Thank you for taking the time to review this important information regarding restricting opioid prescribing.

We know your time is valuable and this issue is daunting and controversial. This packet is merely highlights of the most important documents released within the last 6 months in addition to documents for supporting evidence. Some of the source documents are hundreds of pages long, filled with valuable information. We have done our best to simply extract the most powerful and even highlighted the most critical wording in each document. There is also a link to each of the original documents for your reference.

We look forward to this being the beginning of an ongoing dialogue in order to ensure the most vulnerable members of our society are treated fairly and protected. Our only goal is to help to strike the balance where addiction/overdose risks are minimized while the unintended consequences for those who utilize these medications for function and quality of life are addressed.

AMA RESOLUTION 235
November 2018
INAPPROPRIATE USE OF CDC Guidelines FOR PRESCRIBING OPIOIDS
(Entire Document)

"Resolution 235 asks that our AMA applaud the CDC for its efforts to prevent the incidence of new cases of opioid misuse, addiction, and overdose deaths; and be it further, that no entity should use MME thresholds as anything more than guidance and that MME thresholds should not be used to completely prohibit the prescribing of, or the filling of prescriptions for, medications used in oncology care, palliative medicine care, and addiction medicine care: and be it further, that our AMA communicate with the nation's largest pharmacy chains and pharmacy benefit managers to recommend that they cease and desist with writing threatening letters to physicians and cease and desist with presenting policies, procedures and directives to retail pharmacists that include a blanket proscription against filling prescriptions for opioids that exceed certain numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care; and be it further, that AMA Policy opposing the legislating of numerical limits on medication dosage, duration of therapy, numbers of pills/tablets, etc., be reaffirmed; and be it further, that physicians should not be subject to professional discipline or loss of board certification or loss of clinical privileges simply for prescribing opioids at a quantitative level that exceeds the MME thresholds found in the CDC Guidelines; and be it further, that our AMA encourage the Federation of State Medical Boards and its member boards, medical specialty societies, and other entities to develop improved guidance on management of pain and management of potential withdrawal syndromes and other aspects of patient care for "legacy patients" who may have been treated for extended periods of time with high-dose opioid therapy for chronic non-malignant pain.

RESOLVED, that our American Medical Association (AMA) applaud the Centers for Disease Control and Prevention (CDC) for its efforts to prevent the incidence of new cases of opioid misuse, addiction, and overdose deaths

RESOLVED, that our AMA actively continue to communicate and engage with the nation's largest pharmacy chains, pharmacy benefit managers, National Association of Insurance Commissioners, Federation of State Medical Boards, and National Association of Boards of Pharmacy in opposition to communications being sent to physicians that include a blanket proscription against filing prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care.

RESOLVED, that our AMA affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate, and be it further

RESOLVED, that our AMA advocate against misapplication of the CDC Guideline for Prescribing Opioids by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients' medical access to opioid analgesia, and be it further

RESOLVED, that our AMA advocate that no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids.""

Pain Management Best Practices Inter-Agency Task Force - Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations
Official Health and Human Services Department Released December 2018

"The Comprehensive Addiction and Recovery Act (CARA) of 2016 led to the creation of the Pain Management Best Practices Inter-Agency Task Force (Task Force), whose mission is to determine whether gaps in or inconsistencies between best practices for acute and chronic pain management exist and to propose updates and recommendations to those best practices. The Task Force consists of 29 experts who have significant experience across the disciplines of pain management, patient advocacy, substance use disorders, mental health, and minority health."

In addition to identifying approximately 60 gaps in clinical best practices and the current treatment of pain in the United States, HHS PMTF provided recommendations for each of these major areas of concern. In alignment with their original charter, the PMTF will submit these recommendations to Congress to become our 'National Pain Policy'.
The 60+ gaps and inconsistencies with their recommendations will serve to fill gaps in pain treatment at both the state and federal level; and the overwhelming consensus was that the treatment of pain should be multimodal and completely individualized based on the individual patient. The heart of each recommendation in each section was a resounding call for individualization for each patient, in regards to both non-pharmacological and pharmacological modalities; including individualizations in both opioid and non-opioid pharmacological treatments.

While each of the gap+recommendation sections of what is poised to become our national pain policy is extremely important, one that stands out the most (in regards to opioid prescribing) is the ***Stigma*** section. Contained in this section is one of the core statements that shows our Health and Human Services agency - the one that should have always been looked to and followed - knew the true depth of the relationship (or lack of) between the overdose crisis and compassionate prescribing to patients with painful conditions:

"The national crisis of illicit drug use, with overdose deaths, is confused with appropriate therapy for patients who are being treated for pain. This confusion has created a stigma that contributes to raise barriers to proper access to care."

The recommendation that follows - "Identify strategies to reduce stigma in opioid use so that it is never a barrier to patients receiving appropriate treatment, with all cautions and considerations for the management of their chronic pain conditions" - illustrates an acknowledgment by the top health agency of the federal government that the current national narrative conflating and confusing compassionate treatment of pain with illicit drug use, addiction, and overdose death is incorrect and only serving to harm patients.

Since March of 2016 when the CDC Guidelines were released, advocates, patients, clinicians, stakeholders, and others, have began pointing out limitations and unintended consequences as they emerged. In order to address the unintended consequences emerging from the CDC Guidelines, this task force was also charged with review of these guidelines; from expert selection, evidence selection, creation, and continuing to current misapplication in order to provide recommendations to begin to remedy these issues.

"A commentary by Busse et al. identified several limitations to the CDC guideline related to expert selection, evidence inclusion criteria, method of evidence quality grading, support of recommendations with low-quality evidence, and instances of vague recommendations. In addition, the CDC used the criterion of a lack of clinical trials with a duration of one year or longer as lack of evidence for the clinical effectiveness of opioids, whereas Tayeb et al. found that that was true for all common medication and behavioral therapy studies.

Interpretation of the guideline, in addition to some gaps in the guideline, have led to unintended consequences, some of which are the result of misapplication or misinterpretation of the CDC guideline.

However, at least 28 states have enacted legislation related to opioid prescription limits, and many states and organizations have implemented the guideline without recognizing that the intended audience was PCPs; have used legislation for what should be medical decision making by healthcare professionals; and have applied them to all physicians, dentists, NPs, and PAs, including pain specialists.441–444 Some stakeholders have interpreted the guideline as intended to broadly reduce the amount of opioids prescribed for treating pain; some experts have noted that the guideline emphasizes the risk of opioids while minimizing the benefit of this medication class when properly managed."

