Opioid Position Statement

Nebraska Palliative Care and Quality of Life Advisory Council

Disclaimer: Positions taken by the Nebraska Palliative Care Council are not endorsed by the Nebraska Department of Health and Human Services. The Palliative Care Council is an independent council.

Introduction

Across all states, there has been a significant increase in the introduction of new policies and initiatives to combat the opioid epidemic. Many of these policies seek to limit access to opioids through a variety of mechanisms; however, an unintended consequence of this approach is that it can restrict access for patients with serious illnessⁱ who legitimately need these medications. As Nebraska policymakers explore additional optionsⁱⁱ to protect Nebraskans from the harms of opioid misuse and abuse, the Nebraska Palliative Care and Quality of Life Council recommends a balanced, evidence-based approach that will address the underlying causes of the opioid crisis while preserving access for patients in need.

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Background/Problem Statement

National Efforts to Address the Opioid Epidemic

Nationwide, the opioid epidemic has hit a critical point. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), there were approximately 11.5 million people with prescription opioid misuse in 2016 (equivalent to 4.4 percent of the U.S. population), resulting in over 42,000 deaths. This widespread impact has led to significant policy activity at the Federal level, including development of the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain in 2016, Setablishment of the Pain Management Best Practices Inter-Agency Task Force, and passage of H.R. 6, the "SUPPORT for Patients and Communities Act" in the 115th Congress. While Proposed solutions at this level range from investment in research and innovation in pain management and opioid alternatives, to restrictions on patient access to opioids through prescription limits and lock-in policies. While most agree that it is critical to address opioid misuse and abuse among the general patient population, there have been early consequences for people with serious medical illness. Recent polling research funded by the American Cancer Society Cancer Action Network and the Patient Quality of Life Coalition shows that in the last two years, patients with cancer, chronic pain, and other serious illness have reported significantly more difficulty accessing opioids. Will Reported barriers include problems with insurance, problems at the pharmacy, and general hesitation among clinicians to prescribe opioids.

Nebraska and the Opioid Epidemic

While the opioid epidemic has cut across patient populations and geographic regions, different states have fared differently. Recent data from the Kaiser Family Foundation showed that Nebraska had among the fewest recorded deaths from opioid overdose nationwide in 2017; this was supported by analysis from the Nebraska Department of Health and Human Services, which found a slight decrease in opioid-related deaths over the last decade. As a public health issue, the number of documented cases of opioid use disorder is far lower than that of alcohol or methamphetamine use disorders. Yet, the Governor's Office found that at least 38 Nebraskans died of an opioid-related overdose in 2016. High burden areas include Douglas and Lincoln/Lancaster Counties, and to a lesser extent, the Panhandle, Southeast, and West Central Districts. XIV

Council Authority

The Nebraska Palliative Care and Quality of Life Council ("Council") was established in 2017 by Statute § 71-4501 through 71-4504 and charged with advising the Department of Health and Human Services on matters relating to palliative care initiatives. Palliative care is specialized medical care for people with serious illness. This type of care focuses on providing relief from the symptoms and stress of a serious illness. The goal is to improve quality of life for both the patient and the family. Palliative care is provided by a specially-trained team of doctors, nurses and other specialists who work together with a patient's other doctors to provide an extra layer of support. It is appropriate at any age and at any stage in a serious illness, and it can be provided along with curative treatment. In the context of the opioid discussion, palliative care helps support people with serious illness 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.

By Governor appointment, the Council is comprised of nine members that have significant expertise in improving care for patients with serious illness — across populations and care settings — through the provision of palliative care. Access to appropriate medications is a critical component of ensuring high-quality care for these patients; thus, it is within the Council's expertise to provide guidance on how to address factors contributing to the opioid use disorder epidemic while preserving access for patients with legitimate need.

