



American Cancer Society
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August 29, 2019

Brenda Destro
Deputy Assistant Secretary for Planning and Evaluation
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 434E,
Washington, DC 20201

Transmitted electronically

Re: 2019-16145; Request for Information: Ensuring Patient Access and Effective Drug Enforcement
84 Fed. Reg. 36932 (July 30, 2019)

Dear Ms. Destro:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to respond to the request for information regarding ensuring legitimate access to controlled substances, including opioids. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

Pain is one of the most feared symptoms for cancer patients and survivors - nearly 60 percent of patients in active treatment and 30 percent of patients who have completed treatment experience pain.¹ Pain can be caused by the cancer itself, for instance when tumors interfere with normal body function. Pain can also be caused by cancer treatments. Research has concluded that about one-quarter of women who have had breast cancer surgery have significant and persistent breast pain six months after the procedure.²

Despite the fact that millions of cancer patients and survivors experience chronic pain, it remains a highly stigmatized issue. But given proper attention most pain can be treated and relieved. Integrative pain care that includes non-drug therapies along with medications can be effective in keeping patient pain under control. While not the only tool, opioid medications are recognized as a mainstay of treatment for moderate to severe cancer pain and can be a beneficial treatment for managing serious,

¹ Institute of Medicine. (2011). *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*. National Academy of Sciences.

² Miaskowski C, Cooper B, Paul SM, et al. (2012). Identification of Patient Subgroups and Risk Factors for Persistent Breast Pain Following Breast Cancer Surgery. *J Pain*; 13(12) pp 1172-1187.

persistent pain for patients in active cancer treatment as well as cancer survivors. If not treated, chronic pain can have long-term negative effects, including prolonged recovery and a weakened immune system. It can also affect a patient's quality of life; their ability to eat, sleep, work and carry on every aspect of their daily life.³

Many cancer patients, as well as other patients with serious illness, receive pain treatment as part of palliative care services.⁴ Palliative care – which is essential throughout the course of cancer treatment – helps prevent and relieve pain by systematically screening and assessing for pain and other symptoms, tailoring pharmacological and other interventions to patients' individual circumstances (including medical history and stated goals of care), and carefully monitoring and adjusting treatment regimens as needed over the course of the illness.⁵

As a nation, we must take steps to identify balanced solutions that address the opioid epidemic, while also not causing harm to patient access to opioid medications for cancer patients, cancer survivors, and others with serious illness.

Following are our comments regarding a selection of the topics included in the RFI:

Obstacles to legitimate patient access to controlled substances

ACS CAN has been concerned for several years that new limits on opioid prescriptions will reduce needed access to pain management treatment for cancer patients, cancer survivors, and those with other serious illness. We strongly urge HHS, Congress, and all other relevant policymakers to consider all potential unintended consequences of new opioid limits – particularly consequences to patients with serious illness.

Our research confirms that some cancer patients, cancer survivors, and others with serious illness are having problems accessing their needed pain treatments. A 2018 survey conducted on behalf of ACS CAN and the Patient Quality of Life Coalition showed that patients are reporting a good deal more difficulty in getting access to their prescription opioid medications compared to baseline data collected in 2016.

The following tables are taken directly from research conducted for ACS CAN by Public Opinion Strategies in Spring 2018 – in some cases compared to a baseline survey conducted by the same firm in 2016. More information can be found in the summary memo, available here:

<https://www.fightcancer.org/sites/default/files/ACS%20CAN%20PQLC%20Opioid%20Research%20Project%20Key%20Findings%20Summary%20Memo%20FINAL.pdf>

³ Institute of Medicine. "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research." June 2011. <http://www.nationalacademies.org/hmd/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>

⁴ "Serious illness" is defined as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers. See Kelley AS, Bollen-Lunds E. Identifying the Population with Serious Illness: The "Denominator" Challenge. *J Palliat Med.* 2017 Nov 10. doi: 10.1089/jpm.2017.0548.

⁵ Morrison LJ, and Morrison RS. Palliative care and pain management. *Med Clin N Am.* 2006; 90(5):983-1004. doi: 10.1016/j.mcna.2006.05.016. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/16962853>

There has been a significant increase in cancer patients and survivors being unable to access their opioid prescriptions since 2016, when the Centers for Disease Control and Prevention (CDC) finalized opioid prescribing guidelines (referred to subsequently as “the CDC Guideline”).⁶

Problems at the Pharmacy

| <i>Among Cancer Patients/Survivors</i> <i>Ranked by Net Difference</i> | December 2016 | May 2018 | Net Difference |
|---|--------------------------|---------------------|---------------------------|
| Have you been unable to get your opioid prescription pain medication because the pharmacy did not have the particular drug in stock? | 16% | 41% | +25% |
| Have you been questioned by a pharmacist about why you needed your opioid prescription pain medication? | 16% | 35% | +19% |
| Have you been unable to get your opioid prescription pain medication because the pharmacist would not fill it for whatever reason even though they had it in stock? | 12% | 27% | +15% |

Problems with Insurance

| <i>Among Cancer Patients/Survivors</i> <i>Ranked by Net Difference</i> | December 2016 | May 2018 | Net Difference |
|---|--------------------------|---------------------|---------------------------|
| Have you been unable to get your opioid prescription pain medication because the pharmacy did not have the particular drug in stock? | 16% | 41% | +25% |
| Have you been questioned by a pharmacist about why you needed your opioid prescription pain medication? | 16% | 35% | +19% |
| Have you been unable to get your opioid prescription pain medication because the pharmacist would not fill it for whatever reason even though they had it in stock? | 12% | 27% | +15% |

⁶ U.S. Centers for Disease Control and Prevention. Guideline for Prescribing Opioids for Chronic Pain. 2016. http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm

A growing number of restrictions on opioid prescribing are already impacting these patient populations.

| % Yes Ranked by Cancer Patients & Survivors | Cancer | Chronic Pain | Other Serious |
|--|---------------|---------------------|----------------------|
| Has your doctor indicated his or her treatment options for your pain were limited by laws, guidelines, or your insurance coverage? | 48% | 40% | 56% |
| Has your insurance company or pharmacy required you to only have opioid prescriptions from one doctor? | 36% | 25% | 26% |
| Has your doctor refused to give you a prescription for an opioid pain medication? | 35% | 25% | 36% |
| Has the pharmacist given you only part of your opioid prescription (for example: for 7 days instead of 30 days the prescription was written), and told you to call your doctor for a new prescription if you need more? | 31% | 18% | 21% |
| Have you been unable to get your opioid prescription pain medication because the pharmacist or pharmacy sent you home without your prescription because they had to contact your doctor before filling the prescription? | 26% | 30% | 22% |
| Has the pharmacist given you only part of your opioid prescription (for example: for 7 days instead of 30 days the prescription was written), and told you to come back if you need more? | 25% | 26% | 26% |
| Has your doctor or pharmacist told you that you have been flagged in their system as a potential opioid abuser? | 21% | 14% | 11% |

The availability of medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing, and any gaps that should be addressed

Regarding the availability of medical education and training opportunities: Provider education is an important way to address the opioid epidemic. We also view the education of controlled substance prescribers as an opportunity to educate more providers on palliative care and best practices in pain

management more generally. ACS CAN has identified expanding provider education on palliative care – along with building public awareness and increasing research – as a top organizational priority.⁷

While ACS CAN is open to reasonable education requirements for prescribers of opioids, we stress that any requirements should be harmonized to the greatest degree possible across agencies and entities with a stake in such education, including, but not limited to FDA, DEA, CMS, and state and professional licensing and accreditation bodies.

It is crucial that any provider education requirements do not negatively impact appropriate patient access to opioids, pain management treatment more generally, or palliative care for patients who have a legitimate medical need. Excessive or uncoordinated requirements could prompt providers to simply forgo certification and therefore treatment of patients in pain. Policymakers must closely monitor the effects of any new requirements to determine how they are impacting treatment access.

It is also important to recognize that medical recommendations for multi-modal pain management frequently are not matched by corresponding coverage by insurers, setting up the possibility that education would be moot if providers cannot provide the recommended care because of payment restrictions, or refer their patients to a provider or evidence-based treatment that is not covered by the patient's insurance.

Regarding comprehensive clinical guidance for pain management and opioid prescribing, and any gaps that should be addressed: ACS CAN continues to have concerns regarding one of the most well-known opioid prescribing guidelines, the CDC Guideline, and how it has been interpreted and implemented. Recently the Pain Management Best Practices Inter-Agency Task Force recommended major revisions to the guideline, stating that “Unfortunately, misinterpretation, in addition to gaps in the guideline, has led to unintended adverse consequences. Our report documented widespread misinterpretation of the CDC Guideline — specifically, the recommendation regarding the 90 morphine milligram equivalents (MME) dose.”⁸ We agree that the CDC Guideline is often mis-used as a reason to limit or not provide pain treatment. We urge HHS and Congress to review the Task Force recommendations regarding the CDC Guideline, and rely on its data to update the Guideline, paying close attention to its effects on cancer patients, cancer survivors and other patients with serious illness.

Additionally, we want to call HHS' attention to other evidence-based guidelines that already exist for many types of patients receiving pain management.⁹ The CDC has acknowledged that patients receiving cancer treatment, palliative care, or end-of-life care often have unique therapeutic goals and balance the risks and benefits of opioids differently. Clinical practice guidelines specific to these populations should be used to guide treatment and reimbursement decisions regarding use of opioids as part of pain control in pain treatment in these cases.¹⁰ The Food and Drug Administration Commissioner has also

⁷ See <http://patientqualityoflife.org/wp-content/uploads/2017/04/PQLC-PCHETA-Bill-Summary-115th-Congress-03.28.2017.pdf>

⁸ Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. May 9, 2019. <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>

⁹ See Clinical Practice Guidelines for Quality Palliative Care, 4th edition; National Consensus Project and National Coalition for Hospice and Palliative Care: Domain 2: Physical Aspects of Care; 2.1.6 a-d; 2.1.7; 2.3.2-13; 2.4.1 a-c; American Thoracic Society: Assessment and Palliative Management of Dyspnea Crisis; National Comprehensive Cancer Network Guidelines on: Adult Cancer Pain, Dyspnea, Survivorship, and Management of Chronic Pain in Survivors.

¹⁰ See

https://www.nccn.org/professionals/meetings/oncology_policy_program/pdf/2019_CDC_letter_to_NCCN_ASCO_ASH.pdf

acknowledged this need.¹¹ An updated CDC Guideline should be evidence-based, directly acknowledge and incorporate these other guidelines for the appropriate patient populations, and integrate their promotion and use with the CDC Guideline.

On behalf of the American Cancer Society Cancer Action Network thank you for the opportunity to give input regarding your upcoming report to Congress. If you have any questions, please feel free to contact me or have your staff contact Jennifer Hoque of our policy team at Jennifer.Hoque@cancer.org or 202-585-3233.

Sincerely,

A handwritten signature in black ink that reads "Lisa A. Lacasse". The signature is fluid and cursive, with the first name "Lisa" and last name "Lacasse" clearly legible.

Lisa A. Lacasse, MBA
President

¹¹ Gottlieb, Scott, M.D. Remarks by Dr. Gottlieb at the NCCN-ASCO Workshop. November 8, 2018.
<https://www.fda.gov/NewsEvents/Speeches/ucm625333.htm>