"The CDC guideline was not intended to be model legislation for state legislators to enact"

"In essence, clinicians should be able to use their clinical judgment to determine opioid duration for their patients"

https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html

HHS Review of 2016 CDC Guidelines for responsible opioid prescribing

The Pain Management Task Force addressed 8 areas that are in need of *update* or *expansion* with recommendations to begin remediation for each problem area:

(1) Lack of high-quality data exists for duration of effectiveness of opioids for chronic pain; this has been interpreted as a lack of benefit
    (a) Conduct studies
    (b) Focus on patient variability and response for effectiveness of opioids; use real-world applicable trials

(2) Absence of criteria for identifying patients for whom opioids make up significant part of their pain treatment
    (a) Conduct clinical trials and/or reviews to identify sub-populations of patients where long-term opioid treatment is appropriate

(3) Wide variation in factors that affect optimal dose of opioids
    (a) Consider patient variables for opioid therapy:
        (i) Respiratory compromise
        (ii) Patient metabolic variables
        (iii) Differences in opioid medications/plasma concentrations
    (b) Preform comprehensive initial assessment it's understanding of need for comprehensive reevaluations to adjust dose
    (c) Give careful considerations to patients on opioid pain regimen with additional risk factors for OUD

(4) Specific guidelines for opioid tapering and escalation need to be further clarified
    (a) A thorough assessment of risk-benefit ratio should occur whenever tapering or escalation of dose
        (i) This should include collaboration with patient whenever possible
    (b) Develop taper or dose escalation guidelines for sub-populations that include consideration of their comorbidities
    (c) When benefit outweighs the risk, consider maintaining therapy for stable patients on long term opioid therapy

(5) Causes of worsening pain are not often recognized or considered. Non-tolerance related factors: surgery, flares, increased physical demands, or emotional distress
    (a) Avoid increase in dose for stable patient (2+ month stable dose) until patient is re-evaluated for underlying cause of elevated pain or possible OUD risk
    (b) Considerations to avoid dose escalation include:
        (i) Opioid rotation
        (ii) Non-opioid medication
        (iii) Interventional strategies
        (iv) Cognitive behavior strategies
        (v) Complementary and integrative health approaches
        (vi) Physical therapy

(6) In patients with chronic pain **AND** anxiety or spasticity, benzodiazepine co-prescribed with opioids still have clinical value; although the risk of overdose is well established
    (a) When clinically indicated, co-prescription should be managed by specialist who have knowledge, training, and experience with co-prescribing.
        (i) When co-prescribed for anxiety or SUD collaboration with mental health should be considered
    (b) Develop clinical practice guidelines focused on tapering for co-prescription of benzodiazepines and opioids

(7) The risk-benefit balance varies for individual patients. Doses >90MME may be favorable for some where doses <90MME may be for other patients due to individual patient factors. Variability in effectiveness and safety between high and low doses of opioids are not clearly defined. Clinicians should use caution with higher doses in general
    (a) Using carefully monitored trial with frequent monitoring with each dose adjustment and regular risk reassessment, physicians should individualize doses, using lowest effective opioid dose that balances benefit, risk, and adverse reactions
    (b) Many factors influence benefits and risk, therefore, guidance of dose should not be applied as strict limits. Use established and measurable goals:
        (i) Functionality
        (ii) ADL
        (iii) Quality of Life

(8) Duration of pain following acute and severely painful event is widely variable
    (a) Appropriate duration is best considered within guidelines, but is ultimately determined by treating clinician. CDC recommendation for duration should be emphasized as **guidance only** with individualized patient care as the goal
    (b) Develop acute pain management guidelines for common surgical procedures and traumas
    (c) To address variability and provide easy solution, consideration should be given to partial refill system

The Fentanyl Failure

Washington Post, March 13, 2019

In May 2016, a group of national health experts issued an urgent plea in a private letter to high-level officials in the Obama administration. Thousands of people were dying from overdoses of fentanyl — the deadliest drug to ever hit U.S. streets — and the administration needed to take immediate action. The epidemic had been escalating for three years.

The experts wrote to six administration officials, including the nation's "drug czar" and the chief of the Centers for Disease Control and Prevention.

The administration considered the request but did not act on it. (Instead focusing solely on prescribing; accurate numbers often lag 1-3 years behind; prescribing was already declining which should have triggered the search for true causation rather than assuming correlation)

The decision was one in a series of missed opportunities, oversights and half-measures by federal officials who failed to grasp how quickly fentanyl was creating another — and far more fatal — opioid epidemic.

In the span of a few short years, fentanyl, a synthetic painkiller 50 times more powerful than heroin, became the drug scourge of our time. Fentanyl has played a key role in reducing the overall life expectancy for Americans.

If current trends (and approaches) continue, the annual death toll from fentanyl will soon approach those from guns or traffic accidents. Among the dead are the anonymous and the famous, including musicians Prince and Tom Petty . It is so powerful that just a few flecks the size of grains of salt can cause rapid death.

The number of deaths, the vast majority from fentanyl, has risen sharply each year. In 2017, synthetic opioids were to blame for 28,869 out of the overall 47,600 opioid overdoses, a 46.4 percent increase over the previous year.

"This is a massive institutional failure, and I don't think people have come to grips with it," said John P. Walters, chief of the White House Office of National Drug Control Policy between 2001 and 2009. "This is like an absurd bad dream and we don't know how to intervene or how to save lives."

Federal officials saw fentanyl as an appendage to the overall opioid crisis rather than a unique threat that required its own targeted strategy. As law enforcement began cracking down in 2005 on prescription opioids such as OxyContin and Vicodin, addicts turned to heroin, which was cheaper and more available. Then, in 2013, fentanyl arrived, and overdoses and deaths soared.

“Fentanyl was killing people like we’d never seen before,” said Derek Maltz, the former agent in charge of the Drug Enforcement Administration’s Special Operations Division in Washington. “What the hell is going on? We needed a serious sense of urgency.”

But for years, Congress didn’t provide significant funding to combat fentanyl or the larger opioid epidemic. U.S. Customs and Border Protection didn’t have enough officers, properly trained dogs or sophisticated equipment to curb illegal fentanyl shipments entering the country from China and Mexico. The U.S. Postal Service didn’t require electronic monitoring of international packages, making it difficult to detect parcels containing fentanyl ordered over the Internet from China. CDC data documenting fentanyl overdoses lagged behind events on the ground by as much as a year, obscuring the real-time picture of what was happening.