Nebraska policymakers have already taken steps to address different components of the opioid epidemic. In 2018, the Legislative Research Office prepared an in-depth report describing the status of the epidemic in the state and strategies to combat it at various levels of government.** These included establishing and strengthening the state prescription drug monitoring programs (PDMP), removing barriers to the administration of naloxone to block or reverse the effects of an opioid-related overdose, and working across multiple state agencies to increase education on the risks of opioids.xvi In the 105th Legislature, the state passed two new bills: (1) LB923, xvii which protects law enforcement and allows them to administer naloxone to persons experiencing an opioid-related overdose (expanding on a naloxone-related bill from 2015); and (2) LB931, which sets a seven-day limit on opioid prescriptions for minors (with some exceptions), requires clinicians to have 3 hours of opioid education biannually, requires clinicians to educate patients on the risk of opioid addiction, and requires adults to provide identification when picking up opioid prescriptions. Additionally, SAMHSA awarded \$2 million to the Nebraska Division of Behavioral Health "to support opioid use disorder prevention, treatment, and recovery efforts from May 2017-April 2018". xix Most of these activities and policy changes reflect a balanced, evidence-based approach that addresses the underlying causes of opioid abuse without restricting access for patients who legitimately need these medications.

If Nebraska policymakers plan to pursue additional policies and initiatives in response to the opioid use disorder epidemic, it is critical that any proposals continue to take this balanced approach to ensure medications are available to patients in need, while limiting access for those who are at risk of misuse.**

The Council supports the state strategies provided by the Nebraska Legislative Research Office and its partners in the 2018 Research Report.**

The remainder of this position statement seeks to build on this report by describing the consequences of overly restrictive policy on opioid access, and suggesting additional balanced proposals that will protect access for Nebraskans with pain associated with serious medical illness. The appendix contains testimonies from three Nebraskan health care professionals on the impact of recent opioid policies.

Consequences of Overly Restrictive Policy

The Council wishes to impress upon state policymakers that there are patients in serious, chronic pain, for whom taking opioids means that they can get out of bed, go to work, and spend time with loved ones. We are concerned that this reality may be lost in any policy solutions that undermine clinicians' ability to comprehensively assess each patient, weigh the benefits and burdens of opioids, and make appropriate treatment decisions. This is particularly true for policies restricting prescribing, which can increase clinicians' reluctance to prescribe opioids to seriously ill patients, even if they are appropriate candidates for opioid therapy. XXIII Please refer to the Appendix for specific examples from Nebraskans regarding the impact of recent policies on their ability to prescribe and/or access opioids.

Consequences for Patients. Patients with serious illness regularly experience pain and other symptoms resulting from their underlying illness; however, this pain is routinely *under*treated. *xxiii Poorly managed pain in this population causes enormous human suffering and contributes to decreased productivity and ability to function, increased health care utilization, and even increased mortality. *xxiv While well-intentioned, official policies or guidance that discourage prescribing can exacerbate this undertreatment to devastating effect. *xxv For instance, the recent draft report from the Pain Management Best Practices Inter-Agency Task Force observed that there was "growing consideration of suicide resulting from unrelieved pain and in some cases lack of access to treatment." Other recent news coverage has explored the linkages between overly restrictive policies on opioid access and untreated pain, particularly for patients with cancer and those near the end of life. *xxvii,xxviii,xxxiii

Consequences for Prescribers. Many clinicians caring for patients with serious illness report that it has become increasingly difficult to balance the medical and ethical obligation to treat these patients' symptoms with the risk of professional repercussions resulting from new policies. **xx* Policies that arbitrarily place limits on opioid dosing or duration can undermine clinician judgement or lead to a chilling effect on prescribing, particularly if the policies (including exclusions for relevant populations) are not well understood. Anecdotally, Council members have heard that these policies have trickle-down effects that disproportionately harm rural providers and their patients. For instance, small practices and/or pharmacists are hesitant to prescribe or dispense opioids due to fears of being audited. This results in pressure on health plans to contract with large national chains that can endure more regulatory scrutiny. This threatens the sustainability of community pharmacists, which further reduces access to care for rural residents.

One of the challenges in passing sound policy is the lack of evidence for policies that limit access. For instance, as mentioned earlier, the CDC developed a Guideline for Prescribing Opioids for Chronic Pain in 2016. Several organizations expressed concerns with the Guideline, including that the resulting recommendations were not wholly supported by the evidence, or appropriately balanced to accommodate the legitimate needs of all patients who experience severe physical pain due to illness or injury.***Colored pain pain acceptation on the guideline into the Guideline cautions against prescribing more than 90 morphine milligram equivalents (MME) per day, some providers have noted that "effective dosage often depends on how individuals metabolize drugs, and some need more to achieve the same effect."**

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Guidance on Balanced Policy

The Council recognizes that the opioid crisis is a multi-faceted problem, and thus requires multi-faceted solutions. Nebraska remains a leader in thoughtful, balanced responses to the opioid epidemic. XXXVIIII Therefore, we urge policymakers and other stakeholders to build on this foundation with balanced proposals that preserve access to appropriate pain management for patients who have legitimate needs and benefit from the use of opioid medications as part of their plan of care. These include policies focused on clinician training, data sharing, patient advocacy and support.

