June 6, 2018

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Mr. Demetrios Kouzoukas
Principal Deputy Administrator & Director of the Center for Medicare
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma and Deputy Administrator Kouzoukas:

The Patient Quality of Life Coalition (PQLC) welcomes the opportunity to work with the Department on potential policy changes regarding opioid medications. Like the Department, we are concerned about the public health emergency that exists today as a result of inappropriate use of prescription opioids and the harms associated with such use. As a nation, we must take steps to address the issue. We understand that imposing limits on opioid prescriptions is one way in which the Department is attempting to address these problems. PQLC remains concerned about these policy changes, however, because we believe they could impede or prevent access for certain patients who can benefit from opioids to treat their pain or other symptoms of serious illness and who can take them safely. However, recognizing that such limits are already being discussed, and in some cases implemented, if you are to move forward in this regard, we ask you to provide exemptions for people with pain and other symptoms due to cancer and other serious illnesses within any regulatory changes imposing opioid restrictions and limits. We have included language below that proposes how the agency might identify such exemptions.

The PQLC was established to advance the interests of patients and families facing serious illness. The coalition includes over 40 organizations dedicated to improving quality of care and quality of life for all patients from pediatrics to geriatrics, as well as to advancing public policies that improve and expand patient access to palliative care and appropriate pain and symptom management. PQLC members represent patients, health professionals, and health care systems.

Palliative care is patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice.[1] This intensive interdisciplinary care also provides an additional layer of safety for seriously ill patients treated with opioids through patient and family education, risk assessment and monitoring for undesirable effects of treatment.

CMS, state legislators, and other policymakers have recently proposed or are beginning to implement several restrictions and limits on opioid use in pain treatment. These restrictions include dosage and duration limits for opioid prescriptions, and pharmacy and prescriber lock-in programs for patients at-

[1] 42 CFR 418.3 – See definition of palliative care.

risk for substance use disorder or diversion. Most of these proposals contain exemptions for certain types of patients, but these exemptions have not always been consistent across proposals or evidence-based.

While recognizing the importance of addressing the problems of opioid use disorder and overdose deaths, the undersigned organizations remain concerned that new policies will impede or prevent access for certain patients who can benefit from opioids to treat their pain or other symptoms of serious illness and who take them safely. One way to address these concerns is to insert carefully-constructed exemptions into opioid restrictions that protect these vulnerable patients and their access to opioid treatment.

Guiding Principles

In general, exemptions to opioid restrictions should:

- 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;
- Include patients receiving hospice care;
- 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;
- Be standardized in definition and application across all plans or programs affected by the policy;
- 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 restrictions for patients who are ultimately exempted;
- Be clearly explained and included in aggressive outreach and education efforts to prescribers so they can anticipate access challenges for their patients and proactively minimize these obstacles; and
- Include a clear and timely appeals process for patients that should be exempt but are not.

Exemptions to Opioid Restrictions in Integrated Systems

In integrated healthcare settings like managed care (Medicare Advantage, Medicaid managed care, some employer-sponsored coverage) and integrated health systems, implementers of opioid restrictions are able to access data from a patient's medical and claims history. This should enable patient exemptions to be identified through these data, and implemented automatically before or in conjunction with a submission of a prescription for opioids. Automatic, data-based identification of exemptions is preferred whenever possible because it causes the least impact to patient access (in most cases the patient won't even know they are exempted) and to clinical and pharmacy workflow.

Identifying exempted patients by diagnosis

Serious Illness is a condition that carries a high risk of mortality, negatively impacts quality of life and daily function, and/or is burdensome in symptoms, treatments or caregiver stress[2]. Kelley, et al[3] identifies the following diagnoses as "severe medical conditions" that carry a high risk of mortality and are identifiable within medical data:

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[2] Kelley, AS, et al. "Identifying Older Adults with Serious Illness: A Critical Step Toward Improving the Value of Health Care." Health Serv Res, (March 18, 2016). https://www.ncbi.nlm.nih.gov/pubmed/26990009

[3] Kelley, AS, et al. "Identifying the Population with Serious Illness: The "Denominator" Challenge." J Palliat Med. 2018 Mar;21(S2):S7-S16. doi: 10.1089/jpm.2017.0548. https://www.ncbi.nlm.nih.gov/pubmed/26990009