“How many people had to die before Congress stood up and did the right thing with regard to telling our own Post Office you have to provide better screening?” Sen. Rob Portman (R-Ohio).

“Everybody was slow to recognize the severity of the problem, even though a lot of the warning signs were there,” said New Hampshire Gov. Chris Sununu (R).

In Sununu’s state, Narcan, which delivers an opioid-overdose antidote, has become standard issue for some school districts.

He said politicians and policymakers held numerous roundtable discussions to talk about solutions, but there was little action.

“I said, ‘If I had to go to another roundtable, I’m going to jump out the window myself because we’re going nowhere with these roundtables,’ ” he said.

What you need to know about fentanyl

Drug treatment experts compared the government’s slow response to an earlier failure to face the AIDS epidemic. (Where it took years to address the root issue instead of glossy solutions)

Barack Obama, U.S. president, January 2009-January 2017

The opioid epidemic exploded during his time in office. He didn’t focus on the rise of fentanyl until the final months of his administration. His spokeswoman said it is “impossible to divorce fentanyl from the broader opioid epidemic” and the administration took a “comprehensive approach” to the crisis. (I.e. supply sides approach, only focused on restricting prescribing)

Full article

https://www.washingtonpost.com/graphics/2019/national/fentanyl-epidemic-obama-administration/

Human Rights Watch
December 2018
(Excerpt from 109 page report)

"If harms to chronic pain patients are an unintended consequence of policies to reduce inappropriate prescribing, the government should seek to immediately minimize and measure the negative impacts of these policies. Any response should avoid further stigmatizing chronic pain patients, who are increasingly associated with — and sometimes blamed for — the overdose crisis and characterized as "drug seekers," rather than people with serious health problems that require treatment.

Top government officials, including the President, have said the country should aim for drastic cutbacks in prescribing. State legislatures encourage restrictions on prescribing through new legislation or regulations. The Drug Enforcement Administration (DEA) has investigated medical practitioners accused of overprescribing or fraudulent practice. State health agencies and insurance companies routinely warn physicians who prescribe more opioids than their peers and encourage them to reduce prescribing. Private insurance companies have imposed additional requirements for covering opioids, some state Medicaid programs have mandated tapering to lower doses for patients, and pharmacy chains are actively trying to reduce the volumes of opioids they dispense.

The medical community at large recognized that certain key steps were necessary to tackle the overdose crisis: identifying and cracking down on "pill mills" and reducing the use of opioids for less severe pain, particularly for children and adolescents. However, the urgency to tackle the overdose crisis has put pressure on physicians in other potentially negative ways: our interviews with dozens of physicians found that the atmosphere around prescribing for chronic pain had become so fraught that physicians felt they must avoid opioid analgesics even in cases when it contradicted their view of what would provide the best care for their patients. In some cases, this desire to cut back on opioid prescribing translated to doctors tapering patients off their medications without patient consent, while in others it meant that physicians would no longer accept patients who had a history of needing high-dose opioids.

The consequences to patients, according to Human Rights Watch research, have been catastrophic."

https://www.hrw.org/report/2018/12/18/not-allowed-be-compassionate/chronic-pain-overdose-crisis-and-unintended-harms-us

Opioid Prescribing Workgroup

December 2018

This is material from the **Board of Scientific Counselors** in regards to their December 12, 2018 meeting that culminated the works of a project titled the "Opioid Prescribing Estimates Project."
This project is a descriptive study that is examining opioid prescribing patterns at a population level. Pain management is a very individualized process that belongs with the patient and provider.
The Workgroup reviewed work done by CDC and provided additional recommendations.

SUMMARY
There were several recurrent themes throughout the sessions.

Repeated concern was voiced from many Workgroup members that the CDC may not be able to prevent conclusions from this research (i.e. the benchmarks, developed from limited data) from being used by states or payors or clinical care systems to constrain clinical care or as pay-for- performance standards – i.e. interpreted as "guidelines". This issue was raised by several members on each of the four calls, raising the possibility that providers or clinical systems could thus be incentivized against caring for patients requiring above average amounts of opioid medication.

Risk for misuse of the analysis. Several members expressed concerns that this analysis could be interpreted as guidance by regulators, health plans, or clinical care systems. Even though the CDC does not plan to issue this as a guideline, but instead as research, payors and clinical care systems searching for ways to reign in opioid prescribing may utilize CDC "benchmarks" to establish pay-for-performance or other means to limit opioid prescribing. Such uses of this work could have the unintended effect of incentivizing providers against caring for patients reliant upon opioids.

…It was also noted that, in order to obtain sufficient granularity to establish the need for, dosage, and duration of opioid therapy, it would be necessary to have much more extensive electronic medical record data. In addition, pain and functional outcomes are absent from the dataset, but were felt to be important when considering risk and benefit of opioids.

...*Tapering*: Concerns about benchmarks and the implications for tapering were voiced. If tapering occurs, guidance was felt to be needed regarding how, when, in whom tapering should occur. This issue was felt to be particularly challenging for patients on chronic opioids (i.e. "legacy" patients). In addition, the importance of measuring risk and benefit of tapering was noted. Not all high-dose patient populations benefit from tapering.

Post-Surgical Pain

General comments. Workgroup members noted that most patients prescribed opioids do not experience adverse events, including use disorder. Many suggested that further discussion of opioids with patients prior to surgery was important, with an emphasis on expectations and duration of treatment. A member suggested that take-back programs would be more effective than prescribing restrictions.

Procedure-related care. Members noted that patient factors may drive opioid need more than characteristics of a procedure.

Patient-level factors. Members noted that opioid-experienced patients should be considered differently from opioid-inexperienced patients, due to tolerance.

Chronic Pain

It was noted that anything coming out of the CDC might be considered as guidelines and that this misinterpretation can be difficult to counter. There was extensive discussion of the 50 and 90 MME levels included in the CDC Guidelines. It was recommended that the CDC look into the adverse effects of opioid tapering and discontinuation, such as illicit opioid use, acute care utilization, dropping out of care, and suicide. It was also noted that there are major gaps in guidelines for legacy patients, patients with multiple diagnoses, pediatric and geriatric patients, and patients transitioning to lower doses.

