Office of Attorney General
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The Honorable Rochelle Walensky
Director
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Submitted via https://www.regulations.gov

Re: Comments by the States of West Virginia, Arkansas, Indiana, Kansas, Mississippi, Nebraska, South Carolina, South Dakota, and Utah, the Commonwealth of Kentucky, and the Commonwealth of Virginia, on the request for comment entitled *Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids* (Docket No. CDC-2022-0024)

Dear Director Walensky:

The undersigned States submit these comments on the Centers for Disease Control and Prevention's Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids, 87 Fed. Reg. 7,838 (Feb. 10, 2022) (Proposed Guidelines). We write principally to urge the CDC to keep the danger from potential diversion of opioids top of mind when revising these Guidelines. The Proposed Guidelines do not seem to do so.

Prescription drug abuse is an epidemic in West Virginia and the other undersigned States. In 2021, over 1,400 West Virginians fatally overdosed, and opioids accounted for about 1,200 of those deaths. *See* NAT'L CTR. FOR HEALTH STAT., CTRS. FOR DISEASE CONTROL AND PREVENTION, PROVISIONAL DRUG OVERDOSE DEATH COUNTS (Mar. 6, 2022), https://bit.ly/3qZwEoV. Meanwhile, drug overdoses across the nation are skyrocketing, too. From April 2020 to April 2021, roughly 100,300 people died from drug overdose in the United States, an increase of 28.5 percent from the year before. *See* Press Release, Ctrs. for Disease Control and Prevention, Drug Overdose Deaths in the U.S. Top 100,000 Annually (Nov. 17, 2021), https://bit.ly/3LABLnb. Here again, opioids accounted for a staggering 75,673—more than 75%—of these deaths.

These statistics are as shocking as they are tragic. They make it clear that the opioid crisis is far from over. Any prescribing guidelines must be made with a keen awareness of this terrible reality.

One of the main sources fueling the opioid epidemic is the ready availability of controlled substances from legal sources. Diverted drugs—drugs manufactured and sold legally but that make it into the hands of users without legitimate prescriptions—factor into a substantial percentage of opioid deaths and instances of abuse. For example, in West Virginia diverted drugs played a role in roughly one-third of all fatal drug overdoses involving state residents in 2016. *See* W. VA. DEP'T OF HEALTH & HUM. RES., 2016 WEST VIRGINIA OVERDOSE FATALITY ANALYSIS 4 (Dec. 20, 2017), https://bit.ly/2EDdHU4. The same study found similar results in Tennessee as well. *Id.* Nationwide, five million Americans reported having recently abused opioids during the same timeframe. Of these five million, 71 percent obtained their drugs through diversion, not legitimate prescriptions. *See* Maureen V. Hill et al., *Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures*, 265 ANNALS OF SURGERY 709, 709 (2017). Thus, prescribing guidelines must look beyond care of the individual patient. They must also consider how prescribing practices would ameliorate or exacerbate the problems stemming from more pervasive opioid use.

DISCUSSION

The States take seriously their role in mitigating and responding to the opioid crisis in our communities. And overall, many of the CDC's practice guidelines reflect reasonable medical judgments about opioid use that reflect a serious approach on the CDC's part, too. Still, we believe that the Proposed Guidelines are insufficient to prevent abuse and diversion. Diversion is a major problem in many States, and any guidelines must meaningfully address this issue. As is, the Proposed Guidelines underplay the seriousness of diversion and do not go far enough to prevent it.

The Proposed Guidelines understate the risk of abuse. For instance, the Proposed Guidelines say that "in 2019, 9.7 million [people 12 and older] reported misuse of prescription opioids in the past year." Proposed Guidelines at 13. They note this figure is a decrease from 2015. Based on this self-reported data, the CDC reasons that "[t]he prevalence of prescription opioid misuse and opioid use disorder has … declined in recent years." *Id.* The use of a self-report survey to determine the prevalence of opioids' harm is unjustified. It ignores the on-the-ground conditions in some States, where the horrific circumstances of the opioid crisis are not only continuing but also escalating. Even if the CDC believes that opioid abuse is decreasing in some places, it is not in others.

Additionally, though the Proposed Guidelines agree that "[o]pioids should not be considered first-line or routine therapy," they also say this concept means only that prescribers have to believe that "expected benefits … should be weighed against risks before initiating" opioid treatment. Proposed Guidelines at 85. This position is insufficient. Opioids should not be a first-line treatment—full stop. That commitment becomes meaningless if it can be evaded through an

illusory risk assessment, as prescribers face too many variables to accurately make this calculation.[1]

And the Proposed Guidelines fail to adequately address the issue of diversion of opioids. In over 200 pages, the Proposed Guidelines contain only three short discussions of diversion. *See* Proposed Guidelines at 10, 117-18, 141. This passing-shot approach is unacceptable. Perhaps the CDC does not appreciate the continuing scale of the problem. Perhaps it is seeking to avoid criticism from persons who considered the 2016 Guidelines too aggressive. *See, e.g.*, Andrew Joseph, *In a Victory for Pain Experts, CDC Tones Down Its Prescribing Guidelines*, STAT (Feb. 10, 2022), https://bit.ly/3NyAFKn. But neither concern justifies an unwillingness to engage with this serious issue.

