@asahq.org if you have any questions about this submission, or if we can be of further assistance on any other matter.

Sincerely,



Linda Mason, M.D., FASA
President

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August 13, 2019

Robert R. Redfield, M.D.
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30329-4027

Deborah Dowell, M.D.,
Chief Medical Officer
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1600 Clifton Road
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Dear Dr. Redfield and Dr. Dowell:

On behalf of the 53,000 members of the American Society of Anesthesiologists®(ASA), I am writing to express concerns regarding the misapplication of the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain ("Guideline") by state medical and disciplinary boards, public and private payers, pharmacies and others. **ASA recommends that the CDC Guideline be reviewed and revised to both clarify the intent of the Guideline and include the most up-to-date scientific evidence available.**

We believe the CDC Guideline has been misapplied in a number of venues. The Guideline was meant as guidance for primary care providers, not for its recommendations to be applied to all patients in all circumstances. With a membership of experts in pain medicine, ASA is especially concerned about the negative impact such sweeping policy and misapplication of the Guideline is having on patient care. The across-the-board application of the Guideline is not undertaken for any other medical disease where guidelines have been developed. While we acutely recognize and greatly appreciate the concerns with overprescribing of opioids, we worry that the pendulum has swung too far in the direction of not treating chronic pain in accordance with evidence-based methodology. Chronic pain is a disease— with systematic effects, impacting a range of organs, including the brain— which must be diagnosed, evaluated and properly treated.

In November 2018, the American Medical Association (AMA) issued a directive, *Inappropriate Use of CDC Guideline for Prescribing Opioids*. This directive advocates against the misapplication of the CDC Guideline and opposes "communications that include a blanket proscription against filling prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care." ASA strongly supports this directive and the stipulation that "no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical

privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline."

Clarifying Intent of the Guideline
Though the Society is pleased with two recent developments regarding the Guideline, **ASA believes the CDC should take a more direct approach to ensure the Guideline is clearly understood and used appropriately**. First, on April 9, *Medpage Today* reported that the CDC clarified in a letter dated February 28, to three national cancer organizations, "The Guideline was developed to provide recommendations for primary care clinicians…the guideline is not intended to deny any patients who suffer from chronic pain opioid therapy as an option for pain management." ASA is pleased that CDC has made this clarification, but we believe it is necessary for the agency to make a more prominent statement that is widely distributed and not just meant for a limited audience. Second, we are pleased the authors of the CDC Guideline published an article in the *New England Journal of Medicine,* acknowledging that the Guideline has been used to develop policies beyond those meant for primary care providers treating chronic pain patients. Again, ASA urges that CDC go one-step further and ensure this is widely distributed and endorsed as an official statement of the agency. It is important for CDC to send official communications to medical boards, payers, pharmacies and state government entities to ensure there is wide-spread knowledge about the intent of the Guideline.

Chronic Pain and Individualized Patient Care
In September 2018, the CDC released a report in the Morbidity and Mortality Weekly Report (MMWR), Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016, which provided new insight into how pain affects the nation. The report estimates that chronic pain affects approximately 50 million U.S. adults, and high-impact chronic pain (i.e., interfering with work or life most days or every day) affects approximately 20 million U.S. adults. Population-based estimates of chronic pain among U.S. adults range from 11-40 percent, with considerable population subgroup variation. This report's newer, more precise estimates indicating the prevalence of chronic pain and high-impact chronic pain, demonstrate the great need to ensure patients have all necessary treatment options, including opioids where appropriate.

Individualized patient care and safety should be the utmost priority when treating chronic pain. The treatment plan and modality should be the decision of the treating physician and the patient after jointly discussing options, weighing benefits and risks, as well as expectations. Physician anesthesiologists treat both acute and chronic pain. Some physician anesthesiologists specialize in pain medicine, a separate board certification involving extra training and education, treating patients with complex chronic pain conditions. Pain medicine physicians have the expertise to manage this unique and complicated subset of patients and in some cases, the best treatment for the patient does not fall within the purview of the CDC Guideline. **Thus, ASA is urging CDC to clarify the intent of the CDC Guideline as a mechanism to ensure patients continue to receive compassionate pain care.**

Value of CDC Guideline
ASA recognizes the importance of the CDC Guideline during this time when the nation is facing an opioid crisis. The Guideline was created to improve patient care, comprehensively promoting best practices in patient selection and monitoring, as well as in treatment planning with the end goal of improving the safety of opioid prescribing. It was also developed with intense scrutiny by clinical stakeholders from dozens of professional societies and medical specialties. However, it was intended to be a clinical tool for patients in the primary care setting, not under the care of pain specialists.

