Public Comments to AMDG Interagency Guideline on Prescribing Opioids for Pain

Guideline Section	Comments	Response
General	This is a huge document, but appears well written. You have done a very nice job discussing the negative impacts of opioids on health and function as opposed to many prior guidelines looking only at abuse and misuse issues.	No change
	These are called guidelines but I think they are actual rules? I oppose the rule's part because in my opinion it has unfortunately interfered with proper medical care out of fear of regulatory interventions. The risks have been greater than generally accepted benefits…I say all this even though I agree with the reasonableness of most of the guidelines. As reasonable as the guidelines may be, I am aghast of how many people simply ignore the "fear" and unintended consequences these rules promote in an area of medicine already too fraught with fear and ignorance. There is an old dictum in medicine: Primare non nocere? While risks are inherent in the practice of medicine and any active physician always risks doing harm, do these "rules" clearly do more good than harm. I am a seasoned, well trained physician on the front lines. My opinion is that while guidelines are most helpful, these rules have done more harm than good.	No change. The AMDG *Interagency Guideline on Prescribing Opioids for Pain* is a guideline, not a rule.
	Why is that Molina and apple care will not allow for the use of deterrents with in opioids such as oxycodone hydrocodone, methadone and morphine? Currently these two insurance companies protocol is to start off with hydro and oxy and then jump to Morphine, methadone or dilaudid then they go all the way up to fentanyl. Once the pt has failed these meds we can go down. This seems very much against logic… My question to you can you help change the insurance companies policy's on abuse deterrents for opioids? Pain management is very difficult at times due to the insurance companies un wiliness to listen to providers, and seems as if they are practicing medicine and not the providers. Even with a Per to Per most of the time they will not listen. At our end we have continued with very strict pain management policy, however we cannot control human behavior good or bad. They only thing we can do is ensure that these medications will not be used other than there intended purposes.	No change. The AMDG *Guideline* does not address health plans' policies and benefits.
	I find it absolutely disgusting that in this report you indicate that 46 people die everyday from accidental overdose of these terrible pharmaceuticals yet this is the only form of treatment that is allowed. These drugs are habit forming almost 100% of the time. It is the rare person who does not become addicted to these medications when on them for any length of time. In the report I also see that you have marijuana listed as a drug of abhorrent behavior. I would challange you to find any deaths attributed to marijuana. I also suggest you look at the wonderful studies out there regarding this treatment and how it helps many patients with cronic pain and those recovering from, or going	The AMDG *Guideline* provides guidance on prescribing opioids appropriately and medical marijuana is beyond the scope of this guideline. Added, under Non-opioid Analgesics Introduction for clarification, "The use of

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	through, cancer treatments.	medical marijuana for pain is beyond the scope of this guideline."
	As both a retired oncologist and a previous Chief Medical Officer of Yuma Regional Medical Center in Arizona, I have seen the good, bad, and the ugly of prescribing opioids. For terminally ill cancer patients and acute pain, there is little controversy. YRMC had the third busiest emergency department in Arizona, and when I resigned last August to move to Seattle, our ED was in the midst of an escalating crisis of patients with non-acute, non-cancer, opioid- escalated emotional and physical turmoil. The proposed guidelines go a long way to turning such a crisis around. They are clearly well-considered, well-researched, and a compassionate approach to patients with pain. They are a major advance over the previous guidelines and, if adopted into standard practice. will result in significant benefits to patients, families, and their communities. Again, I appreciate the opportunity to comment and thank all for the good work that has been done.	No change
	I request that the comment period be extended – significantly – that would allow for adequate review, particularly by a larger range of physicians practicing in our state	The AMDG has extended the public comment period to May 18, 2015.
	I would like to request an extension of the time for public comment, and I would like to recommend that a letter be sent to all practicing physicians and physicians assistants/ARNP's advising them of the opportunity for public review and comment. Otherwise it will appear that this "public comment" was really only a sham opportunity.	The AMDG has extended the public comment period to May 18, 2015.
	Hello, as a long term chronic pain patient on opioid therapy I can tell you these laws make extreme hardships on legitimate patients that unfortunately need to rely on opioids to have some slight chance of quality of life. As it is- I am often forced to drive 75 miles round trip- just to pick up a piece of paper from my doctor to take to the pharmacy every 28 days- while I am knowingly "under the influence" of said medications. This is not acceptable! ...Why isn't there a national clearing house for such chronic patients on opioid therapy? Your efforts are valiant however the laws only effect the law abiding citizens- as criminals will always find ways around your laws. You are hurting the wrong people!	No change. The best practices in the AMDG *Guideline* are not rules. By providing clear guidance, we hope it will encourage more primary care providers to provide appropriate pain management.

