March 5, 2018

Dear Centers for Medicare and Medicaid Services:

**Re: Response to the CMS Draft CY 2019 Call Letter, in Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter**

Thank you for the opportunity to provide feedback to the CMS Draft 2019 Call Letter and to offer input and suggestions for CMS proposals to address opioid utilization for pain management and Medication Assisted Treatment (MAT) in light of the increase in drug overdoses in recent years.

As a physician who is Board Certified in Pain Medicine through the American Board of Medical Specialties, I am a stakeholder experienced in the front lines of dealing with opioid misuse and abuse, as well as treating patients with intractable pain who require opioid medications to control their pain so they can function more effectively and live more productive lives.

I fully agree with the CMS goal to address prescription opioid overuse in Medicare Part D from a medication safety perspective while preserving beneficiary access to medically necessary drug regimens. But I emphasize that medication safety is not improved by impeding access to medically necessary drug regimens. The drugs that are medically necessary are not the ones causing the opioid crisis. Please consider my suggestions below in response to your request for feedback.

***Medication Assisted Treatment and*** ***Hard Safety Edits***

It is appropriate that the proposed restrictions on opioid prescribing exclude Medicare patients with cancer or in hospice, as well as those undergoing MAT. However, if the patient’s preferred status in one of these classes is not known to the pharmacist or the Part D plan when the prescription is presented to the pharmacy, then this idealized goal of protecting these classes of patients does not necessarily prevent a delay in filling an opioid Rx due to a hard edit while awaiting authorization anyway. How would the pharmacy and the Part D plan both know which opioid prescriptions should not be subject to a hard edit, based on the patient’s status in a protected class of cancer, hospice, or MAT treatment?

What about those patients suffering with pain who are not in one of these protected classes? Clearly, the nature of the proposals for hard edits at POS at the pharmacy at a dosage level of 90 MME per day, and implementation of a days’ supply limit for initial fills of prescription opioids for the treatment of acute pain, will both make it more difficult for the affected Medicare beneficiaries to access medically necessary opioid therapy.

Results inevitably will force many Medicare beneficiaries to experience a delay in filling their medically necessary opioid prescriptions, thereby causing them to suffer withdrawal symptoms, increased pain, difficulty functioning effectively due to uncontrolled pain, and loss of time at work or increased burden of care on their families, and associated financial losses.

However, I commend CMS for its commitment to exclude Buprenorphine for MAT from impediments to access, such as excluding Buprenorphine products from the proposed hard edit at 90 MME, excluding Buprenorphine when a duplicative LA prescription soft edit is triggered for concurrent use of opioids and buprenorphine, expecting Part D plans to NOT require authorization for Buprenorphine products any more frequently than once during a plan year, and to carry that authorization through to the next plan year when MAT has been authorized for a patient in the prior plan year. It is critically important to provide clear access to MAT for patients for whom reduced opioid prescribing is practical and beneficial for their treatment plan, in order to reduce suffering from opioid withdrawal symptoms, increased pain, and functional impairment from opioid reduction.

But is it not just as important to provide the same access to other medically necessary treatment plans, particularly those for patients with chronic pain diagnoses and for whom chronic opioid therapy is medically necessary, who are at considerable risk of suffering withdrawal symptoms, increased pain, and impaired ability to function?  Are these not the exact same issues facing the Medicare beneficiaries who are prescribed Buprenorphine for MAT?  It seems that the same rules should apply to preserve ALL Medicare beneficiaries’ access to medically necessary drug regimens, including chronic opioid therapy that is legitimately prescribed by the patient’s physician or other appropriate provider.

If the streamlined benefits for beneficiaries receiving MAT are not equally applied to beneficiaries who require chronic opioid therapy, then conceivably valid claims could be made against CMS and/or Part D Plans for discrimination and/or ADA rights violations. These two types of patients are essentially the same group of patients, but who have different treatment plans that their physicians determined to be medically necessary. A patient may be changed from either class to the other or back at any time, depending on the response to treatment, as determined by followup evaluation by the patient’s physician. This means the proposed hard edit for opioids at 90 MME for chronic opioid therapy alone cannot be legally justified when MAT or other classes of patients are excluded from this rule.

I recommend that CMS not restrict access to medically necessary MAT, but keep the same open access opportunities to fill medically necessary prescriptions available to patients who have medical necessity for chronic opioid therapy as well. Regulations that apply to one type of patient should apply to all types of patients equally.

How can we determine which patients truly require opioid medications to treat their pain, and which ones require higher doses? The only realistic answer is to let the physicians and other providers do their job in determining medical necessity for the entire gamut of pain treatments, including opioid therapy, on an individual patient basis, and respect those decisions. Any attempt to restrict access to opioid medication based solely on an arbitrary dosing level will have unacceptable negative consequences on beneficiaries without substantive reductions in opioid abuse, since it targets the compliant patient population that is not abusing opioid medications.

