THE DOCTOR PATIENT FORUM

Proud supporter of the Don't Punish Pain Rally Organization

Fighting for patients and their providers thedoctorpatientforum.com

---

To: The Centers for Disease Control and Prevention (CDC)

Re: Updated/Expanded Opioid Prescribing Guidelines docket # 2022-02802

From: The Doctor Patient Forum/Don't Punish Pain Rally

We are a National Non-Profit working with pain patients and their providers. We haven't taken any money from "industry," and we don't advocate solely for access to opioids for everyone.

Our comment includes main issues with the draft and possible solutions to those problems.

MAIN COMMENTS/SUGGESTIONS:

The 2016 CDC Guidelines have caused widespread harm. Whether it was the intention of the original guidelines or a misapplication, it really doesn't matter. The fact is, as you've acknowledged, at least 33 state laws have been created based on thresholds of dosage and duration. The DEA has targeted doctors due to red flags they created, payers have created their own guidelines, pharmacies have decided not to fill scripts, risk score algorithms have been created, all based on these arbitrary and not evidence-based thresholds from the 2016 CDC Guidelines. This has led to thousands if not millions of medically abandoned pain patients. These patients not only can't find a doctor to prescribe, they can't even find a doctor at all. All of this is a result of your 2016 Opioid Guidelines. Acknowledging harm isn't enough. You guys created this crisis and you must work to fix it. Stating you're not a regulatory agency isn't helpful. You aren't a passive bystander. You must fix this or else we will have 200,000 deaths next year.

Comment #1: **What to do about medically abandoned pain patients?** The recent crisis of medically abandoned CPP's is a direct result of your 2016 Guidelines. CDC has a program called ORRP (Opioid Rapid Response Program) that is "boots on the ground" when DOJ/OIG alerts them when a doctor is being targeted and there will be many abandoned patients. This program was started due to ARPO in 2018, which means you knew there would be a problem of abandoned patients when shutting down a clinic. This sounded great to us, until we called the director of the ORRP to discuss how to access this amazing resource. We were then told last year that they only have been able work to get continuity of care for patients with OUD on Suboxone, but have had much difficulty finding any doctor to accept abandoned CPP's. If your gov't program you have set up to take care of this problem can't find doctors

to take abandoned CPP's, you obviously know that we can't find doctors for them, either. Some scenarios of causes of medically abandoned CPP's (this list isn't exhaustive):

1. A doctor is targeted by DEA or their medical board due to prescribing "outside of the CDC Guidelines."
2. Doctors dismiss patients for the following reasons:
    a. A "failed" UDT (even if it's a false negative or positive)
    b. For breach of contract (sometimes they can't go in for a random pill count because they're on vacation)
    c. For failing a pill count
    d. For reporting worsening pain
    e. For admitting to struggling with MH issues such as depression or anxiety (thanks to data analytics programs like NarxCare)
    f. For being honest about being a survivor of rape or childhood sexual abuse
3. Doctors retire due to having too much red tape to prescribe any controlled substance and fear of the DEA/Medical Board
4. Doctors dismiss CPP's for being "too complicated."
5. CPP's express concern when their doctors force-taper them to 90 or 50 MME, so the doctor dismisses them for being "non-compliant."
6. CPP has an acute pain situation and asks the doctor for more medication to cover that pain (we will address this issue later in this document)

- In most of these cases, the CPP's (or PWOUD taking Suboxone) are stopped cold-turkey from their medication. Now they are going through acute withdrawal in addition to having worsening pain. They aren't welcome to go to the ER because many won't treat CPP's. Some ER's even have signs stating this. They beg their other doctors to help, but they refuse. They call every pain management doctor they can find, and their policies are they won't take any patients from the doctor who was just targeted or who have been dismissed from another doctor, or their waiting lists are months long. Their options? Suicide, obtaining black market medication, alcohol, suffer at home. They go from being stable and present in their families' lives to losing everything. They often lose their jobs, the families, their ability to do anything, and sadly many times their lives. All in the name of "public health." Yes, we've read it said that individuals should be willing to sacrifice themselves for the good of public health, but where is the good of what you've done?

Main suggestion #1: Expand your ORRP program to include CPP's. Don't just have "boots on the ground" when DEA alerts you. Create a way to find continuity of care for ALL abandoned CPP's including

all the scenarios we listed. Possibly a hotline where medically abandoned CPP's can call, or allowing ER doctors to give several 30-day scripts until CPP can find a new doctor. This is the most pressing issue created from your 2016 guidelines, and not one government agency is addressing it other than your ORRP which is a department of 2 staff that nobody knows about. The majority of advocacy calls we get from CPP's are from those who are medically abandoned, and are in withdrawal and in severe pain from their pain condition.