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	Explicit instructions given for treatment may encourage more PCPs to treat chronic pain…There should be a longer comment period for these guidelines. I barely had a chance to read them since I only found out about them earlier this week. We need more input from pain docs to share their thoughts. I request an extension… I would like to see the State create a website that has a template for the "perfect" chart note for pain patients. This would include all the required documentation needed for each patient. These templates could be downloaded into EHR's or printed out to be used by physicians. We would all be on the same page in terms of the required information and would make it easy for FP's and other physicians, PA's, ARNP's etc to know what information they need at the first visit and at return visits. This might encourage PCP's to participate in pain management with much less fear of Board reprisals.	The AMDG has extended the public comment period to May 18, 2015. The AMDG plans to develop additional resources for both providers and patients in the future.
	I want to congratulate the amdg for a terrific job on the new guidelines. They are balanced, clearly written, evidence-based, and well supported with bibliographic references. I hope that the medical community will be widely notified regarding the new guidelines. I think it will succeed on all levels, as a training tool, working reference, and quality tool. Thank you for your efforts!	No change
	Thank you for putting together this set of comprehensive guidelines. Please implement and advocate for its utilization. This is a much needed document to minimize harms due to opiates, for physicians to do a risk benefit analysis and put safety first. Like the tools (scoring systems etc) in the guideline. Thank you!	No change
	Well-constructed guideline, clearly laid out, excellent reference for the provider prescribing or considering prescribing opioids	No change
Part I CMIF	Creating a standard whereby opioid users must attest to a 30% or greater improvement is an arbitrary and poorly defined criterion for functional improvement. Once the patients understand that they need that much improvement, they can easily game the system by claiming the required numbers of functional improvement to reach that threshold. How does one rate function on a 1-10 scale anyway. One person's 5 is another person's 8. Without specific descriptions of activities achieved (walking distance per day, daily chores completed, hours of sleep per night, etc), the numbers are meaningless. If, on the other hand, there is a standardized questionnaire rating activities i.e. Roland Morris, etc, there is a clearer basis for rating function that is universally used. Otherwise, we are comparing apples and oranges.	No change. The AMDG *Guideline* recommends the use of validated instruments to track function and pain. The PEG and Graded Chronic Pain Scale are examples of quick and easy-to-use validated tools. For transferred patients who are already using opioids, the *Guideline* recommends requesting records from previous treating provider and reassessing the need for chronic

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	Furthermore, how can one establish functional improvement in patients already stabilized on opioids when there was no initial functional rating with which to compare. I have inherited many patients who state that they have improved greatly in function with pain management, but never rated function before and after opioid initiation to establish the 30% improvement. What do I do with those many cases?	opioid therapy by tracking function and pain with validated tools, checking the PMP, checking a random UDT, monitoring for opioid-related adverse outcomes, monitoring for medication aberrant behaviors and consulting with a pain management specialist before exceeding 120 mg/day. If current treatment is not benefiting the patient, a dose reduction or discontinuation is warranted. The *Guideline* also recommends considering non-opioid options for pain treatment.
	Proposed rule that opioids only be used if there is 30% objective improvement in function is inconsistent with community experience regarding palliative use for associated mood disorders: A. Opioids were historically used to treat unipolar depression, prior to TCAs and still have an established role as a 3rd line agent, e.g. European College of Neuropsychopharmacology recommendations on buprenorphine. B. Animal models. Leit (Molecular pain, 2014) has data from the chronic formalin pain protocol showing that anhedonia manifest as decreased intracranial self stimulation responds to low-dose morphine C. Survey data: The National Fibromyalgia Association in a survey of 6000 members (in review) found that 27% of members who were abruptly discontinued from opioids, solely due to stigma associated with schedule change of hydrocodone from CIII to CII, considered suicide. D. PTSD prophylaxis: 3 studies show acute IV MS prevents subsequent PTSD E. Imaging data: The Michigan group just this week at Biological Psychiatry reported lower mu binding in SSRI resistant depression. F. Personal experience with buprenorphine. I have treated 100s of addicts. It is interesting to hear from family members that a significant portion of these patients are better on the drug in terms of functionality than they were prior to even using opioids. Certaintly not the majority, but a significant fraction nonetheless.	No change. Opioids are FDA-approved for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