Diversion must remain a key consideration of any prescribing guideline. Deaths are rising higher than ever. Although drug dealers and unethical physicians are responsible for much of the opioid diversion nationwide, legitimate prescriptions remain a prime source of diversion, too. Diverted opioids most commonly reach drug abusers through friends and family members who filled a legitimate prescription. In fact, more than half of prescription opioid abusers report that they obtained drugs "from a friend or relative for free." *See* RACHEL N. LIPARI & ARTHUR HUGHES, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., HOW PEOPLE OBTAIN THE PRESCRIPTION PAIN RELIEVERS THEY MISUSE (Jan. 12, 2017), https://bit.ly/3NLJQHx. Another 15 percent either buy or steal drugs from their friends or relatives. This trend is not isolated to one-time or infrequent abuse. *Id.* Family and friends are a common source of narcotics for even habitual opioid abusers. *Id.*

The Proposed Guidelines overlook diversion in key places. For instance, recommendation 10 says "clinicians should consider toxicology testing to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances." Proposed Guidelines at 139. The Proposed Guidelines elaborate that this testing should assess the "risk for overdose." *Id.* at 140. Identifying high levels of opioid use that might lead to overdose is certainly a good reason to do toxicology testing—but prescribers should not merely "consider" doing these tests. Toxicology tests should be done routinely for patients with long-term opioid prescriptions, *both* to prevent overdose *and* to identify patients who are not taking their prescribed opioids and may be diverting them instead. In fact, the CDC itself agrees that these tests "might in some cases indicate diversion" when a patient is not taking their prescribed opioids. *Id.* at 141.

As the CDC also acknowledges, "[t]oxicology screening can be performed" at "a relatively inexpensive" cost. Proposed Guidelines at 140. We therefore see no reason for refusing to

[1] Prescribers should use a tiered approach for prescribing opioids for pain that specifically evaluates the possible non-opioid alternatives. They should discuss the value and effectiveness of these alternatives with patients and outline other appropriate care pathways. Patients may be unaware of these alternatives or simply want a "quick fix" without fully considering the consequences. The CDC's own research found evidence that, at least in some contexts, various non-opioid—and even non-pharmacological—treatments are linked to improvements in pain. *See* Proposed Guidelines at 62. By going through other options and holistically evaluating them for their fit with the patient, a prescriber may realize that opioids are unnecessary when a standardized "risk assessment" might find otherwise.

recommend this non-invasive diagnostic as standard practice to prescribers, given that the test will both protect the patient and others. The given reasons that toxicology screenings might lead to "stigmatization," encourage "inappropriate termination from care," or be "misinterpreted" are unsatisfactory—again, if not everywhere, at least for some regions and communities at the opioid crisis's epicenter. *Id.* at 141.

First, what stigma would the patient face? Diagnostic results are private information. The only people who would know that the test is performed are the patient and the prescriber. The prescriber is already familiar with the patient's prescriptions, so this process would not reveal any new information—unless, of course, the patient had lied or not followed the prescriber's directions. In this case, this information is even more important for the safety of that patient and others at potential risk of harm from drug diversion.

Second, the CDC presents no reason to suspect this approach would lead to "inappropriate termination from care." Proposed Guidelines at 141. Prescribers should not be forced to give opioids to patients who either abuse them or don't use—and perhaps divert—them. Again, the CDC is more concerned with imagined harms than with the real and growing danger of diversion and opioid abuse.

Third, the idea that prescribers might "misinterpret" the results is also a poor defense. Why would the CDC promulgate guidelines that presuppose the inadequacy of the very professionals they seek to regulate? The answer is clear: They wouldn't. The Proposed Guidelines themselves say that prescribers "should understand how to interpret results" for toxicology screenings. Proposed Guidelines at 140. So there is no reason to say that screenings should not be used based on the idea that prescribers *can't* interpret the results. Including the recommendation to "consider" using the screenings shows that the CDC knows they have value. The agency should take diversion seriously enough to recommend the screenings as standard practice.

The CDC also does not directly address the major issue of over-prescription of opioids, which in turn enables diversion. Indeed, the amount of opioids prescribed in recent years has been excessive and far beyond the amount necessary to support legitimate medical need.[2] And over-

[2] For example, many studies show that opioids are commonly dispensed in excessive quantities after surgeries and hospital stays. A 2017 University of Michigan study, for example, analyzed post-surgery opioid use among 89 hysterectomy patients. This study showed that, on average, patients consumed less than half of the hydrocodone pills they were prescribed—leaving a surplus equivalent to 22 hydrocodone tablets per patient. *See* Sawsan As-Sanie, MD, MPH et al., *Opioid Prescribing Patterns, Patient Use, and Postoperative Pain After Hysterectomy for Benign Indications*, 130 OBSTETRICS & GYNECOLOGY 1261, 1264 (2017). Even with this habitual underuse of prescribed pain medication, 97 percent of the women in the study reported adequate pain control, and 40 percent believed they received more opioids than necessary. *Id.* In other words, the study supported a conclusion that opioids are prescribed at levels well beyond the patients' actual medical needs. Extrapolating this data out across the roughly 600,000 hysterectomy procedures each year, an average of 22 surplus pills means that this one surgery may correspond to the equivalent of 13 million medically unnecessary hydrocodone pills prescribed each year. *See* Beata Mostafavi, *Study: Patients Use Only About Half of Opioids Prescribed After Hysterectomy*, UNIV. MICH. HEALTH (Dec. 4, 2017, 7:00 AM), https://bit.ly/3LstO3w.