Main Comment #2: Implementing the new guidelines and de-implementing the old ones.
When you were discussing the original guidelines prior to publishing them, you put a lot of energy and money into how to ensure they were implemented. You contracted Abt. Associates ($1.4 million) to create a QI Implementation Guide, gave a contract to AHRQ to created CDS (Clinical Decision Support Tools), and acknowledged the fact that legislation could be created based on them. After all, you used similar guidelines to the AMDG guidelines, even using some of the same people on your workgroups. Since AMDG guidelines were worked into legislation, you had to have known this would be a distinct possibility. One of the 2017 National Opioid Commission's main suggestion was to make sure states followed your guidelines.

Main Suggestion #2: Create a plan of how to de-implement your 2016 Guidelines and to implement the updated guidelines. Since dosage and duration thresholds were removed from the main recommendations, create a plan to ensure:

1. The removal of thresholds from CDST's created by AHRQ and used by hundreds of Electronic Health Records.
2. The Removal of thresholds from risk score algorithms used to target both doctors and patients such as NarxCare and the one OIG uses created by Qlarant.
3. Actively work with every state who has laws based on dosage or duration thresholds and ensure that those are removed.
4. Make sure you remove thresholds of dose and duration from the entire document, and not just the main guidelines. If you don't do this, nothing will change, and it will actually be worse for CPP's since 50 MME is mentioned more than 90 MME in the updated draft. There are many reasons why MME needs to be removed from the entire document. Please listen to Dr. Dasgupta's presentation explaining why MME isn't accurate. We will also upload this document to the document section along with our comment.
5. Actively work with DOJ/DEA/OIG/local medical boards/payers suggesting they remove "red flags" based on your 2016 dose and duration thresholds.

Main Comment #3: **Measure patient outcomes and the fallout of your guidelines**. In the meetings of the BSC prior to publishing the 2016 Guidelines, you mentioned that you would measure patient outcome. As far as we can tell, this hasn't happened yet. This is essential. The only metric that seems to matter to you or any other gov agency is rate of prescribing. But, as we've seen by skyrocketing deaths, lowering prescribing seems to be associated with increased deaths.

Main Suggestion #3: The following actions must be taken to properly measure the effect of the CDC Guidelines:

- Fund studies to measure patient outcome since 2016 Guidelines were implemented.

- Create an RFP for a data analytics company to measure the risk of harms when a CPP is medically abandoned or force-tapered. We already have studies showing that these patients have increased risk of harm such as suicide or Mental Health crises.

Main Comment #4: **Address COI's and violation of your own rules about how to create guidelines with integrity and without COI's**. There was tremendous secrecy and COI's in the creation of the original guidelines. Any concern that was raised prior to the Guidelines being published were discounted. Instead of actually addressing the concerns, you supported the analysis of those who raised the concerns, and stated the reason for anyone making a statement against them was due to opioid lobby. Had you actually addressed the legitimate concerns raised 7 years ago, you could have prevented so much suffering and harm. Some issues of COI's and lack of transparency are the following:

- One of your main authors (Dr. Chou) from both versions of the guidelines had tremendous COI's. These are explained in detail in the linked article. He was involved in every step of the process, which is highly concerning. He did the evidence review the guidelines were based on, he was a main author, he was in several of the workgroups, he was the expert consult for GRADE evidence rating, he was on the BSC (Fed Advisory Committee) who would approve or not approve the submitted work from the OWG (which he was also on), he did the updated evidence review, then co-authored the updated guidelines. He recused himself from the July 2021 meeting which shows he shouldn't have been an author at all to either set of guidelines. This issue has been

raised many, many times over the years and as far as I know you actually have never addressed it.

- Another one of your main authors of both sets of guidelines, Deb Dowell, had previously worked closely with PROP and Kolodny, assisting with their 2012 FDA PROP petition and working with him and others for a document that's cited as evidence for needing an MME threshold. A supporting document submitted with the PROP petition itself on the FDA docket was on NYC Health letterhead, asking for the exact requests as PROP asked for. This wasn't submitted as a document under the comment of the NYC Health, but a supporting document for the petition itself. Dowell never declared her COI, and neither did Lewis Nelson who was an expert witness in opioid litigation, was on a workgroup, and also worked with Kolodny and Dowell in NYC.