- Cancer (poor prognosis, metastatic or hematologic)
- Chronic obstructive pulmonary disease or interstitial lung disease, only if using home oxygen or hospitalized for the condition
- Renal failure, end stage
- Dementia with evidence of length of illness or advanced disease
- Congestive heart failure, only if hospitalized for the condition
- Advanced liver disease or cirrhosis
- Diabetes with severe complications (ischemic heart disease, peripheral vascular disease, and renal disease)
- Amyotrophic lateral sclerosis
- Hip fracture, age >70 years
- Multimorbidity, ≥3 chronic conditions (Dartmouth Atlas list)

While this list of diagnoses can serve as a starting point for identifying patient exemptions, there are other considerations to be made, such as additional diagnoses appropriate for inclusion. These include non-metastatic cancer, acquired immune deficiency syndrome, and sickle cell disease. Research shows that patients with localized cancer experience a similar symptom burden as those with metastatic disease, due to the disease process itself and/or treatments of the disease.[4,5,6] Meanwhile, people with sickle cell disease experience chronic, disabling pain more often than previously recognized, and opioids are a critical therapy to managing this pain.[7,8] While the issue is complicated by racial disparities in health care,[9] it is nonetheless important to proactively identify patients with this diagnosis for further examination, rather than automatically limiting their access to opioids.

At the same time, Kelley's list of serious conditions may contain some that would be inappropriate for automatic exclusion. For example, Hip Fracture and Three or More Comorbid Conditions may only be appropriate for a geriatric population. Additionally, note that these studies referenced focused on adult populations. For healthcare settings or insurance plans that include children, diagnoses relevant to pediatric populations will also need to be incorporated. The most common severe illnesses in the pediatric population tend to differ depending on age, so this may involve multiple lists.[10]

So, again, the coalition offers this information as a *starting point* for further discussion and refinement.

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[4] Kim Y, Yen IH, Rabow MW. Comparing symptom burden in patients with metastatic and nonmetastatic cancer. *J Palliat Med.* 2016; 19(1):64-68. doi: 10.1089/jpm.2011.0456

[5] Fenlon D, et al. The JACS prospective cohort study of newly diagnosed women with breast cancer investigating joint and muscle pain, aches, and stiffness: pain and quality of life after primary surgery and before adjuvant treatment. *BMC Cancer.* 2014; 14:467. doi: 10.1186/1471-2407-14-467

[6] Hamood et al. Chronic pain and other symptoms among breast cancer survivors: Prevalence, predictors, and effects on quality of life. *Breast Cancer Res Treat.* 2018; 167(1):157-169. doi: 10.1007/s10549-017-4485-0

[7] Smith WR. Treating pain in sickle cell disease with opioids: Clinical advances, ethical pitfalls. *J Law Med Ethics.* 2014; 42(2):139-146. doi: 10.1111/jlme.12129

[8] Yawn BP, John-Sowah J. Management of sickle cell disease: Recommendations from the 2014 expert panel report. *Am Fam Physician.* 2015; 92(12):1069-1076.

[9] Ezenwa MO, et al. Coping with pain in the face of healthcare injustice in patients with sickle cell disease. *J Immigr Minor Health.* 2017; 19(6): 1449-1456. doi: 10.1007/s10903-016-0432-0

[10] See Hain R, Devins M, Hastings R, Noyes J. Paediatric palliative care: development and pilot study of a "Directory" of life-limiting conditions. *BMC Palliative Care*. 2013;12:43. doi:10.1186/1472-684X-12-43.

Other ways to identify exemptions with data
Other indicators in medical data could be used to identify exempt patients, or used in combination with diagnoses as part of larger algorithms to identify exemptions:

- Number of hospital admissions in the past 12 months (see Kelley, et al.)
- Number of conditions combined with measures of frailty (see taxonomy in Joynt, et al.[11])
- Claims history of certain treatments which are known to cause lasting pain – like chemotherapy, certain surgeries, etc.

The undersigned organizations would welcome the opportunity to work further with policymakers, policy implementers and healthcare systems to further define these details.

Exemptions to Opioid Restrictions in Non-Integrated Systems
In healthcare systems that are not integrated (fee-for-service coverage) it may be difficult to identify patient exemptions from their health data or claims history because the segment of the system that is implementing the restrictions does not have access to all the data on that patient. For example, a Medicare Part D drug plan sponsor is meant to implement restrictions, but does not have access to the patient's hospital- or physician services-related Medicare Parts A or B claims history. We recognize that in this context, it may be impossible for the healthcare system to identify a patient exemption automatically.

In these settings, the prescribing provider should identify an exemption at the time in which he/she writes the prescription. In this case, the exemptions and the process by which they are implemented should be clear. Recent opioid restriction regulations in Maine (developed as a result of legislation) can offer insight into how to approach developing exemptions identified by prescribers. While this list, copied below directly from Maine regulations, can serve as a starting point for such exemptions, the coalition welcomes the opportunity to discuss more and refine this list with policymakers.