There were concerns that insufficient clinical data will be available from the dataset to appropriately consider the individual-level factors that weigh into determination of opioid therapy. The data would also fail to account for the shared decision-making process involved in opioid prescribing for chronic pain conditions, which may be dependent on primary care providers as well as ancillary care providers (e.g. physical therapists, psychologists, etc).

Patient-level factors. Members repeatedly noted that opioid-experienced patients should be considered differently from opioid-experienced patients, due to tolerance.

Members noted that the current CDC guidelines have been used by states, insurance companies, and some clinical care systems in ways that were not intended by the CDC, resulting in cases of and the perception of patient abandonment.
One option raised in this context was to exclude patients on high doses of opioids, as those individuals would be qualitatively different from others. A variant of this concern was about management of “legacy” patients who are inherited on high doses of opioids.
Members voiced concerns that results of this work has caused harm to patients currently reliant upon opioids prescribed by their providers.

Acute Non-Surgical Pain

Patient-level factors. Members felt that opioid naïve versus experienced patients might again be considered separately, as opioid requirements among those experienced could vary widely.

...Guidelines were also noted to be often based on consensus, which may be incorrect.

Cancer-Related and Palliative Care Pain

It was noted that the CDC guidelines have been misinterpreted to create a limit to the dose of opioids that can be provided to people at all stages of cancer and its treatment. It was also noted that the cancer field is rapidly evolving, with immunotherapy, CAR-T, and other novel treatments that affect response rates and limit our ability to rely upon historical data in establishing opioid prescribing benchmarks.

Concern that data would not be able to identify all of the conditions responsible for pain in a patient with a history of cancer (e.g. people who survive cancer but with severe residual pain). Further, it was noted that certain complications of cancer and cancer treatment may require the least restrictive long-term therapy with opioids.

The definition of palliative care was also complicated and it was suggested that this include patients with life-limiting conditions.

Overall, it was felt that in patients who may not have long to live, and/or for whom returning to work is not a possibility, higher doses of opioids may be warranted.

https://www.cdc.gov/injury/pdfs/bsc/NCIPC_BSC_OpioidPrescribingEstimatesWorkgroupReport_December-12_2018-508.pdf

CDC Scientists Anonymous
'Spider Letter' to CDC

Carmen S. Villar,
MSW Chief of Staff
Office of the Director MS D-14
Centers for Disease Control and Prevention (CDC)

August 29, 2016

Dear Ms. Villar:

We are a group of scientists at CDC that are very concerned about the current state of ethics at our agency. It appears that our mission is being influenced and shaped by outside parties and rogue interests. It seems that our mission and Congressional intent for our agency is being circumvented by some of our leaders. What concerns us most, is that it is becoming the norm and not the rare exception. Some senior management officials at CDC are clearly aware and even condone these behaviors. Others see it and turn the other way. Some staff are intimidated and pressed to do things they know are not right. We have representatives from across the agency that witness this unacceptable behavior. It occurs at all levels and in all of our respective units. These questionable and unethical practices threaten to undermine our credibility and reputation as a trusted leader in public health. We would like to see high ethical standards and thoughtful, responsible management restored at CDC. We are asking that you do your part to help clean up this house!

It is puzzling to read about transgressions in national media outlets like USA Today, The Huffington Post and The Hill. It is equally puzzling that nothing has changed here at CDC as a result. It's business as usual. The litany of issues detailed over the summer are of particular concern:

Recently, the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) has been implicated in a "cover up" of inaccurate screening data for the Wise Woman (WW) Program. There was a coordinated effort by that Center to "bury" the fact that screening numbers for the WW program were misrepresented in documents sent to Congress; screening numbers for 2014 and 2015 did not meet expectations despite a multi-million dollar investment; and definitions were changed and data "cooked" to make the results look better than they were. Data were clearly manipulated in irregular ways. An "internal review" that involved staff across CDC occurred and its findings were essentially suppressed so media and/or Congressional staff would not become aware of the problems. Now that both the media and Congresswoman DeLauro are aware of these issues, CDC staff have gone out of their way to delay FOIAs and obstruct any inquiry. Shouldn't NCCDPHP come clean and stop playing games? Would the ethical thing be to answer the questions fully and honestly. The public should know the true results of what they paid for, shouldn't they?

Another troubling issue at the NCCDPHP are the adventures of Drs. Barbara Bowman and Michael Pratt (also detailed in national media outlets). Both seemed to have irregular (if not questionable) relationships with Coca-Cola and ILSI representatives. Neither of these relationships were necessary (or appropriate) to uphold our mission. Neither organization added any value to the good work and science already underway at CDC. In fact, these ties have now called into question and undermined CDC's work. A cloud has been cast over the ethical and excellent work of scientists due to this wanton behavior. Was cultivating these relationships worth dragging CDC through the mud? Did Drs. Bowman and Pratt have permission to pursue these relationships from their supervisor Dr. Ursula Bauer? Did they seek and receive approval of these outside activities? CDC has a process by which such things should be vetted and reported in an ethics review, tracking and approval system (EPATS). Furthermore, did they disclose these conflicts of interest on their yearly OGE 450 filing. Is there an approved HHS 520, HHS 521 or "Request for Official Duty Activities Involving an Outside Organization" approved by Dr. Bauer or her Deputy Director Ms. Dana Shelton? An August 28, 2016 item in The Hill details these issues and others related to Dr. Pratt.

It appears to us that something very strange is going on with Dr. Pratt. He is an active duty Commissioned Corps Officer in the USPHS, yet he was "assigned to" Emory University for a quite some time. How and under what authority was this done? Did Emory University pay his salary under the terms of an IPA? Did he seek and receive an outside activity approval through EPATS and work at Emory on Annual Leave? Formal supervisor endorsement and approval (from Dr. Bauer or Ms. Shelton) is required whether done as an official duty or outside activity.

If deemed official, did he file a "Request for Official Duty Activities Involving an Outside Organization" in EPATS? Apparently Dr. Pratt's position at Emory University has ended and he has accepted another position at the University of California - San Diego? Again, how is this possible while he is still an active duty USPHS Officer. Did he retire and leave government service? Is UCSD paying for his time via an IPA? Does he have an outside activity approval to do this? Will this be done during duty hours? It is rumored that Dr. Pratt will occupy this position while on Annual Leave? Really? Will Dr. Pratt be spending time in Atlanta when not on Annual Leave? Will he make an appearance at NCCDPHP (where he hasn't been seen for months). Most staff do not enjoy such unique positions supported and approved by a Center Director (Dr. Bauer). Dr. Pratt has scored a sweet deal (not available to most other scientists at CDC). Concerns about these two positions and others were recently described in The Huffington Post and The Hill. His behavior and that of management surrounding this is very troubling.