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Part I Dosing Threshold	Consultations are required only from pain specialists. It would seem reasonable to me that Addiction Medicine specialists are even more qualified to assess patients for possible Opioid Use Disorders and risks for overdoses and complications. Structural diagnoses or common pain management options often do not correlate with these concerns. What training do anesthesiologists have in complex psychiatric, or substance use disorders, the high risk group needing to be identified? Anesthesiologists tend to make up the bulk of pain specialists. Why are not Diplomates of the American Academy of Pain Management recognized as Pain specialists? You are wanting to encourage non-opioid and unnecessary procedures? It would seem that AAPM provides duly qualified practitioners, perhaps even more so than the Amer. Academy of Pain Medicine, particularly given the breadth of expertise and alternatives they embrace? One cannot fairly speak of the risks of a medicine without discussing proven benefits. Higher doses of opioids are potentially life saving in patients who are opioid dependent. Patients who are opioid dependent often do best on 80-120mg/day of methadone. It is not the dose of opiates that best predicts risks but the context: patient, prescriber expertise in evaluating and managing risk factors, co-morbid conditions, and other often under appreciated cultural, financial, and medical factors. No where does one address that having Medicaid coverage is a significant risk for abuse and overdoses, despite what I think is compelling evidence. I think it is a more potent predictor than dose alone. For some of the above reasons I will continue to object to making the dose the issue. Medications or substances are villified. Rather better patient selection and management is what is indicated.	No change. The AMDG *Guideline* does not specify the qualification of a pain specialist. This has been defined in rules by the five Boards and Commissions with prescriptive authority (MDs/PAs, DO/PAs, DPMs, ARNPs, DDS). The AMDG agrees that there are other risk factors besides opioid dose and have emphasized them throughout the guideline.
	Disagree with sweeping statements with benzodiazepines. This recommendation should be vetted closely with a broad swath of psychiatry since there is no consensus on this issue in academic circles but absolute consensus in practice (60% of RX for anxiety are benzodiazepines). Guidelines are clearly discriminatory against individuals with mental illness. Happy to discuss further non-causal epidemiological associations between overdose deaths and opioid use.	No change. There is clear evidence of increased risk for overdose due to the additive effect of benzodiazepines and opioids on respiratory depression.
	There is some ambiguity regarding the benzodiazepines use policy. In one section, it says that the use of benzos and opioids together is not recommended. In another section, it states that benzos should never be used with opioids. I think that the prohibition of benzos with opioids is too restrictive. There are many chronic pain patients who have panic disorder, PTSD, and other anxiety disorders for whom benzos are the only medications that have any benefit. It is unfair to treat the pain yet allow patients to have panic attacks. I suggest that if a physician feels that the two need to be used together, that patients be asked to sign an informed consent form warning them of the dangers of	No change. There is clear evidence of increased risk for overdose due to the additive effect of benzodiazepines and opioids on respiratory depression. Specific guidance on the treatment of anxiety, PTSD and other anxiety disorders is beyond the scope of this

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	accidental OD when used together. The physician would need to document in the chart that the benefits outweigh the risks with specific description of those benefits. The physician would also include a description of what other treatments were tried and failed for anxiety management before deciding on using the two in combination. An added stipulation might be that a sleep study be done with the two medicines on board to document whether central sleep apnea is present and whether the use of CPAP or BiPAP would be adequate to reduce the risks of accidental death while asleep. We should avoid absolutes where some chronic pain patients don't demonstrate any central sleep apnea despite the use of these two medications. This approach allows the physician and patient to use the two provided there is proper consent and documentation to support their use together.	guideline.
Part I Non-opioid Options	I like the emphasis on the multi-modal, CAM alternatives that this brings. Perhaps this can bring pressure to bear on insurance companies to provide better coverage for a comprehensive approach that includes these therapies. Too often my pain patients say they cannot afford CAM therapies like massage, acupuncture, meditation, yoga classes since they don't have any or adequate coverage with their insurance. Exercise deserves emphasis, yet there is little guidance in practice except by some physical therapists. Usually this is inadequate too.	No change
	In addition to the pain conditions listed above, acupuncture has been demonstrated to be effective in treatment of shoulder pain (Vas, et al, 2008; Lathia, et al, 2009), neck pain (Irnich, et al, 2001; White, et al, 2008; Trinh, et al, 2010) headache (Coeytaux, et al, 2005, Khusid, 2015), and other chronic pain conditions (Vickers, et al, 2012).	No change. The studies are heterogeneous in their design and use of varied acupuncture techniques, limiting generalizability. Currently, there are not sufficient high quality studies to support a recommendation.
	Form stating the 4000mg/day acetaminophen "ceiling dose", which is currently being debated as being too high; to vague references to drug classes (NSAIDs and Tricyclics), without adequate discussion of the risks and contraindications, too little rigor appears to have been taken in their inclusion…to my reading, including less rigorous discussion of non-opioid options weakens the credibility of the entire guideline. Pages 13-20…are not up to the evidence based standard, and concise format, of the original guideline, and the first revision.	Clarified dosing recommendation for acetaminophen and added potential adverse outcomes for other drug classes.