Examples of Inappropriate Interpretation and Enforcement
Many state medical boards have used the Guideline to discipline physicians prescribing outside of the recommendations in the CDC Guideline. The Federation of State Medical Boards (FSMB) have attempted to apply the dosing thresholds of the Guideline to all patients regardless and to physicians beyond primary care. Additionally, many payers— such as Medicare, Cigna, Aetna, and Oregon Medicaid— to name a few have used the Guideline to implement strict prescribing policies. Last, some of the retail pharmacy chains, such as CVS and Walmart— have required soft and hard limits to opioid prescribing and used the CDC Guideline as justification.

Unintended Consequences
With the misapplication of the Guideline, patients have suffered the consequences. A patient on a chronic stable regimen of opioids that has a successful level of function and quality of life, can be cut-off based on daily dosing thresholds based upon the CDC Guideline. This is especially problematic because the CDC Guideline is being applied retroactively. For some patients, the rapid decrease in their medications has been unmanageable— resulting in depression, illegal substance use and even suicide. Consequently, the FDA recently announced the harm caused from sudden discontinuation of opioid pain medicines and required label changes to guide prescribers on gradual, individualized tapering.

Other unintended consequences have been both a reduction in physicians willing to treat chronic pain patients and an overwhelming flood of patients to physicians still willing to provide care to these patients and prescribe opioids. This can also have negative impacts on physician wellbeing, due to the high volume of transfers in care and may ultimately lead to burn out— in turn, this affects patients.
Finally, **an underlying problem that is exacerbated by misapplication of the Guideline is a lack of comprehensive pain care options available to patients.** Barriers to access to many pain care treatments, including insurance coverage and payment for different pain modalities, often results in opioids as a first line of therapy when another treatment might be more appropriate. Therefore, **it is important to address these barriers by improving insurance coverage and reimbursement for evidence-based medical, behavior and complementary pain services.** This is particularly necessary for non-pharmacological treatments such as interventional procedures and behavior health care.

Revise and Update of Guideline Supported by HHS Pain Task Force
The CDC Guideline is primarily consensus-based and is lacking scientific evidence. For example, there is an absence of high-quality data on the duration of opioid effectiveness for chronic pain. However, this has been interpreted as a lack of benefit. ASA believes these shortcomings can be addressed and the **HHS Pain Management Best Practices Inter-Agency Task Force has developed recommendations to support building the applicable evidence necessary for the Guideline**. In fact, the Task Force released a report recognizing the misinterpretation of the Guideline and the consequences of unintended adverse outcomes, especially the recommendation regarding the 90 MME dose. The Task Force recommends 1) updating the scientific evidence and 2) emphasizing or expanding on content already in the Guideline. ASA fully supports these recommendations.

The Task Force recommends studies to determine the long-term efficacy of opioids in the treatment of chronic pain and clinical trials on specific disease entities, with a focus on patient variability and response to tissue injury and on the effectiveness of opioid analgesics. Additionally, the Task Force recommends specific pathways for expanding on the CDC Guideline. Developing recommendations that take into consideration patient variables that may affect dose as well as additional risk factors for opioid use disorder are two such examples. In addition, recommendations to address opioid tapering and escalation need to be addressed.

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ASA supports the recommendations of the Task Force to build the applicable evidence for revising and updating the Guideline and the considerations that should be accounted for to expand the Guideline. Other priorities to include in an updated Guideline should be how patients and clinicians should discuss pain, recommendations on where to find resources on best practices, as well as key information on safe storage and disposal. **The Society encourages the CDC to revise and update the Guideline through collaborating with others.** All stakeholders should be engaged—including medical specialties, patients, insurance companies, retail pharmacies and state licensure boards.

Conclusion

The CDC Guideline for Prescribing Opioids for Chronic Pain has negatively impacted patients with chronic pain. While ASA commends the agency for taking steps to rectify negative outcomes and clarify the intent of the Guideline, there is more to be done. The Society urges the CDC to do more and welcomes the opportunity to work together to ensure a revised and updated Guideline is not only best for patient care but also appropriate for physician practice.

Thank you for your time. ASA appreciates the opportunity to provide this input and hopes the CDC will take this information into careful consideration.

Sincerely,

Linda Mason, M.D., FASA
President
American Society of Anesthesiologists