SOCIETY *of*
PALLIATIVE CARE PHARMACISTS
An organization for pain and palliative care pharmacist practitioners

March 2, 2018

Bridget Scullion, PharmD, BCOP
President, Society of Palliative Care Pharmacists

Re: Docket "CMS-2017-0163"

The Society of Palliative Care Pharmacists (SPCP) was developed in late 2015 by 25 core leaders within the specialty areas of Pain Management, Palliative Care, and Hospice to provide a professional organization for pharmacists practicing in these three specialties and in part to advocate for meaningful impact and practice at their maximum aptitude commensurate with their advanced professional education and post-graduate training. SPCP's mission is to promote exceptional patient care by advancing pain and palliative pharmacists through education, development, and research in collaboration with the transdisciplinary team. Please see below our comments regarding the 2018 Draft Call Letter for Improving Drug Utilization Review Controls (Opioids).

First and foremost, we encourage you to include pharmacists, including our Society, in any future medication-related strategies or policy development. Pharmacists are the medication experts and are on the front lines of healthcare in many communities, behind the scenes within inpatient and outpatient healthcare institutions, are integrally involved in direct patient care, and sometimes the only healthcare resource in rural America. They serve an essential role in patient access and medication safety.

1. Enhancing the OMS by such that it identifies high risk beneficiaries who use "potentiator" drugs (such as gabapentin and pregabalin) in combination with prescription opioids to ensure that plans provide appropriate case management. Potentiators are drugs that when taken with an opioid increase the risk of an adverse event. OMS already flags concurrent benzodiazepine use by plan enrollees.

We remind CMS that all analgesics affect the central nervous system (CNS) by the very nature of their pharmacology. If gabapentinoids are considered for monitoring, then all medications that affect the CNS should be monitored, including anticonvulsants, antidepressants, skeletal muscle relaxants, and certain antihypertensives (e.g., centrally-acting alpha agonists and beta antagonists) that are used as analgesics. This should also include antihistamines (e.g. diphenhydramine, hydroxyzine) as well as antiemetics (e.g. promethazine, prochlorperazine). All of these substances depress the CNS, are commonly seen in overdose, and are used to potentiate illicit drug use effects. We also note, that by combining some of these drugs at low doses, we can obtain desirable potentiation or synergy for analgesia while keeping the doses of each individual drug low in an effort to minimize side effects and risks of each individual agent. Almost all overdoses are polysubstance in nature including alcohol, which is not generally tracked by sales or use.

2. Implementing technical revisions to the Pharmacy Quality Alliance (PQA) measures used by CMS to evaluate Part D sponsors' progress in combatting the opioid crisis, and consideration of a new PQA measure, Concurrent Use of Opioids and Benzodiazepines. Given the danger of combining opioids and benzodiazepines, we seek feedback in the Call Letter on starting to track a new measure to address this issue. This measure assesses the percentage of individuals 18 years and older with concurrent use of opioids and benzodiazepines.

We support the CMS decision to implement technical revisions to the PQA measures used by CMS to evaluate sponsor progress in combating the opioid crisis. These measures should be sensitive to patients with cancer or other serious, life limiting illnesses so that access to medication in these vulnerable populations is not affected, while maintaining safety in the home and community. We endorse universal monitoring for all patients (palliative and non-palliative), as this can help ensure that family members, healthcare workers, and others are not diverting drugs. We strongly support common sense measures to evaluate the use of opioids in patients without serious life limiting illness as the PQA has already addressed, including "Use of Opioids at High Dosage in Persons without Cancer" and, "Polypharmacy: Use of Multiple CNS-Active Medications in Older Adults." We also support the measures that attempt to curtail doctor- and pharmacy-shopping such as "Use of Opioids from Multiple Providers in Persons Without Cancer" and "Use of Opioids and from Multiple Providers in Persons Without Cancer." We strongly support the implementation of the new measure "Concurrent Use of Opioids and Benzodiazepines" but ask that this measure again be sensitive to patients with cancer or serious, life limiting illness.

With the continued evaluation of measures, we suggest consideration of additional quality measures that investigate the provision of naloxone for patients on high dose opioids, as well as measures investigating continued opioid and benzodiazepine utilization after documented naloxone administration. We support providing prescriber and dispensing reports on a scheduled basis so that any prescriber or dispenser can see their trends and measures for their patient population in a non-punitive manner.

While the PQA measures are careful to exclude patients with cancer from their quality measures, we would like to express our concern that the OMS draft letter provides for no such exceptions, specifically with regard to OMS recommendations for hard level formulary stops, soft edit and supply quantity limits. We encourage consistency throughout the measures, understanding that CMS, like SPCP, wishes to support cancer patients and those patients with serious, life limiting illness, not yet on hospice, to ensure adequate availability of pain treatments. We recommend that these hard formulary stops and supply limits may be overridden by the pharmacist for patients with confirmed ongoing cancer diagnoses with appropriate universal risk management strategies in place.

3. Expecting all sponsors to implement hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy (which can only be overridden by the sponsor) at 90 morphine milligram equivalent (MME), with a 7 days supply allowance.