Finally, most of the scientists at CDC operate with the utmost integrity and ethics. However, this "climate of disregard" puts many of us in difficult positions. We are often directed to do things we know are not right. For example, Congress has made it very clear that domestic funding for NCCDPHP (and other CIOs) should be used for domestic work and that the bulk of NCCDPHP funding should be allocated to program (not research). If this is the case, why then is NCCDPHP taking domestic staff resources away from domestic priorities to work on global

health issues? Why in FY17 is NCCDPHP diverting money away from program priorities that directly benefit the public to support an expensive research FOA that may not yield anything that benefits the public? These actions do not serve the public well. Why is nothing being done to address these problems? Why has the CDC OD turned a blind eye to these things. The lack of respect for science and scientists that support CDC's legacy is astonishing.

Please do the right thing. Please be an agent of change.

Respectfully,

CDC Spider
(CDC Scientists Preserving Integrity, Diligence and Ethics in Research)

https://usrtk.org/wp-content/uploads/2016/10/CDC_SPIDER_Letter-1.pdf

January 13, 2016

Thomas Frieden, MD, MPH
Director
Centers for Disease Control and Prevention 1600 Clifton Road
Atlanta, GA 30329-4027

Re: Docket No. CDC-2015-0112; Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

Dear Dr. Frieden:

There is no question that there is an opioid misuse epidemic and that efforts need to be made to control it. The Centers for Disease Control and Prevention (CDC) is applauded for its steps to undertake this lofty effort. However, based on the American Academy of Family Physicians' (AAFP's) review of the guideline, it is apparent that the presented recommendations are not graded at a level consistent with currently available evidence. The AAFP certainly wants to promote safe and appropriate prescribing of opioids; however, we recommend that the CDC still adhere to the rigorous standards for reliable and trustworthy guidelines set forth by the Institute of Medicine (IOM). The AAFP believes that giving a strong recommendation derived from generalizations based on consensus expert opinion does not adhere to evidence-based standards for developing clinical guideline recommendations.

The AAFP's specific concerns with the CDC's methodology, evidence base, and recommendations are outlined below.

Methodology and Evidence Base

- All of the recommendations are based on low or very low quality evidence, yet all but one are Category A (or strong) recommendations. The guideline states that in the GRADE methodology "a particular quality of evidence does not necessarily imply a particular strength of recommendation." While this is true, it applies when benefits significantly outweigh harms (or vice versa). When there is insufficient evidence to determine the benefits and harms of a recommendation, that determination should not be made.

- When evaluating the benefits of opioids, the evidence review only included studies with outcomes of at least one year. However, studies with shorter intervals were allowed for analysis of the benefits of nonopioid treatments. The guideline states that no evidence shows long-term benefit of opioid use (because there are few studies), yet the guideline reports "extensive evidence" of potential harms, even though these studies were of low quality. The accompanying text also states "extensive evidence" of the benefits of non-opioid treatments, yet this evidence was from shorter term studies, was part of the contextual review rather than the clinical systematic review, and did not compare non- opioid treatments to opioids.

- The patient voice and preferences were not explicitly included in the guideline. This raises concerns about the patient-centeredness of the guideline.

https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/risk/LT-CDC-OpioidGuideline011516.pdf

The Myth of Morphine Equivalent Daily Dosage
Medscape Neuro Perspective

For far too many years, pain researchers and clinicians have relied on the concept of the morphine equivalent daily dosage (MEDD), or some variant of it, as a means of comparing the "relative corresponding quantity" of the numerous opioid molecules that are important tools in the treatment of chronic pain.

...And, most unfortunately, opioid prescribing guideline committees have relied on this concept as a means of placing (usually arbitrary) limits on the levels of opioids that a physician or other clinician should be allowed to prescribe. Although these guidelines typically bill themselves as "voluntary," their chilling effect on prescribers and adaptation into state laws[2] makes calling them "voluntary" disingenuous.

Although some scientists and clinicians have been questioning the conceptual validity of MEDD for several years, a recent study[3] has indicated that the concept is unequivocally flawed—thereby invalidating its use empirically and as a tool in prescribing guideline development.

The authors used survey data from pharmacists, physicians, nurse practitioners, and physician assistants to estimate daily morphine equivalents and found great inconsistency in their conversions of hydrocodone, fentanyl transdermal patches, methadone, oxycodone, and hydromorphone—illustrating the potential for dramatic under-dosing or, in other cases, fatal overdosing.

Patients with chronic pain (particularly that of non-cancer origin) who are reliant on opioid analgesia are already sufficiently stigmatized and marginalized[7] to allow this type of practice to continue to be the norm.

Although the use of MEDD in research and, to a greater extent, in practice, is probably due to unawareness of its inaccuracy, we posit that the use of MEDD by recent opioid guideline committees (eg, the Washington State Opioid Guideline Committee[8] and the Centers for Disease Control and Prevention Guideline Committee[9]) in the drafting of their guidelines is based more heavily on disregarding available evidence rather than ignorance. Furthermore, their misconduct in doing so has been more pernicious than the use of MEDD by researchers and individual clinicians, because these guidelines widely affect society as a whole as well as individual patients with persistent pain syndromes. We opine that these committees are strongly dominated by the antiopioid community, whose agenda is to essentially restrict opioid access—irrespective of the lack of data indicating that opioids cannot be a useful tool in the comprehensive treatment of carefully selected and closely monitored patients with chronic pain.

Above 100% extracted from:
Medscape Journal Brief
https://www.medscape.com/viewarticle/863477_2

Actual Study
https://www.dovepress.com/the-medd-myth-the-impact-of-pseudoscience-on-pain-research-and-prescri-peer-reviewed-article-JPR

Are Non-Opioid Medications Superior in Treatment of Pain than Opioid Pain Medicine?
Ice Cream Flavor Analogy...

In the Oxford University Press, a November 2018 scientific white paper was released that examined the quality of one of the primary studies that have been used to justify the urgent call to drastically reduce opioid pain medication prescribing while claiming that patients are not being harmed in the process.

The study is commonly referred to as 'the Krebs study'. "The authors concluded that treatment with opioids was not superior to treatment with non opioid medications for improving pain-related function over 12 months."