***Hard Safety Edits for at Least 90 MME/day***

The number of patients affected by these changes would have been almost 1.6 million Medicare beneficiaries alone in 2016 for prescriptions for at least 90 MME per day, in addition to millions more for initial acute opioid prescriptions. The numbers affected patients suffering as a result of these changes can be expected to be higher in 2019.

The existing (2018) CMS Overutilization Management System (OMS) generally requires soft edits at the pharmacy for opioid prescriptions totaling at least 90 MME and hard edits for at least 200 MME (or some variation of these purported values) with most Part D plans, but this is already causing access problems and supply interruptions to Medicare beneficiary access for medically necessary drug regimens.

Significant medication access problems due to these edits already occur routinely in the current system. Patients are already receiving denials of coverage for several days to weeks at times. There are problems and administrative delays encountered at the pharmacy in notifying the physician and starting the prior authorization process, at the physician’s office in completing numerous and often complicated requests for prior authorization, and by the Part D plan sponsor in reviewing, trying to understand, and hopefully approving the authorizations when appropriate, which is the vast majority of the time. This process is already delaying timely fills of appropriately prescribed opioid medications for medically necessary treatment plans. As a result, the beneficiaries are affected and subjected to needless stress, pain, and suffering.

The administrative burden of imposing these hard edits on patients, pharmacists, prescribers, and Part D sponsors for over 1.6 million prescriptions per year is substantial. The benefits are not shown to outweigh the burden.

Implementation of a more restrictive policy of hard edits for opioid prescription totals of at least 90 MME will only compound the beneficiary access problem. There is no evidence that setting hard edits at 90 MME will in any way decrease overutilization of opioids over the current system. There is also no evidence to support setting a value of 90 MME for any type of cutoff level. The current CMS system in OMS is already effective to prevent the unsafe dosing of drugs at the time of dispensing, to help ensure providers are aware when potentially high risk levels of opioids will be dispensed to their patients, and to promote care coordination.

I recommend against this increase in regulatory burden on the basis that there is not adequate justification for it, and it creates new impediments to Medicare beneficiary access to medically necessary drug regimens.

As clarification I would like to point out that, contrary to the language stated on page 209 of the Call Letter, the 2016 CDC Guideline does NOT simply recommend “to generally avoid increasing the daily dosage of opioids to 90 MME.” Instead, the 2016 CDC Guideline actually says that clinicians (not pharmacies or insurance plans) "should avoid increasing dosage to ≥90 MME/day OR carefully justify a decision to titrate dosage to ≥90 MME/day."  (2016 CDC Guideline, Recommendation #5, p. 18) The stated of the CDC recommendations is to treat chronic pain, using opioids appropriately when necessary at doses that are justified. They do not set any particular limit. The CDC Guideline specifically states that its purpose is to provide recommendations for primary care clinicians who are prescribing opioids for chronic pain. It is not a blueprint for regulatory or policy making restriction of opioid access by CMS or insurance plans.

***7 Days’ Supply Exception on First Prescription to Reduce Unintended Consequences of Hard Edits***

Regarding the proposal to implement a one-time 7 days’ supply exception of the first opioid prescription that triggers a hard edit, this is an idea that has potential but needs to be expanded. It offers some opportunity to reduce the potential for any unintended consequences for patients already taking opioids, such as opioid withdrawal, by providing a short term supply to patients to allow time to pursue coverage through the exceptions process. But there are numerous problems with the one-time 7 days’ supply proposal.

I instead recommend an initial 30 days’ supply, as this would provide relatively similar protection for the beneficiary while providing ample opportunity for prior authorization and substantially reducing the burden on the beneficiary, as well as much simpler implementation. This is similar to the system CMS uses for authorization of nonformulary drugs for the first prescription of a plan year or following a change in formulary.

There are numerous benefits of the 30 days’ supply over a 7 days’ supply. It would avoid the need for the beneficiary to return to the prescriber for a second prescription within the original prescription period, which is typically 1 month for chronic pain patients. It also reduces the need for multiple trips to the pharmacy, not just in the first month of the prescription, but every month thereafter, because delaying the full 30 days’ supply fill at the pharmacy for 7 days typically throws the beneficiary off of his or her usual refill schedule, causing that prescription to come due at a different time every month than the Medicare beneficiary’s other prescriptions.

Given the current problems with increased incidence of opioid overdoses and overutilization, most physicians **must** see the patient for a separate visit and physical exam on the day that a prescription is written for most opioids. This requires an additional trip and copayment for the beneficiary if they only receive a 7 days’ supply, as well as additional trips to the pharmacy.