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	There is not any mention of the use of neuraxial or peripheral nerve block techniques as analgesic alternatives that are known to be opioid sparing and associated with significant improvements in pain and function. There is less clear benefit in terms of preventing chronic pain and also influence on cancer recurrence.	No change. Injections and nerve blocks were not part of the review.
Part II Acute and Subacute Phase	Statement on consensus on use of opioids in fibromyalgia again in my opinion is not representative of the field. Many individuals with neurogenic pain have substantial palliative improvement in quality of life even in function is not improved.	No change. There is no evidence from randomized trials to support the use of opioids for fibromyalgia.
Part III Opioids for Peri-operative Pain	Under the clinical recommendations, point 2b. It currently reads: "There is insufficient evidence to recommend the routine use of more sophisticated currently available noninvasive methods (such as capnography) for monitoring hypoventilation postoperatively." I disagree with the above statement as I think there is support for the notion (and expanding evidence) that "smart PCA" enabled devices linked with capnography improve the early detection and prevention of respiratory depression. I recognize there is significant cost associated with such devices, but they do add some benefit particularly to higher risk patients. ''	No change. Although it may be useful in a select group of patients, there is no evidence to support *routine* use of expensive monitoring technologies.
	Systematic reviews of acupuncture treatment for postoperative pain have produced promising, but mixed results. Sun, et al (2008) concluded that acupuncture is a useful alternative for postoperative pain management.	No change. This section discusses opioid use for perioperative pain and is not a comprehensive pain management guideline.
Part IV Prescribing Opioids for Chronic Non-cancer Pain	I'd like to suggest a slightly broader set of chronic pain patients on opioids for whom providing overdose education and potentially take-home-naloxone would be appropriate: There are additional risks for those prescribed opioids besides dose, such as poor care coordination/access, and co-prescribed sedatives as well as ongoing use of alcohol.	Added, under Dose Threshold Recommendation 2, "and consider prescribing naloxone".
	We have read your new, very comprehensive guidelines and offer the following observations for your consideration: While the guidelines encourage providers to discuss safe storage of opioids at home, many newer guidelines are encouraging the use of locked safes as a prerequisite for COAT therapy. Newer opioid COAT guidelines are recommending a written contract between the patient and provider outlining patient responsibilities and expectations.	No change. The AMDG *Guideline* recognizes the importance of safe storage and recommends that providers educate their patients on the safe storage and disposal of opioids based on federal guidance. Additionally, the

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	The guidelines focus only on the legitimate pain patient. Unfortunately, many opioid prescriptions are fraudulently obtained from an unsuspecting physician. Our market research indicates many physicians look for suspected abusers based on: (1) short term knowledge of the patient, (2) pain levels not consistent with the diagnosis, and (3) patient "steering" the provider to a specific opioid. Perhaps a section on identifying these patients could be useful. Newer opioid formulations are being introduced that have some safeguards against abusing. Perhaps these types of formulations can play and expanded role in appropriate opioid prescribing. While the guidelines encourage providers to discuss safe storage of opioids at home, many newer guidelines are encouraging the use of locked safes as a prerequisite for COAT therapy.	*Guideline* recommends that providers screen using validated tools, obtain a baseline urine drug test and check the PMP before prescribing chronic opioid analgesic therapy (COAT). These tools help the providers to objectively identify risk of opioid misuse. For patients with current substance use disorder (except nicotine), the guideline does not recommend COAT.
	I am concerned by the growing amount of paperwork that is required. I suggest that the functional questions and pain questions be required no more than every three to six months provided there are no changes in status. The pain patient who is deemed "high risk" solely if he/she is on more the 120 MED should not have to be seen monthly if stable, has a low risk based on ORT results, and has shown no aberrant behaviors. This patient simply has tolerance. It is too expensive for many of these patients to come in monthly if they would be appropriate candidates for q three month visits were it not for the dose of opioids. I suggest that those taking over 120 MED and who also have at least one additional risk factor i.e. aberrant drug behaviors, abnormal UDTs, Moderate risk based on ORT, COMM, or SOAPPR scores or higher, etc be told they need to come in monthly. If they show the ability to behave appropriately and show negative findings on these tests over one year's time, they can graduate to a lower frequency of visits.	No change. The AMDG Guideline recommends that patients with aberrant behaviors, such as inconsistent UDT's should be tapered off COAT. High dose COAT, even in compliant patients, requires frequent monitoring due to risk for adverse outcomes including overdose.
Part VI Recognition and Treatment of OUD	The Washington State Agency Medical Directors' Group (AMDG) indicated in a recent draft proposal for opiate guidelines for the state of Washington (page 40) that "there is very little evidence that antagonist therapy with naltrexone is effective for patients with opioid use disorder, and there is no evidence in patients with chronic pain. However, it might be considered in selected, highly motivated patients (e.g., impaired professionals)." Please note this statement only applies to oral naltrexone as the Minozzi study referenced did not include VIVITROL (extended-release naltrexone). References submitted: • VIVITROL® (package insert). Waltham, MA: Alkermes, Inc. July 2013.	Added "oral" to the reference to naltrexone.