Nebraska remains a leader in thoughtful, balanced responses to the opioid epidemic. Therefore, we urge policymakers to build on this foundation and preserve access to appropriate pain management for patients who have legitimate needs.

Some suggestions for balanced proposals include:

- 1. Increasing training for health care providers in pain assessment, pain management, and palliative care. Training should include pharmacologic and non-pharmacologic modalities.
- 2. Continuing to invest in Nebraska's highly-rated prescription drug monitoring program (PDMP) databases, including exploring strategies for greater integration with electronic health records that could support real-time information sharing such as immediate access to patient prescription records. Expand access to this database across state lines.
- 3. Implementing public and private health plans that include benefits, reimbursement models, and integrated team approaches that support early access to non-pharmacologic interventions (including physical therapy) for the primary care of pain conditions.
- 4. Reducing or eliminating patient out-of-pocket costs and increasing access to payment for person-centered, multi-disciplinary, non-pharmacologic pain management and treatment interventions.
- 5. Continuing to support and expand prescription drug take-back programs and drug disposal policies to limit access to unused opioid medications.
- 6. Allowing pharmacists to dispense partial fills of opioid medications.
- 7. Reviewing existing and new laws to make sure precise language and guidance is in place, monitoring for unintended consequences that restrict patient access to necessary medications, and establishing a pathway for quickly modifying or repealing harmful policy.
- 8. Consulting recommendations from the Federal Pain Management Best Practices Inter-Agency Task Force to inform future policy activities. xxxix

If legislation MUST include opioid limits, it must also include clear exceptions for patients with serious illness. In general, exemptions to opioid restrictions should:xl

- 1. Include cancer patients in active treatment and cancer survivors who continue to receive treatment for pain because of the effects of cancer treatment or the cancer;
- 2. Include patients receiving hospice or non-hospice palliative care;
- 3. Include other non-cancer patients experiencing pain or other symptoms related to a serious illness who are receiving, or would be eligible for, palliative care services;
- 4. Be standardized in definition and application across all plans or programs affected by the policy;
- 5. Be applied as early in the process as possible so that a patient who qualifies for an exemption will experience little or no disruption to treatment and to minimize the time plans, prescribers and pharmacists must spend in resolving inappropriate restrictions for patients who are, in fact, eligible for exemption;
- 6. Be clearly explained and included in aggressive outreach and education efforts to prescribers and pharmacists so they can anticipate access challenges for their patients and proactively minimize these obstacles; and
- 7. Include a clear and timely appeals process for patients that should be exempt but are not.

The state of Maine is in the process of implementing regulations that identify several exemptions to opioid restrictions, which could serve as a model for Nebraska.^{xli}

Please visit the DHHS Palliative Care website^{xlii} for more information on palliative care training resources for clinicians.

Conclusion

As Nebraska policymakers continue to develop policies to address the opioid epidemic, it is critical that any legislation, regulation, or other initiatives take a balanced approach that ensures these medications are available to patients who need them, while also keeping them away from those who are likely to misuse them. xliii

Appendix – Testimonies from Nebraska

Testimony #1 – Todd M. Sauer, MD (Palliative Care Physician)

As a palliative care physician, I have observed firsthand how recent national and state policy efforts to combat the opioid epidemic have resulted in unintended consequences for patients living with serious illness. My patients are among the most vulnerable in the health care system; they often have multiple chronic, progressive illnesses that limit their activity and create significant symptom burden. Much of my role involves working with these patients and their families to improve their quality of life by helping manage symptoms. Opioids are a critical tool in this work; for instance, I care for many patients who rely on opioids to treat their severe cancer pain. Without these medications, few would be able to get through the day. However, recent policies have undermined my ability to prescribe and my patients' ability to access necessary medications. The barriers I have encountered most frequently as of late are supply shortages and bureaucratic hurdles to prescribing.