- The process you used violated your own guidelines for how to create guidelines. Please refer to the following documents (they will also be submitted to the document section of our comment):
    - CDC Guidelines: Improving the Quality (1996)
        - "The composition of guideline panels can shape the recommendations themselves. From the size of the panel to the characteristics of the members, each decision may affect the group dynamics or potential bias of the group as a whole. **The importance of an unbiased panel in creases as the strength of the scientific evidence decline**." Since there is very little evidence on which the guidelines are based, the lack of bias is crucial. Instead, you purposely included those with extreme anti opioid views on every workgoup.
    - Guidelines and Recommendations A CDC Primer (2012)
        - "Guidelines, unlike some types of policies, are not mandatory. In health care and public health, guidelines are not meant to enforce but rather to recommend programs or practices based on the best evidence available. **Often, however, CDC and others' guidelines become "the standards of practice," unintentionally acquiring the force of policy**. The adoption of a set of guidelines can affect an entire organization."
        - "Whatever the organization (for-profits, nonprofits, public health departments, or federal government agencies), guidelines provide information for decision making. Implementation of guidelines might improve organization effectiveness and efficiency."

- "Users of guidelines and recommendations need to feel confident that those participating in the development process **were not unduly influenced by personal interests**. Minimizing competing interests among members of steering committees and technical groups improves guideline acceptability, credibility, and scientific **rigor. These interests might be financial, intellectual or professional. For example, competing financial interests might include research support, stock holdings, or employment at organizations affected by the guidelines. Intellectual and professional interests might include authorship of studies or provision of expert opinion publicly or in testimony related to the guideline's topic**."
- "Each release of a new CDC guideline might have a lasting impact on clinical and public health practice. Guidelines may be converted to policy, implying widespread implementation by a broad range of groups. **Guidelines may be even converted into law, entailing subsequent regulatory enforcement**. Because of the high-profile CDC guidelines may acquire following their release, we recommend guidelines be vetted before publication. Vetting of CDC guidelines ensures that key stakeholders have the opportunity to review and provide critical input. Vetting not only assists in fostering transparency and credibility but also improves the clarity and understanding of the guidelines. Even though it may not be possible to incorporate all the feedback received, vetting of the guidelines has many benefits." (You had members of PROP and others who had clear bias on every single workgroup).
- "**Responses should be prepared for each individual who provided comments**. The writing group will typically review the comments and craft responses. Having a record of responses will demonstrate that CDC considered each comment. This documentation is especially important when requests for follow-up occur through controlled correspondence or the Freedom of Information Act. Although the vetting process might vary slightly for different guidelines, each must have a process in place. Vetting is the critical step in the CDC guidelines development process that ensures transparency and credibility"

- Ensuring the Integrity of Clinical Practice Guidelines: A Tool for Protecting Patients (2013)
  - "However, widespread financial conflicts of interest among the authors and sponsors of clinical practice guidelines **have turned many guidelines into marketing tools of industry**. Financial conflicts are pervasive, under-reported,

influential in marketing, and uncurbed over time. **Biased guidelines can cause grave harms to patients, while creating a dilemma for doctors, who may face professional or legal consequences when they choose not to follow guidelines they distrust. Such guidelines fail to place patients' needs foremost, and instead protect livelihoods and preserve ideologies."**

- "The biasing impact of financial conflicts—such as "panel stacking," which we discuss below—can be invisible to guideline readers."
- "We are concerned with two major types of financial conflicts, the most obvious of which arises when a panelist or the sponsoring organization derives material benefit—such as consulting or speaker's fees, research grant funding, stock ownership, or donations—from a commercial entity that stands to win or lose revenue on the basis of the guideline recommendation. The other type of financial conflict is a professional conflict, which arises when guideline creators are clinicians who specialize in the area under review."

- "Financially conflicted panel leadership can extend the impact of bias even to those who may not have direct financial ties to industry through a process of "committee stacking," or the selection of panelists known to support a desired outcome."
- "Guidelines can have a powerful effect on the behavior of clinicians. Highly publicized guidelines from prestigious institutions might be issued (and viewed) as clinical "rules," making some doctors reluctant to deviate from recommendations, especially in the face of professional censure or potential legal consequences for failure to adhere to a "standard of care."
- "Biased or non-evidence-based guidelines can also reduce variation, even when they should not, thus potentially causing harm because the recommended intervention is suboptimal, ineffective, dangerous, or recommended for inappropriate patients."
- "The first task of any guideline panel is to review the evidence to decide if there is an uncontested "best" answer; if not, and scientifically based controversy exists, then the panel constituency must reflect that diversity of thought. "Panel stacking" with individuals known to believe disproportionately in one school of thought, must be avoided."
- "Because content experts are generally conflicted when reviewing topics in their own specialty**, they should be consulted for content/topical issues, but should not be the authors of the systematic reviews informing recommendations nor of the guidelines themselves**."

