United Ostomy Associations of America, Inc. (UOAA) is a 501(c)(3) national nonprofit organization that supports, empowers, and advocates for people who have had or will have ostomy or continent diversion surgery. There are between 725,000 to one million Americans living with an ostomy or continent diversion, and over 100,000 new life-saving ostomy surgeries occur in America yearly.

We applaud the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (and task force) recognizing the issues within the *CDC Guideline for Prescribing Opioids for Chronic Pain* (2016 Guideline) and it's work throughout the revision process, and for hearing and addressing the concerns of patients, caregivers, and clinicians! We support the revisions to the *CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022* including but not limited to emphasizing that it is not a replacement for clinical judgment or individualized person centered care, and that the document should not be applied as inflexible standards of care across patient populations by clinicians, payers, health systems, or governmental jurisdictions.

This will certainly help those with chronic pain; however, notably absent within the proposed revisions is that they <u>still do not</u> address the negative impact the 2016 guidelines have had for those patients managing **non-pain** chronic and acute digestive diseases/medical conditions and require opioid treatment.

For the reasons provided below, to ensure that there is no misapplication going forward for patients managing NON-PAIN chronic and acute digestive diseases (such as patients with digestive diseases resulting in an ostomy or fecal continent diversion who may use opioids to manage high output stomas) already on opioid medications and those considering opioid therapy in accordance with the recommendations of their physicians, **we, along with the undersigned organizations**, strongly recommend and **request** that you add a new bullet to the call out box with a new supporting section that clearly states:

*The guidelines are not intended for primary care physicians and other clinicians providing **<u>non-pain care</u>** for outpatients with chronic and acute digestive diseases (such as patients with digestive diseases resulting in an ostomy or fecal continent diversion who may use opioids to manage high output stomas or patients with refractory high volume diarrhea).*

Some patients with an ileostomy, or patients with Short Bowel Syndrome (SBS) with or without an ostomy, and others with continent fecal diversion may have High Output Stoma's (HOS). In patients with HOS the ostomy fluid (effluent) can increase to several liters (range 2-6 liters) every 24 hours. Patients with HOS suffer with life altering fluid and electrolyte imbalance which may lead to acute or even chronic kidney disease. Patients with HOS have difficulty maintaining their ostomy pouching systems, resulting in increased utilization of costly ostomy supplies. Many patients with HOS may require home intravenous fluids, or multiple Emergency Room visits and hospital admissions. These patients may need to be prescribed opioids such as diphenoxylate (Lomotil) loperamide (Imodium), codeine and distilled tincture of opium (DTO) at doses closely monitored by their physician to manage this condition. These drugs can be life-saving for these patients.

There is growing concern that new regulations and laws being enacted to address the opiate epidemic are restricting and/or prohibiting access to the prescription and coverage of opioids prescribed for control of significant uncontrollable diarrhea resulting in an increasing threat to our patients' quality of life and increasing medical costs by needing to resort to aforementioned costly intravenous fluids, increased utilization of costly ostomy supplies, Emergency Room visits and inpatient hospitalizations. Opioids are usually the last line of defense against this difficult problem. However, for some low dose opioids are prescribed to better and more effectively manage this non-pain condition and restore the quality of life for these patients.

Our organization has been made aware of doctors receiving notifications from the government and being fined for prescribing what they believe in their medical opinion is best for their ostomy patients, and states that have implemented laws and policies wherein, the entire scope, practice, and focus of the law is based on the premise that opiates are ONLY used for pain control. It has become an expensive, humiliating, frustrating, and infuriating experience for many.

Actual patient story:

"I lost my large intestine to ulcerative colitis in 1996. In 2015 I lost 7 inches of small intestine. To manage the consistency and amount of output, I was successfully placed on morphine elixir, the same dosage for 20 years. Due to uncompromising legislation, I was forced to see a pain doctor for chronic diarrhea, not pain. To be reimbursed, they diagnosed me with "chronic pain". I now have this misdiagnosed syndrome on my permanent record! This misunderstanding that opioids are for pain only hurts those of us who don't fall into that category." - Mary H.

UOAA has been advocating for proper accommodations and considerations for patients who utilize opioids for non-pain treatments for years. In 2019 as a member of the Digestive Disease National Coalition (DDNC), the coalition sent this letter to the Pain Management Best Practices

Inter-Agency Task Force where we asked the Task Force to consider the needs of patients managing chronic and acute digestive diseases.

Our organizations recognize and support the need to address the opioid epidemic facing the country. Furthermore, regardless of the purpose of the drug-use (pain versus other medical treatment such as controlling refractory diarrhea), we also appreciate the necessity for careful monitoring for side effects and that the proper dosage is prescribed to minimize the risks associated with opioid use. However, any CDC guideline, and/or legislative/regulatory approach to control opiate prescriptions that will impact chronic pain treatment must ensure that patients who are already utilizing opioids for non-pain treatments in accordance with the recommendations of their physician are:

- protected;
- appropriately accommodated;
- not restricted access to their lifesaving treatment

Sincerely,

James Murray
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<u>Supporting Organizations:</u>
American College of Gastroenterology
American Society of Colon and Rectal Surgeons
Digestive Disease National Coalition
The Oley Foundation
Wound Ostomy Continence Nurses Society®