Here is an excerpt from the first paragraph of the *design section* (usually behind a paywall) from the Krebs study that gives the first hint of the bias that led to them to 'prove' that opioids were not effective for chronic pain:

"The study was intended to assess long-term outcomes of opioids compared with non opioid medications for chronic pain. The patient selection, though, specifically excluded patients on long-term opioid therapy."

Here is an analogy given in the Oxford Journal white paper to illustrate how the study design was compromised:

If I want to do a randomized control study about ice cream flavor preferences (choices being: vanilla, chocolate, or no preference), the results could be manipulated as follows based on these scenarios:

Scenario A: If a study was done that included only current ice-cream consumers, the outcome would certainly be vanilla or chocolate, because of course they have tried it and know which they like.

Scenario B: If a study was done that included all consumers of all food, then it can change the outcome. If the majority of study participants do not even eat ice-cream, than the result would certainly be 'no preference'. If the majority do eat ice-cream it would likely be 'chocolate'. Although this study is wider based, it still does not reflect real world findings.

Scenario C: In an even more extreme example, if this same study is conducted excluding anyone who has ever ate ice-cream at all, then the conclusion will again be 'no preference' and the entire study/original question becomes so ludicrous that there is no useful information to be extracted from this study and one would logically question why this type of study would even be conducted (although we know the answer to that)

Scenario C above is how the study that has been used to shift the attitudes towards the treatment of pain in our nation's medical community was designed. “One has to look deep into the study to find that they began with 9403 possible patients and excluded 3836 of them just because they had opioids in their EMR. In the JAMA article, they do not state these obvious biases and instead begin the explanation of participants stating they started with 4485 patients and excluded 224 who were opioid or benzo users.” That is the tip of the iceberg to how it is extremely misleading.

The Oxford white paper goes into further detail of the studies “many flaws and biases (including the narrow focus on conditions that are historically known to respond poorly to opioid medication management of pain)”, but the study design and participant selection criteria is enough to discredit this entire body of work. Based on study design alone, regardless of what happened next, the result would be that opioids are no more effective than NSAIDs and other non-opioid alternatives.

Here is the link to the actual review of this now heavily citied study:
https://academic.oup.com/painmedicine/advance-article/doi/10.1093/pm/pny234/5193809

The DEA Is Fostering a Bounty Hunter Culture in its Drug Diversion Investigators[8]

A Good Man Speaks Truth to Power
January 2019

Because I write and speak widely on public health issues and the so-called "opioid crisis", people frequently send me references to others' work. One of the more startling articles I've seen lately was published November 20, 2018 in Pharmacy Times. It is titled "Should We Believe Patients With Pain?"[9]. The unlikely author is Commander John Burke, "a 40-year veteran of law enforcement, the past president of the National Association of Drug Diversion Investigators, and the president and cofounder of the International Health Facility Diversion Association."

The last paragraph of Commander Burke's article is worth repeating here.

"Let's get back to dealing with each person claiming to be in legitimate pain and believe them until we have solid evidence that they are scamming the system. If they are, then let's pursue them through vigorous prosecution, but let's not punish the majority of people receiving opioids who are legitimate patients with pain."

This seems a remarkable insight from anyone in law enforcement — especially from one who has expressed this view in both Pain News Network, and Dr Lynn Webster's video "The Painful Truth". Recognizing Commander Burke's unique perspective, I followed up by phone to ask several related questions. He has granted permission to publish my paraphrases of his answers here.

"Are there any available source documents which establish widely accepted standards for what comprises "over-prescription?" as viewed by diversion investigators?"
Burke's answer was a resounding "NO". Each State and Federal Agency that investigates doctors for potentially illegal or inappropriate opioid prescribing is pretty much making up their own standards as they go. Some make reference to the 2016 CDC Guidelines, but others do not.

2. "Thousands of individual doctors have left pain management practice in recent years due to fears they may be investigated, sanctioned, and lose their licenses if they continue to treat patients with opioid pain relievers.. Are DEA and State authorities really pursuing the worst "bad actors", or is something else going on?

Burke's answer: "Regulatory policy varies greatly between jurisdictions. But a hidden factor may be contributing significantly to the aggressiveness of Federal investigators. Federal Agencies may grant financial bonuses to their in-house diversion investigators, based on the volume of fines collected from doctors, nurse practitioners, PAs and others whom they investigate.

"No law enforcement agency at any level should be rewarded with monetary gain and/or promotion due to their work efforts or successes. This practice has always worried me with Federal investigators and is unheard of at the local or state levels of enforcement."

Commander Burke's revelation hit me like a thunder-clap. It would explain many of the complaints I have heard from doctors who have been "investigated" or prosecuted. It's a well known principle that when we subsidize a behavior, we get more of it. Financial rewards to investigators must inevitably foster a "bounty hunter" mentality in some. It seems at least plausible that such bonuses might lead DEA regulators to focus on "low hanging fruit" among doctors who may not be able to defend themselves without being ruined financially. The practice is at the very least unethical. Arguably it can be corrupting.

I also inquired concerning a third issue:

3. I read complaints from doctors that they have been pursued on trumped-up grounds, coerced and denied appropriate legal defense by confiscation of their assets – which are then added to Agency funds for further actions against other doctors. Investigations are also commonly announced prominently, even before indictments are obtained – a step that seems calculated to destroy the doctor's practice, regardless of legal outcomes. Some reports indicate that DEA or State authorities have threatened employees with prosecution if they do not confirm improper practices by the doctor. Do you believe such practices are common?"

Burke's answer: "I hear the same reports you do – and the irony is that such tactics are unnecessary. Lacking an accepted standard for over-prescribing, the gross volume of a doctor's prescriptions or the dose levels prescribed to their patients can be poor indicators of professional misbehavior. Investigators should instead be looking into the totality of the case, which can include patient reports of poor doctor oversight, overdose-related hospital admissions, and patterns of overdose related deaths that may be linked to a "cocktail" of illicit prescribing. Especially important can be information gleaned from confidential informants – with independent verification – prior patients, and pharmacy information."