- "If content experts with a professional conflict are involved as authors of systematic reviews or guidelines, their inclusion should be explicitly justified."
- "If the evidence does not support straightforward conclusions, pretending it does is worse than admitting uncertainty."

Main Suggestion #4:

- Due to violation of your own standards for how guidelines should be created, the guidelines should be redacted and not just updated or expanded. Your own guidelines state that if there is little scientific evidence then elimination of all bias is essential. This obviously didn't happen.
- If you refuse to redact the guidelines completely, then at the very least each member who participated in the original or updated needs to submit an updated COI/Disclosure form. The fact that many of the workgroup members were already expert witnesses in opioid litigation prior to the guidelines is a problem. Not all of them even came forward after the fact disclosing this information. We are aware of at least one person on your workgroup who was an expert witness in opioid litigation and didn't disclose that information when others did. Also, several of the workgroup members have consulting firms that contract with the DOJ or other agencies, so they directly benefit from these guidelines. There are many forms of "industry funding" that aren't taking money directly from pharma. The following COI's/disclosures need to be updated **not just from those in the workgroups but those who you personally invited to give comments (such as Gary Mendell from Shatterproof and Judy Rummler from Rummler Hope)**:
    - All expert witnesses in litigation
    - Anyone who owns or works with a consulting firm that gives advice regarding opioids
    - Any Non-Profit (not just pain advocacy orgs) that has taken money from pharma (Shatterproof), labs or treatment centers (Rummler Hope-which PROP is under).
    - Any legislator who was invited to comment that took money from law firms that directly benefit from these guidelines in opioid litigation
    - Those who took money from pharma or medical device companies that would directly benefit from these guidelines (Pacira, Medtronic)

Main comment #5: **Dosage and duration limits mentioned throughout the document**. You removed mention of 50 and 90 MME from the main guidelines but left them in the document. You did the same

thing with duration of 3, 5, or 7 days. State laws, payers, DEA red flags, hospital policies, Med Board policies all have been created based on these thresholds.

Main Suggestion #5:

- Make sure you remove thresholds of dose and duration from the entire document, and not just the main guidelines. If you don't do this, nothing will change, and it will actually be worse for CPP's since 50 MME is mentioned more than 90 MME in the updated draft.
- There are many reasons why MME needs to be removed from the entire document. Some of them are:
    - There isn't a standard way to figure MME.
    - Many other things go into risk of opioid and dose is a small part of it.
    - Metabolism of medication is different for different patients.
    - Please read our MME document here.

Main comment #6: **Address in detail how to treat acute pain in opioid dependent and tolerant patients**. The updated draft addresses acute pain, but doesn't address how to treat acute pain in a patient who is on daily opioids for either pain or OUD. The way many doctors are dealing with this is either to stop all opioids completely for CPP's when dealing with an acute pain situation, or just telling them their daily dose will be sufficient, which it isn't. Those with OUD also need acute pain treatment, and that needs to be addressed. There are guidelines that were recently published on how to address this in CPP's on daily opioid therapy, and it needs to be included. You mention opioid tolerant patient just 2 times in the document and it was only to warn against extra meds, but you didn't warn against not giving adequate pain relief.

Main suggestion #6:

- Address acute pain treatment when given to someone who is on daily opioids. Someone who doesn't have OUD, but who does have a higher tolerance due to daily medication regimen. Not treating acute pain can cause patient to break their pain contract in an attempt to self-treat pain.
- Address acute pain treatment with someone who has OUD and is on Suboxone or Methadone for maintenance. Not treating acute pain can cause relapse.

Main comment #7: **"Chronic Pain" isn't one condition and the distinction of cancer vs non-cancer pain isn't based on science or evidenc**e. Please read our document about cancer vs non-cancer pain. When FDA held a hearing about changing the labels on opioids to make the distinction of cancer vs non cancer pain, they were told the distinction doesn't exist.