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	• Krupitsky E, Nunes EV, Ling W, et al. Injectable extended-release naltrexone for opioid dependence: • a double-blind, placebo-controlled, multicentre randomised trial. Lancet. 2011;377:1506-1513. • Data on file (Final Clinical Study Report ALK-21-013). Waltham, MA: Alkermes, Inc. • Krupitsky E, Nunes EV, Ling W, Gastfriend DR, Memisoglu A, Silverman BL. Injectable extended release naltrexone (XR-NTX) for opioid dependence: long-term safety and effectiveness. *Addiction*. 2013;108(9):1628-37 • Data on file (Final Clinical Study Report ALK-21-013EXT). Waltham, MA: Alkermes, Inc.	
	Acupuncture has a long history as a successful drug treatment modality (Liu, et al, 2009, Chang & Sommers, 2014), yet was not mentioned in Part VI: Recognition and Treatment of Opiate Use Disorder (p. 39).	No change. Currently, there are not sufficient high quality studies to support a recommendation.
Part VII Pregnancy and NAS	Acupuncture is a beneficial, non-pharmacological alternative for treatment of pain during pregnancy (Ee, et al, 2008), when opiates are to be avoided. Reproductive health is a certified, post-graduate specialty within acupuncture practice (ABORM).	No change. This section discusses opioid use in pregnancy and does not include other pain treatments.
Part VII Children and Adolescents	Over the past ten years, pediatricians report that acupuncture is requested by parents in conjunction with standard hospital treatment (Gilmour, et al, 2011) and hospitals have begun to integrate acupuncture into pediatric care (Children's Hospital LA, 2015). Acupuncture provides a safe, cost effective treatment for post-surgical pain in children (Ochi, 2013). Pediatrics is a specialty within acupuncture studies, with post-graduate coursework and certification.	No change. This section focuses on opioid use in chronic pain (not acute pain) and does not include other pain treatments.
Part VII Cancer Survivors	I am a provider who cares for cancer patients and I routinely work with cancer survivors. While the problems with opioids are well outlined in the proposed AMDG opioid guidelines, I believe these guidelines are too restrictive. My primary concern is that patients will be denied pain functional and seemingly safe pain care if they are implemented. I have reviewed and support the amendment submitted to you by Dr Dermot Fitzgibbon based on my direct experience with this population.	Authors for this section have reviewed the content and revised it.
Part VII Older Adults	Elderly and frail populations benefit from acupuncture for pain (Itoh, et al, 2006). A recent study found acupuncture was well accepted by seniors for treatment of chronic pain, and this study recorded beneficial side effects including improved quality of sleep and reduced anxiety (Couilliot et al, 2013).	No change. This section discusses opioid use in older adults and does not include other pain treatments.

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Appendix D – UDT	Under FAQ – Can I tell whether my patient has taken the dose of opioid(s) I prescribed? Although the provided answer to this question is technically correct, it does not address the benefits of blood testing for compliance monitoring. AIT offers blood steady state analysis in which a patient's weight, medication, dose, and dosing interval is used to calculate an expected steady-state range…	No change. This appendix is on urine drug testing.
	Under FAQ – My patient says he is a "high metabolizer" and that is why the expected drug is not found in the urine. Is this possible? Blood testing is a viable option for a patient claiming to be a "high metabolizer." Additionally, a patient who claims to be a "high metabolizer" could undergo genetic testing for known P450 mutations that affect drug metabolism…	No change. This appendix is on urine drug testing.