We request clarification of this measure. Does it include or exclude patients with cancer or those followed by palliative care service, hospice service or at end-of-life care, as many of the PQA measures state? (Please see above) Is it only for initial fills? Sponsors and state legislatures are already mandating quantities and durations, much to the suffering of patients and frustration of providers. This presents an additional hardship for patients with pain in getting to pharmacies and also requires multiple co-pays. For example, Optum Rx, a Medicare Part D sponsor, is limiting opioid supply to #21 (3 doses/day for 7 days) for any type of acute pain. For those who have scoliosis corrective surgery, the majority of whom are taking chronic opioids prior to surgery, this is not only dangerous but inhumane. Those patients at higher risk for harm may benefit from smaller, more frequent supplies with additional monitoring and counseling in the local community. CMS and sponsors should embrace the pharmacist care provider, encourage medication review and clinical decisions to be made in conjunction with providers, and as an advocate for the patient.

We would also recommend a provision that all sponsors be required to add a soft edit on all opioid prescriptions with a morphine milligram equivalent (MME) greater than or equal to 50mg, or category 4 on a RIOSORD assessment to consider co-prescribing or co-dispensing at least one form of naloxone. This may be done in the office or the pharmacy. Pharmacists are already determining appropriate candidates for dual co-prescribing of naloxone as well as counseling the patient and caregiver. CMS should encourage a comprehensive approach to safety by utilizing the pharmacist medication experts as well as supporting provider status for the pharmacist, since they are critical access providers in many parts of the country

4. Implementing a supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME).

See above, however, a clinical assessment by a pharmacist would be most appropriate, to determine history of analgesic use, risk assessments and provide recommendations. This is already being done in some health systems and incorporates current best practices and the patient's own experience and thoughts.

We recommend that CMS limit initial supplies of ALL new medications to be 2 weeks in duration, with close follow-up by a pharmacist to determine efficacy and safety. For example, a cancer patient is given a new prescription for oxycodone 5mg 2 tabs orally every 3 hours as needed. If calculating for a 30-day supply, this would give #480 tablets for a completely justified indication. However, if that patient goes home and tries this new mediation and it makes him/her sick (or they die from a terminal illness), the patient or family may be left with a large supply of medication. If small amounts are given (e.g. 2 week supply) and the prescriber is able to e-prescribe a different medication to the local pharmacy (which may be hundreds of miles away in rural states), this would allow a more flexible and responsive system. As an extension of this, we encourage enforcement of electronic prescribing of all medications, including

controlled substances, so that prescribers may order small supplies of medication and have the ability to be responsive to patient needs. Some states have already implemented this.

As a correlate, we recommend prohibiting 90-day supplies of any controlled substance, which is commonly promoted by mail order pharmacies and sponsors, even for newly prescribed medications. This puts an extraordinary number of dosage forms in a medicine cabinet (or counter top or bedside table). Consider this scenario for the patient situation described above. This is dangerous for the patient and the community, for the sole purpose of maximizing profit by decreasing workload.

5. Expecting all sponsors to implement soft POS safety edits (which can be overridden by a pharmacist) based on duplicative therapy of multiple long-acting opioids, and request feedback on concurrent prescription opioid and benzodiazepine soft edits.

We request clarification of this measure. Does this refer to different size tablets of the same drug (e.g. 15mg tablet + 30mg tablet of morphine ER to make a dose of 45mg)? Or does it refer to duplicative but different long-acting opioids (e.g. transdermal fentanyl + morphine ER)? May the pharmacist override the benzodiazepine and opioid edit but needs to document the reason? Please see recommendations noted in #2 above.

Supplementary comments:

For each patient that is considered for opioid therapy, multiple factors must be considered, including; evaluation of past and current therapies, the potential for drug-drug, drug-food, drug-nutritional supplement, and drug-disease interactions, counsel and initiate a consent for long-term opioid therapy, choose non-pharmacological and non-opioids therapies that might be more appropriate, order and evaluate baseline urine toxicology screens, provide and interpret validated risk assessment tools for opioid abuse and misuse, assess percent risk of opioid-induced respiratory depression, if applicable prescribe and counsel for naloxone therapy for in-home use, if indicated, order and interpret pharmacogenetic testing that can affect response and toxicity to opioid and other medications. To expect any primary care provider that has less expertise in these areas to accomplish such tasks in a fifteen-minute office visit is shortsighted and risks patient safety. Pharmacists within advanced practice settings are involved in daily direct patient care in the pain management and palliative fields and add a valuable aspect of care with regard to safety and appropriate analgesic therapies.

Pharmacists should be an active participant in the development of guidelines for safe opioid use given their expertise and direct involvement with medication use. We also encourage you to consider holding sponsors accountable not only for mental health care but for the reimbursement of adequate pain management visits, including extended and group visits, and visits with pharmacists and other integral professionals such as social workers and psychologists in order to address the complexities seen in these patients.

Pharmacists are the ONLY healthcare clinicians that do not have official national "provider status" and therefore a clinic visit in all but three states cannot be billed out to Medicare. This is

one area that SPCP takes very seriously, as implementation of pharmacist providers working side-by-side with physicians could ease the burden on physician providers, allowing the pharmacist to complete comprehensive opioid risk assessments, order and interpret urine drug screens and other appropriate chemistries, including but not limited to serum opioid levels and/or pharmacogenetic testing to ensure appropriate individualized therapy when indicated. And, depending on the state, pharmacists can also prescribe controlled substances. This has been occurring within the VA and DoD for decades.

Moving forward we gladly offer our expertise on this important topic.

Respectfully,

Bridget Scullion

Bridget Scullion, PharmD, BCOP
President, Society of Palliative Care Pharmacists