Main suggestion #7:

- The exclusion of those on "palliative care" needs to be better defined and explained. Although you mention in the supporting text that the definition of palliative care you're using is "care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness," this won't be sufficient as many CPP's who qualify as palliative care patients are being denied access to palliative care. The definition needs to be added to a main guideline, and not just in the supporting text. It needs to make it clear that this includes patients with incurable painful conditions that won't necessarily cause death, and that it's not just synonymous with "hospice care/end-of-life care."
- Including the need to exclude SCD is good (since many are not being treated adequately) but exclusions for some painful conditions and not others doesn't make sense. Pain is pain and many conditions cause excruciating pain, and exclusions need to include ALL painful conditions. It doesn't mean all pain will be treated with opioids, but not listing them as an exclusion often means they will NEVER be treated with opioids, which is discriminatory. There is no way to list every possible painful condition that may require opioids, so removing the exclusions and then just expanding the palliative care definition and giving some examples would be more appropriate than just listing cancer and SCD.

Main comment #8: **Promoting Subuxone/Subutex for CPP without OUD**. Under the section titled "other challenges to tapering," you state "Emerging evidence suggests that patients for whom risks of continued high-dose opioid use outweigh benefits but who are unable to taper and who do not meet criteria for opioid use disorder might benefit from transition to buprenorphine. Buprenorphine for pain is mentioned on page explained showing suboxone or Subutex may not be covered without an OUD dx." You then discuss the Bupe products approved for pain (Butran, Belbuca) and those approved for OUD (Suboxone, Subutex). All of that is find. Then you say "Because the duration of action for analgesia is shorter than the duration of action for suppression of opioid withdrawal and stabilization of opioid use disorder (Alford, Compton, & Samet, 2006), dosing buprenorphine for pain is typically multiple times

daily (e.g., 8mg sublingual tablet three times a day) rather than once a day dosing as done for the treatment of OUD." Based on this dose, the only Bupe product it could be referring to is Suboxone or Subutex, which isn't FDA approved for pain, and either the doctor has to commit insurance fraud by falsely diagnosing patient with OUD or the patient has to pay out of pocket, neither of which is acceptable.

Main suggestion #8:

- When giving the dose recommendation for Bupe for pain, remove the example of Suboxone/Subutex dosing and specify Belbuca or Butran, or mention that Subuxone/Subutex is an off-label use for pain and patient would most likely have to pay out-of-pocket.
- Specify that patient should not be given an OUD dx if patient doesn't qualify based on DSM V criteria, and specify that dependence does not qualify a patient for OUD. Many CPP's are unknowingly labeled with OUD in their EHR so their insurance will pay for Suboxone. That follows a CPP forever and they won't even know it's in their chart.

Main comment #9: **You teach to never reverse a taper which isn't based on evidence**. Your tapering guide, which is listed on your CDC Guideline app as a supporting document, claims never to reverse a taper. You also have the same information in your training modules based on your 2016 guidelines. This contradicts guidelines and suggestions by those considered experts in tapering such as Dr. Beth Darnall. The word tapering is mentioned 102 times in this document.

Main suggestion #9:

- Remove this tapering document and make a stronger statement in the updated guidelines claiming you no longer believe this is the proper method considering it's contrary to what actual tapering experts say.
- Since you mention tapering so frequently, give proper steps clearly stating that
    - Tapering needs to be started only when patient agrees unless there is a life-threatening situation.
    - Go slowly (10% per month)
    - Make sure patient knows that they can reverse taper if it isn't going well

Main comment #10: **The guidelines are based on little to no poor-quality evidence**.

Main suggestion #10: The guidelines should be redacted, but at the very least need to stop being referred to as evidence-based guidelines. They aren't. The majority of the recommendations have very low-quality evidence, which means you depended on the opinion of those involved. The majority of those people are extremely biased.

Main comment #11: False premise based on cherry picked studies. The premise that there aren't studies showing that opioids work for pain is false. The studies used in the evidence review on which the guidelines were based were cherry picked. The Cochrane review should have been included. Also, the concept that unless a study showed 30% increase in function or 30% decrease in pain, it wasn't counted as clinically significant improvement is faulty. Your conclusion, that none of the studies you included showed clinically significant improvement due to your 30% rule is misleading.

Main suggestion #11:

- Instead of using a 30% threshold, it would be more honest and accurate to list the results in the studies. If a study showed 25% improvement, it shouldn't be stated that it didn't show clinically significant improvement. The study you used to determine the need for 30% decrease pain and 30% increase function was limited and only about low back pain and low back pain specific function. This should never be used to apply to all patient groups and all pain. It's incredibly misleading and this 30% concept needs to be removed from the guidelines.
- The Cochrane review, which you wouldn't accept as evidence as well as a recent study shows that LTOT for CNCP can work both show opioids improve pain and function. Include both of these in the "evidence review," instead you just appear to have known the outcome you wanted, and then included studies to support that outcome.