Most chronic pain patients struggle with limited resources in terms of finances, transportation, and often the ability to even get out of their homes with a taxing effort to go to the doctor or the pharmacy. Many have to pay extra for the transportation, which they can ill afford on their typically low, fixed incomes. A 7 days’ supply exception is a good start, but simply making it a 30 days’ supply exception for the initial hard edit for each prescription in a calendar year will cause much less disruption to the beneficiary, improve access to medically necessary drug regimens, and probably work just about as well to reduce prescription opioid overuse in Medicare Part D from a medication safety perspective. It still forces the desired review of the medication regimen and verification of medical necessity by the prescriber.

However, this proposal should apply to any prescription that triggers a hard edit, not just the first one of the year, and not just opioid prescriptions. This policy makes sense for other medications as well. Since the purpose of a supply limit exception is to reduce adverse consequences of supply disruption, there is no reason to limit it to only the one prescription medication, especially when most chronic pain sufferers are prescribed both a long acting and a short acting opioid to fill in the same monthly period, and hopefully other adjunctive medications for pain relief as well, in order to provide better pain control with less opioid medications.

The proposed idea that the pharmacist would help assess the immediate needs of the patient to help determine which prescription should be filled for a one-time exception is fundamentally flawed. This expectation would illegally and unethically presume to force pharmacists to substitute their judgment for the established physician's medically necessary treatment plan, with no reimbursement allowed for the pharmacists' additional time and expertise in doing so. Pharmacists cannot legally or economically provide this medical service, especially in violation of their states’ laws. The pharmacists simply will not be able to provide this service in reality, both for legal and economic reasons, so the patients will be forced to decide on their own which part of their medically necessary treatment plan to forego. Neither the patients nor their pharmacists should be put in this position.

There is no benefit in limiting the exception for a hard edit delay to only a total of one medication prescription in a plan year. On the contrary, it will serve the beneficiary and CMS better allow a hard edit exception to prevent a potential delay in filling any prescription, opioid or otherwise, for the first prescription in a plan year for any new medication. This becomes especially important when a patient suffers an adverse reaction or failure of a medication and must have it changed in mid-month, without delay.

***Days Supply Limits for Initial Opioid Prescription Fills***

CMS should help reduce unnecessary opioid availability in any way it can. But the proposal to implement a days’ supply restriction or daily dose maximum is not supported by any evidence that it would substantially improve medication safety. Rather, these are incursions into the patient-physician relationship that create considerable impediment to beneficiary access to medically necessary drug regimens. It appears to be wishful thinking that will instead result in harm to the Medicare beneficiaries.

By implementing a days’ supply restriction or daily dose maximum, CMS is also indicating that it has no confidence in the patient-physician relationship to determine the appropriate dosing and supply needs of the patients, and it is assuming that role of determining medical necessity for itself. At the very least, these restrictions block access to a treatment and medication regimen determined by the beneficiary’s physician to be medically necessary. This incursion into the practice of pain medicine, though perhaps well-intentioned, can only cause restrictions that compromise appropriate pain treatment and/or result in an excessive burden on both Medicare beneficiaries and their clinicians.

The CDC Guideline’s sixth recommendation offers sage advice to clinicians to prescribe the lowest effective dose of opioids and no greater quantity than needed for the expected duration of acute pain severe enough to require opioids, suggesting that 3 to 7 days is often enough. But the CDC Guideline does not proscribe any hard limits because it recognizes the need for the clinician to evaluate each individual patient and the particular types of pain involved. It is an educational, not regulatory, document. It cannot be used to justify uniform regulatory interventions when it was only meant to suggest treatment considerations to clinicians in the field.

For example, some surgical procedures such as joint replacements often require several weeks of opioid therapy, while others can be managed in 3 to 7 days. More severe traumatic injuries and more complicated types of surgeries will take longer for the patient’s pain to subside to a level that does not require opioid medications. Certain patients are genetically more susceptible to pain and require longer courses of opioid therapy than others. These individual variations require decisions that should be respected between the clinician and the patient, not subject to access barriers by “one size fits all” rules.

It is not a simple process for a patient in pain to go to the doctor for an additional prescription and to the pharmacy to fill it, especially following an acute injury or surgery. First, the pain problems can make these trips unbearable in certain situations. Second, it may involve difficulties with the expense of or lack of transportation. Third, there are extra expenses for additional doctor’s appointments and medication copayments. CMS is not doing its Medicare beneficiaries any service by increasing this burden in the name of protecting them.

I encourage CMS do drop its intent to establish a days’ supply limitation policy for any patients, opioid naïve or otherwise, as this is the role and purview of the clinician in the patient-physician relationship. The perceived benefits in terms of improved medication safety are not established or supported. The needs of a patient for pain control, and to function effectively, cannot possibly be anticipated at the CMS or Part D plan level. This is a situation where we must rely on the clinician to evaluate the patient and make the best judgment possible of the patient’s needs.