While shortages in the opioid supply are a national issue, the impact is clearly felt here in Nebraska. In my practice, I often prescribe intravenous (IV) opioids for several reasons. First, these bring severe pain under control much faster than any other alternative, which is particularly important in the hospital setting. Second, these are the most effective option for patients who are unable to take the medications any other way. However, the pharmacy within my own hospital recently informed me that it is unable to procure this medication. As a result, I have had to prescribe alternatives, significantly delaying or even impeding my ability to manage their pain. Furthermore, I have heard from patients after they leave the hospital that they are unable to fill my prescriptions at their local pharmacy. For many of my patients, getting to the pharmacy at all requires significant effort and coordination due to their symptoms and level of frailty. While I again do my best to arrange alternatives, sometimes I am unable to respond immediately and the back-and-forth communication with my patients and the pharmacists takes a significant amount of time. Being turned away from the pharmacy is a devastating experience for my patients, and one that I am hearing of more and more.

Even when the appropriate medications are available, administrative hurdles resulting from increasing legislation and regulation create a significant barrier to access. Prior authorizations and Insurance denials of needed medications literally take hours of phone calls and paperwork. I am fortunate to be able to absorb some of this in my practice, but it comes at a significant cost. Moreover, most palliative care practices do not have the resources to break through these challenging obstacles. Ultimately, the patients again suffer.

There is no question that we have a crisis in this country regarding opioid use and abuse; combatting the opioid epidemic requires thoughtful policy solutions. From my vantage point, one of the most effective things state and local policymakers can do is invest in more training for all clinicians. Most physicians receive almost no training in symptom management during their medical education, and are uncomfortable using opioids appropriately to alleviate their patients' pain. In many instances, continuing education would be an introduction to the subject rather than a supplement. Critical topics for education include (but are not limited to) conducting a comprehensive pain assessment, matching the drug class to the pain, assessing risk for opioid substance use disorder, and prescribing practice and opioid conversions. Furthermore, there is a shortage of specialty palliative care and hospice physicians in this country. Since clinicians in these specialties are highly trained in symptom management – particularly effective prescribing of opioids – they are an underappreciated asset in managing the opioid epidemic. Therefore, additional investment in this workforce is critical.

It is our collective responsibility to ensure that patients with serious illness have access to necessary medications. While policy is necessary to address the underlying causes of opioid addiction and abuse, these medications play an important role in the care of those who are suffering from their conditions or are at the end of life. Therefore, I urge policymakers to identify ways to reduce unnecessary barriers to access while helping clinicians assess and prescribe opioids more effectively.

Testimony #2 – Michael J. Brodersen, PharmD, BCOP (Pharmacist)

Thank you for the opportunity to share my experience on the impact of recent opioid-related policies. I am a pharmacist working at a specialty practice outpatient pharmacy, and I specialize in dispensing and managing oral oncolytic therapy for cancer patients. I also have a background in community pharmacy.

While I would not say that recent policies such as the passage of LB 931 have had a dire impact on patient care, they have created an extra hurdle. As implementation began last year, my colleagues and I made the necessary changes in our workflow regarding pediatric prescribing limits and the requirement that adults provide identification at point of sale. However, we observed some pharmacies implementing blanket policies that extended the 7-day limit to adults as well. In one instance, our patient who was receiving longer acting pain management for chronic cancer pain was denied his prescription even though he provided official documentation with our practice letterhead that the medication was clinically indicated. The pharmacy required that our provider get on the phone and provide verbal confirmation of the patient's diagnosis and justification for why this patient needed more than a 7-day prescription. This took time that the provider could have used to see other patients and delayed the process of getting the initial patient the medication he needed to maintain quality of life. Several other patients have experienced this or something similar in the last year.

I have also observed a general "chilling effect" on opioid prescribing stemming from new policies, including those that trickle down from the federal level. Newer providers are increasingly hesitant to prescribe due to stigma, and even more seasoned providers have demonstrated apprehension. There is certainly a need to be thoughtful and well-trained in prescribing, but blanket statements and incorrectly applied dosing limits impair clinical judgement. On the other side, we also have patients in excruciating pain who are scared to fill or take their prescriptions because of the catastrophic messaging on opioids. Internally, we have taken steps to address these issues by improving communication with local pharmacies and our patients, being more proactive about justifying why the medications are necessary and thoroughly explaining for patients what each medication does.