No formal legal prosecution should ever proceed from the testimony of only one witness — even one as well informed as Commander John Burke. But it seems to me that it is high time for the US Senate Judiciary Committee to invite the testimony of others in open public hearings, concerning the practice of possible bounty hunting among Federal investigators.

https://internationalpain.org/a-good-man-speaks-truth-to-power/red-lawhern/

C50 Patient, Civil Rights Attorney, Maine Department of Health, and Maine Legislature Collaborative Enacted Definition of Palliative Care

One suggestion that our organization would like to make is altering the definition of “palliative care” in such a manner that it can include high-impact or intractable patients; those who are not dying this year, but our lives have been shattered and/or shortened by our diseases and for whom Quality of Life should be the focus. Many of our conditions may not SIGNIFICANTLY shorten my life, therefore I could legitimately be facing 30-40 years of severe pain with little relief; that is no way to live and therefore the concern is a rapidly increasing suicide rate.

This is a definition that one of our coalition members with a civil rights attorney and the Maine Department of Health agreed upon and legislators enacted into statues in Maine. This was in response to a 100mme restriction. This attorney had prepared a lawsuit based on the Americans with Disability Act that the Department of Health in Maine agreed was valid; litigation was never the goal, it was always patient-centered care.

A. "Palliative care" means patient-centered and family-focused medical care that optimizes quality of life by anticipating, preventing and treating suffering caused by a medical illness or a physical injury or condition that substantially affects a patient's quality of life, including, but not limited to, addressing physical, emotional, social and spiritual needs; facilitating patient autonomy and choice of care; providing access to information; discussing the patient's goals for treatment and treatment options, including, when appropriate, hospice care; and managing pain and symptoms comprehensively. Palliative care does not always include a requirement for hospice care or attention to spiritual needs.
B. "Serious illness" means a medical illness or physical injury or condition that substantially affects quality of life for more than a short period of time. "Serious illness" includes, but is not limited to, Alzheimer's disease and related dementias, lung disease, cancer, heart, renal or liver failure and chronic, unremitting or intractable pain such as neuropathic pain.

Here is the link to the most recent update, including these definitions within the entire statute: https://legislature.maine.gov/statutes/22/title22sec1726.html?fbclid=IwAR0dhlwEh56VgZI9HYczdjdyYoJGpMdA9TuuJLlQrO3AsSljIZZG0RICFZc

January 23, 2019

Dear Pharmacists,

The Board of Pharmacy has had an influx of communication concerning patients not able to get controlled substance prescriptions filled for various reasons, even when signs of forgery or fraudulence were not presented.
As a result of the increased “refusals to fill,” the board is issuing the following guidance and reminders regarding the practice of pharmacy and dispensing of controlled substances:

1. Pharmacists must use reasonable knowledge, skill, and professional judgment when evaluating whether to fill a prescription. Extreme caution should be used when deciding not to fill a prescription. A patient who suddenly discontinues a chronic medication may experience negative health consequences;

2. Part of being a licensed healthcare professional is that you put the patient first. This means that if a pharmacist has any concern regarding a prescription, they should attempt to have a professional conversation with the practitioner to resolve those concerns and not simply refuse the prescription. Being a healthcare professional also means that you use your medication expertise during that dialogue in offering advice on potential alternatives, changes in the prescription strength, directions etc. Simply refusing to fill a prescription without trying to resolve the concern may call into question the knowledge, skill or judgment of the pharmacist and may be deemed unprofessional conduct;

3. Controlled substance prescriptions are not a “bartering” mechanism. In other words, a pharmacist should not tell a patient that they have refused to fill a prescription and then explain that if they go to a pain specialist to get the same prescription then they will reconsider filling it. Again, this may call into question the knowledge, skill or judgment of the pharmacist;

4. Yes, there is an opioid crisis. However, this should in no way alter our professional approach to treatment of patients in end-of-life or palliative care situations. Again, the fundamentals of using our professional judgment, skill and knowledge of treatments plays an integral role in who we are as professionals. Refusing to fill prescriptions for these patients without a solid medical reason may call into question whether the pharmacist is informed of current professional practice in the treatment of these medical cases.

5. If a prescription is refused, there should be sound professional reasons for doing so. Each patient is a unique medical case and should be treated independently as such. Making blanket decisions regarding dispensing of controlled substances may call into question the motivation of the pharmacist and how they are using their knowledge, skill or judgment to best serve the public.

As a professional reminder, failing to practice pharmacy using reasonable knowledge, skill, competence, and safety for the public may result in disciplinary actions under Alaska statute and regulation. These laws are:

AS 08.80.261 DISCIPLINARY ACTIONS

(a)The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable, …

> (7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of
>
> > (A) professional incompetence;
> > (B) failure to keep informed of or use current professional theories or practices; or (E) other factors determined by the board;
>
> (14) engaged in unprofessional conduct, as defined in regulations of the board.

12 AAC 52.920 DISCIPLINARY GUIDELINES

> (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075; …
>
> > (15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;
>
> (b) The board will, in its discretion, revoke a license if the licensee …
>
> > (4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;
> > (5) is professionally incompetent if the incompetence results in a significant risk of injury to a patient.
>
> (c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee ...
>
> > (2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.

We all acknowledge that Alaska is in the midst of an opioid crisis. While there are published guidelines and literature to assist all healthcare professionals in up to date approaches and recommendations for medical treatments per diagnosis, **do not confuse guidelines with law**; they are not the same thing.

Pharmacists have an obligation and responsibility under Title 21 Code of Federal Regulations 1306.04(a), and a pharmacist may use professional judgment to refuse filling a prescription. However, how an individual pharmacist approaches that particular situation is unique and can be complex. The Board of Pharmacy does not recommend refusing prescriptions without first trying to resolve your concerns with the prescribing practitioner as the primary member of the healthcare team. Patients may also serve as a basic source of information to understand some aspects of their treatment; do not rule them out in your dialogue.

If in doubt, we always recommend partnering with the prescribing practitioner. We are all licensed healthcare professionals and have a duty to use our knowledge, skill, and judgment to improve patient outcomes and keep them safe.