Example from Maine
Maine regulations identify the following exemptions to opioid restrictions:[12]

- Exemption Code A: Pain associated with active and aftercare cancer treatment. Providers must document in the medical record that the pain experienced by the individual is directly related to the individual's cancer or cancer treatment;
- Exemption Code B: Palliative care in conjunction with a serious illness;
- Exemption Code C: End-of-life and hospice care;
- Exemption Code D: Medication-Assisted Treatment for substance use disorder;
- Exemption Code E: A pregnant individual with a pre-existing prescription for opioids in excess of the 100 Morphine Milligram Equivalent aggregate daily limit. This exemption applies only during the duration of the pregnancy;

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[11] Joynt, KE et al. Segmenting high-cost Medicare patients into potentially actionable cohorts. Healthc (Amst). 2017 Mar;5(1-2):62-67. doi: 10.1016/j.hjdsi.2016.11.002. Epub 2016 Dec 1. https://www.ncbi.nlm.nih.gov/pubmed/27914968

[12] See Maine Department of Health and Human Services. RULES GOVERNING THE CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM AND PRESCRIPTION OF OPIOID MEDICATIONS**.** August 14, 2017. Available at: https://www.maine.gov/sos/cec/rules/14/118/118c011.docx

- Exemption Code F: Acute pain for an individual with an existing opioid prescription for chronic pain. The seven day prescription limit applies;
- Exemption Code G: Individuals pursuing an active taper of opioid medications, with a maximum taper period of six months, after which time the opioid limitations will apply, unless one of the additional exceptions in this subsection apply; or
- Exemption Code H: Individuals who are prescribed a second opioid after proving unable to tolerate a first opioid, thereby causing the individual to exceed the 100MME limit for active prescriptions. For this exemption to apply, each individual prescription must not exceed 100 MME. Dispensers shall provide patients with guidance on proper disposal of the first prescription.

At the time of writing the prescription, prescribers identify whether their patient qualifies for exemptions A-H. Prescribers write the exemption on the prescription (on paper or – in the majority of cases – through an e-prescribing system). If the prescribers use exemption B for palliative care, they are also required to include the ICD10 code for the diagnosis of the serious illness requiring palliative care. Stakeholders in Maine report this system is functioning as expected thus far. While the effective date of the law passed by the legislature was July 1, 2016, policymakers phased in this implementation to 1) give the Health Department time to propose and finalize regulations and definitions; 2) give provider groups time to educate and train providers; and 3) give healthcare systems time to adjust to the new rules. Therefore, full implementation of prescribing limits and operationalization of the exemptions did not begin until January 1, 2018.

While this method of identifying exemptions requires action from the prescriber (identifying and indicating the exemption) and the pharmacist (verifying the exemption before dispensing), a well-constructed process should not be too burdensome on either group. And most importantly, this process does not require action from the exempted patient, nor does it restrict that patient's access to their medication. We believe this type of process is more protective of patient access than a retrospective exemption process that is only triggered once a patient attempts to fill their prescription (like the process established in the 2019 Medicare Parts C & D Call Letter[13]).

Our coalition member organizations welcome the opportunity to discuss this exemption language and related processes further with interested policymakers. If you have any questions, please contact Keysha Brooks-Coley, Chair of the Patient Quality of Life Coalition/ Vice President, Federal Advocacy, American Cancer Society Cancer Action Network at 202-661-5720 or Keysha.Brooks-Coley@cancer.org.

Sincerely,

Academy of Integrative Pain Management
American Academy of Hospice and Palliative Medicine
American Association of Colleges of Nursing
American Cancer Society Cancer Action Network
American Society of Clinical Oncology
Association of Oncology Social Work

[13] See Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 2, 2018. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

Association of Pediatric Hematology/Oncology Nurses
Cancer Support Community
Catholic Health Association of the US
Center to Advance Palliative Care
Children's National Medical Center
ElevatingHOME / Visiting Nurse Associations of America
Hospice and Palliative Nurses Association
National Coalition for Hospice and Palliative Care
National Palliative Care Research Center
National Patient Advocate Foundation
Oncology Nursing Society
Pediatric Palliative Care Coalition
Physician Assistants in Hospice and Palliative Medicine
Prevent Cancer Foundation
ResolutionCare Network
St. Baldrick's Foundation
Supportive Care Coalition
Trinity Health