Education is important. Providers must know how to prescribe and document appropriately, and communicate effectively. And some limits can be helpful – I have testified in court cases in which people were legitimately abusing these medications. That said, limits must be thoughtfully applied. Certain specialties such as oncology, palliative care, or even pain specialties should have more leeway in prescribing based on the population they serve. Otherwise, all these policies will do increase needless suffering among the most vulnerable patients in the health care system.

Thank you again for your consideration and please let me know if I can provide any further information.

Testimony #3 – Marcia Cederdahl, RN, BS, CHPN (Nurse, Cancer Survivor, Family Member)

I have been a hospice nurse since 1988 and was one of the first Registered Nurses (RNs) in Nebraska to be certified in Hospice and Palliative Nursing in 1995. As part of my 30+ years in this field, I can attest that opioids are a necessary component of the "biopsychosocial spiritual" care that palliative care provides. Specialty palliative care is about treating the whole person when they are facing serious illness – and trust me, these people are the sickest of the sick. We look at all the causes of suffering and work closely with the patient and family to ensure all their needs are met. If the source of pain is physical, we are well-trained in all available evidence-based therapies and take great care to provide the most appropriate treatment possible. However, the reality is that if a patient has Stage IV metastatic bone cancer, most drugs will not make a dent in the pain and could actually cause tremendous damage (for instance, too much acetaminophen will destroy a liver with absolutely no benefit). So, I am justifiably alarmed at the trend in new policies that could limit access to opioids for this population. I realize this is not often the intention of the policies, and certainly steps must be taken to combat the epidemic of opioid misuse and abuse. But I can tell you that the best policy change is improving education for all clinicians who treat patients with serious illness.

This is not just a professional issue for me. My brother was diagnosed with multiple myeloma in 2013, and in the fall of 2014 was placed on hospice when it became clear that his condition was terminal. He moved to a skilled nursing facility after several lengthy hospitalizations. The facility nurses were kind and attentive throughout most of his care, but they had not been educated in pain and symptom management. In my brother's final days, he was non-responsive and began having dyspnea (breathlessness). The facility nurses were terrified to use morphine, even though it was clinically indicated by the hospice team. This put me — a grieving family member — in the position of having to instruct my brother's health care providers on the use of morphine for dyspnea. And despite my credentials, they were still reluctant to administer the drugs. In the last 48 hours of my brother's life, I had to involve the facility's medical director to ensure my brother got the care he needed. To this day, it is hard to disentangle my mourning over the loss of my brother from the sadness and anger I feel about being put in that position. Worse still, he was one of the "lucky" ones — most patients with serious illness and/or facing end of life do not have a sister who is a hospice and palliative care nurse. I have observed this lack of knowledge in how to appropriately prescribe and administer opioids across all health care settings, not just in skilled nursing facilities.

Finally, I submit this testimony as a cancer survivor who wishes there was greater access to palliative care across Nebraska. I was diagnosed with Stage II-C colon cancer in June 2012, went through surgery and chemotherapy, and by the grace of God am still here. I am so grateful that I received wonderful *physical* care, including appropriate access to opioids during my hospitalization and subsequent treatments (although I suspect part of this was due to my palliative care training and ability to advocate for myself). However, I would have benefited from the emotional support that palliative care can provide. My family was overwhelmed, and I felt like I needed to be strong so that I would not be a burden to them. Studies show that unmet psychosocial needs can result in increased physical symptoms. In some cases, patients may self-medicate to lessen their fears, anxiety, depression, and so on. Greater access to palliative care can help address these needs by treating patients holistically, improving coordination and communication with other providers, and connecting both the patients and their families to appropriate resources. This kind of person-centered care reduces symptom burden, improves health care outcomes, and can even save money. But most importantly for me, it would have made me feel truly "cared" for during one of the hardest periods of my life. So, in addition to increasing education on opioid prescribing, I ask policymakers to consider steps they can take to increase palliative care access in our state. I, along with many of my colleagues, stand ready to work with you to make this happen.

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