***Opioid Duplicative Therapy Safety Edits***

Adding additional edits for duplicative LA and SA prescriptions appears to cause more problems than it solves at this point. The multiple edits that will be triggered at the pharmacy will certainly interfere with the ability of the beneficiaries to get their prescriptions filled in a timely manner, and this will also confuse physicians and pharmacists about insurance authorizations. It would be better to hold off implementing these additional edits at this time.

There are good reasons why duplicative LA prescriptions are written for certain patients, so they should not be rejected. Some patients may need to be switched from one LA opioid to another at mid-month due to an adverse reaction or medication failure. Others have very high but legitimate medically necessity for high dose opioid medications that cannot be met with a single formulation, so a second formulation must be used concurrently. At some point the soft edit may be useful to verify that the second LA prescription is not an oversight, but until the problems with multiple edits on the same prescription can be worked out, it will probably cause more problems than benefits. Likewise, there are times when multiple SA opioid prescriptions are medically necessary, such as the option for the patient to use the one less powerful when possible, or a difference in therapeutic effect in some patients. But for now it is best to wait until the other problems are sorted out with multiple edits.

***Opioid Potentiator Drugs***

The addition of more flags to the OMS, such as for Gabapentin and Lyrica at this time, and later for other drugs, is likely to be counterproductive to CMS’ goal to address prescription opioid overuse from a medication safety perspective, and should not be implemented.

In order to treat pain with reduced opioid prescribing, it is necessary to increase utilization of non-opioid pharmacological and non-pharmacological therapies, which are preferred for chronic pain. This approach is consistent with the 2016 CDC Guideline, Recommendation #1. Creating potential barriers to access of non-opioid medications, such as Gabapentin and Lyrica, does nothing to reduce opioid overprescribing of opioids, but instead promotes it. Clinician education measures would be far more appropriate and effective to optimize medically necessary use of non-opioid pain medications, such as Gabapentin and Lyrica.

I agree that concurrent prescribing of an opioid and benzodiazepine should only be done when the benefits outweigh the risks and there is no other treatment with similar efficacy, and that the patient should be fully informed of the increased risks. However, this needs to be done in the clinician’s office, and the addition of another soft POS safety edit is not likely to improve this process. Instead, it simply causes increased time lost to addressing regulatory burdens that is better spent counseling the patient.

Once the physician has determined medical necessity for concurrent use of an opioid and a benzodiazepine, the pharmacist should not be required to second-guess the physician’s determination of medical necessity.

***Conclusion***

In summary, one of the worst unintended consequences of imposing too many burdens or regulations results when physicians decide to not utilize opioids at all or severely limit their use for patients for whom this therapy is medically necessary and appropriate, or when pharmacists refuse to bother with filling opioid prescriptions any longer.  Both of these situations are already happening, causing patients who do not have their pain management needs met in a doctor's office to look elsewhere.  We already know that when patients turn to street drugs it is much more hazardous and fraught with disaster.  We know that physician prescriptions for opioids are already decreasing nationally.  What is increasing is the use of street drugs including fentanyl analogs and heroin which are very deadly and causing a severe increase in the opioid overdose deaths.

Furthermore, CMS should not assume beneficiary opioid overuse as a starting point in setting policy for management of opioid prescriptions, and the language of the Call Letter should be modified to remove such assumptions.

I take exception to the Draft CY 2019 Call Letter assertion that "these efforts will better manage chronic overuse among beneficiaries who are taking high levels of prescription opioids," defined as at least 90 MME/day (p.203), as well as opioid-naive patients.  CMS is not justified in assuming that any or all beneficiaries using over any set amount of opioid are overusing opioids, unless the opioid use is not supported by medical necessity established by the patient’s physician or other prescribing clincian.

Several times, the Draft CY 2019 Call Letter refers to the CDC Guideline for support in creating regulatory restrictions for opioid prescribing, particularly in reference to a limit or threshold of 90 MME/day. However. The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain was only intended by the CDC to be used by “primary care clinicians (e.g., family physicians and internists) who are treating patients with chronic pain (i.e., pain lasting >3 months or past the time of normal tissue healing) in outpatient settings.” The Rationale for the CDC Guideline itself states, “The guideline is intended to inform clinicians who are considering prescribing opioid pain medication for painful conditions that can or have become chronic.” It is an educational document for primary care clinicians.

The CDC Guideline does not state or imply any intent for its recommendations to be used as a framework for regulation or policy making of opioid prescribing. Its true purpose is to inform primary care clinicians who are considering prescribing opioid pain medication for painful conditions that can or have become chronic, and thus improve patient care through the patient-physician relationship. It is not appropriate to incorporate these clinical guidance suggestions for primary care clinicians into regulatory or insurance restrictions that delay, restrict, or override the primary care clinicians’ and specialty physicians’ appropriately documented medically necessary treatment plans.