Professionally,

_____

Richard Holt, BS Pharm, PharmD, MBA
Chair, Alaska Board of Pharmacy

https://www.commerce.alaska.gov/web/portals/5/pub/pha_ControlledSubstanceDispensing_2019.01.pdf

FDA in Brief:
FDA finalizes new policy to encourage widespread innovation and development of new buprenorphine treatments for opioid use disorder

February 6, 2018

Media Inquiries
Michael Felberbaum
240-402-9548

“The opioid crisis has had a tragic impact on individuals, families, and communities throughout the country. We’re in urgent need of new and better treatment options for opioid use disorder. The guidance we’re finalizing today is one of the many steps we’re taking to help advance the development of new treatments for opioid use disorder, and promote novel formulations or delivery mechanisms of existing drugs to better tailor available medicines to individuals’ needs,” said FDA Commissioner Scott Gottlieb, M.D. “Our goal is to advance the development of new and better ways of treating opioid use disorder to help more Americans access successful treatments. Unfortunately, far too few people who are addicted to opioids are offered an adequate chance for treatment that uses medications. In part, this is because private insurance coverage for treatment with medications is often inadequate. Even among those who can access some sort of treatment, it’s often prohibitively difficult to access FDA-approved addiction medications. While states are adopting better coverage owing to new legislation and resources, among public insurance plans there are still a number of states that are not covering all three FDA-approved addiction medications. To support more widespread adoption of medication-assisted treatment, the FDA will also continue to take steps to address the unfortunate stigma that’s sometimes associated with use of these products. It’s part of the FDA’s public health mandate to promote appropriate use of therapies.

Misunderstanding around these products, even among some in the medical and addiction fields, enables stigma to attach to their use. These views can serve to keep patients who are seeking treatment from reaching their goal. That stigma reflects a perspective some have that a patient is still suffering from addiction even when they’re in full recovery, just because they require medication to treat their illness. This owes to a key misunderstanding of the difference between a physical dependence and an addiction. Because of the biology of the human body, everyone who uses a meaningful dose of opioids for a modest length of time develops a physical dependence. This means that there are withdrawal symptoms after the use stops.

A physical dependence to an opioid drug is very different than being addicted to such a medication. Addiction requires the continued use of opioids despite harmful consequences on someone's life. Addiction involves a psychological preoccupation to obtain and use opioids above and beyond a physical dependence.

But someone who is physically dependent on opioids as a result of the treatment of pain but who is not craving the drugs is not addicted.

The same principle applies to replacement therapy used to treat opioid addiction. Someone who requires long-term treatment for opioid addiction with medications, including those that are partial or complete opioid agonists and can create a physical dependence, isn't addicted to those medications. With the right treatments coupled to psychosocial support, recovery from opioid addiction is possible. The FDA remains committed to using all of our tools and authorities to help those currently addicted to opioids, while taking steps to prevent new cases of addiction."

Above is the full statement, find full statement with options for study requests:
https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm630847.htm

Maryland's co-prescribing new laws/ amendments regarding benzos and opioids

Chapter 215

AN ACT concerning
Health Care Providers – Opioid and Benzodiazepine Prescriptions – Discussion of Information Benefits and Risks

FOR the purpose of requiring that certain patients be advised of the benefits and risks associated with the prescription of certain opioids, and benzodiazepines under certain circumstances, providing that a violation of this Act is grounds for disciplinary action by a certain health occupations board; and generally relating to advice regarding benefits and risks associated with opioids and benzodiazepines that are controlled dangerous substances.

Section 1–223

Article – Health Occupations
Section 4–315(a)(35), 8–316(a)(36), 14–404(a)(43), and 16–311(a)(8)
SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
That the Laws of Maryland read as follows:
Article – Health Occupations
(a) In this section, "controlled dangerous substance" has the meaning stated in § 5–101 of the Criminal Law Article.

Ch. 215

2018 LAWS OF MARYLAND
(B) On treatment for pain, a health care provider, based on the clinical judgment of the health care provider, shall prescribe:
(1) The lowest effective dose of an opioid; and
(2)A quantity that is no greater than the quantity needed for the expected duration of pain severe enough to require an opioid that is a controlled dangerous substance unless the opioid is prescribed to treat:
(a.) A substance–related disorder;
(b.) Pain associated with a cancer diagnosis;
(c.) Pain experienced while the patient is receiving end–of–life, hospice, or palliative care services; or
(d.) Chronic pain

(C.) The dosage, quantity, and duration of an opioid prescribed under [subsection (b)] of this [section] shall be based on an evidence–based clinical guideline for prescribing controlled dangerous substances that is appropriate for:

(1.) The health care service delivery setting for the patient;

(2.) The type of health care services required by the patient;

(3.) and The age and health status of the patient.

(D) (1) WHEN A PATIENT IS PRESCRIBED AN OPIOID UNDER SUBSECTION (B) OF THIS SECTION, THE PATIENT SHALL BE ADVISED OF THE BENEFITS AND RISKS ASSOCIATED WITH THE OPIOID.

(2) WHEN A PATIENT IS CO–PRESCRIBED A BENZODIAZEPINE WITH AN OPIOID THAT IS PRESCRIBED UNDER SUBSECTION (B) OF THIS SECTION, THE PATIENT SHALL BE ADVISED OF THE BENEFITS AND RISKS ASSOCIATED WITH THE BENZODIAZEPINE AND THE CO–PRESCRIPTION OF THE BENZODIAZEPINE.

(E) A violation of [subsection (b) OR (D) of] this section is grounds for disciplinary action by the health occupations board that regulates the health care provider who commits the violation.

4-315

(a) Subject to the hearing provisions of § 4–318 of this subtitle, the Board may deny a general license to practice dentistry, a limited license to practice dentistry, or a teacher's license to practice dentistry to any applicant, reprimand any licensed dentist, place any licensed dentist on probation, or suspend or revoke the license of any licensed dentist, if the applicant or licensee:

(35) Fails to comply with § 1–223 of this article.

8–316.

(a) Subject to the hearing provisions of § 8–317 of this subtitle, the Board may deny a license or grant a license, including a license subject to a reprimand, probation, or suspension, to any applicant, reprimand any licensee, place any licensee on probation, or suspend or revoke the license of a licensee if the applicant or licensee:

(36) Fails to comply with § 1–223 of this article.

14–404.

(a) Subject to the hearing provisions of § 14–405 of this subtitle, a disciplinary panel, on the affirmative vote of a majority of the quorum of the disciplinary panel, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:

(43) Fails to comply with § 1–223 of this article.

16–311.

(a) Subject to the hearing provisions of § 16–313 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license or a limited license to any applicant, reprimand any licensee or holder of a limited license, impose an administrative monetary penalty not exceeding $50,000 on any licensee or holder of a limited license, place any licensee or holder of a limited license on probation, or suspend or revoke a license or a limited license if the applicant, licensee, or holder:

(8) Prescribes or distributes a controlled dangerous substance to any other person in violation of the law, including in violation of § 1–223 of this article;

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2018.

Approved by the Governor, April 24, 2018.

https://legiscan.com/MD/text/HB653/id/1788719/Maryland-2018-HB653-Chaptered.pdf