Similar patterns of over-prescription have been observed across a wide range of other procedures as well—mastectomies, cholecystectomies, hernia repairs, and others. Hill et al., at 710. Examples abound. A survey of 210

prescription allows legitimate prescriptions to fall into the hands of patients' family and friends. Yet the Proposed Guidelines say only that prescribers should give the "lowest effective dosage." They do not make it clear that this restraint should also include the duration of the prescription (that is, the number of pills given). Nor do they specifically mention the dangers of diversion from overprescribing. This silence is an unjustified step back from the 2016 Guidelines, which explicitly recommended time limits on opioid use for the treatment of acute pain. *See* Deborah Dowell, MD, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 MMWR RECOMM. REP. 1 (2016), https://bit.ly/3uNqedu.

It does not appear that the CDC evaluated the many studies concerning over-prescription and its role in diversion in its Proposed Guidelines. This lack of empirical analysis is a missed opportunity to enhance these guidelines and work to prevent diversion. While the States acknowledge the limitations in creating nationwide estimates based on studies like these, this difficulty does not excuse inaction. At a minimum, the CDC should examine the available data and more specifically recommend that prescribers be wary of overprescribing and the dangers of diversion. *See, e.g.*, Jessica Bresler & Michael S. Sinha, *The Other Three Waves: Re-Assessing the Impact of Industry-Prescriber Relations on the Opioid Crisis*, 41 J. LEGAL MED. 47, 68 (2021) (collecting studies demonstrating over-prescription and concluding that "[u]pdating [opioid] prescribing guidelines would be a good initial step toward reducing the overall supply and availability of prescription opioids").

Prescribing guidelines, of course, are only one part of a comprehensive approach to battling opioid diversion and abuse. In West Virginia, for example, the State has its own prescribing guidelines, but the West Virginia Attorney General's Office has further paired those with dispensing guidelines for pharmacists to create a "Best Practices Toolkit." Alongside public outreach and educational initiatives, the Toolkit helps everyone involved with opioids make conscientious decisions about their use. But while prescribing guidelines work best when paired

urologic surgery patients revealed that two-thirds of patients received medically unnecessary opioids—and over 90% of them saved their extra pills. Cory Bates et al., *Overprescription of Postoperative Narcotics: A Look at Postoperative Pain Medication Delivery, Consumption and Disposal in Urological Practice*, 185 J. UROLOGY 551, 551 (2011). A study of 250 upper-extremity surgery patients showed that most patients received a prescription for 30 opioid pills, but 77% took less than half that amount, and 45% took only five pills or less. Jeffery Rodgers et al, *Opioid Consumption Following Outpatient Upper Extremity Surgery*, 37 J. HAND SURGERY AM. 645, 645 (2012). A survey tracking 343 children who were discharged from a hospital with an opioid prescription discovered that the patients never took 58% of the prescribed doses, yet only 4% of the excess medication was disposed of properly. C.L. Monitto et al., *Opioid Prescribing for the Treatment of Acute Pain in Children upon Hospital Discharge*, 125 ANESTHESIA & ANALGESIA 2113, 2113 (2017).

Finally, another University of Michigan study revealed that gallbladder removal patients were generally prescribed 250 milligrams of opioid pain medication, or about 50 pills, but only used the equivalent of 6 pills. This study also highlights the important ways this data can be put into practice to reduce prescription amounts: The University's academic medical center reported that the average prescription after gallbladder removal surgery dropped by two-thirds after this study—and importantly, "requests for opioid refills didn't increase" after that change. Ryan Howard et al., *Reduction in Opioid Prescribing Through Evidence-Based Prescribing Guidelines*, 153 JAMA SURG. 285, 285 (2018). To the contrary, patients who received the smaller prescriptions took even fewer pills than the patients in the study, yet reported *the same level* of pain control. *Id.*

with other efforts, they nevertheless remain, as some of us said six years ago, an important and "strong framework for providers." *See Comment Letter from Attorneys General re: Proposed Guideline for Prescribing Opioids for Chronic Pain*, Docket No. CDC-2015-0112 (Jan. 13, 2016). We therefore encourage the CDC to continue to make abuse avoidance a centerpiece of the 2022 Guidelines.

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We certainly do not fault the substance of the Proposed Guidelines in their entirety.

- The Proposed Guidelines say that prescribers should use state prescription drug monitoring programs (PDMP) in their practices. *See* Proposed Guidelines at 135. The undersigned States agree with this comprehensive approach to using PDMP data. PDMPs help to address concerns about diversion and the overall severity of the opioid crisis. Prescribers can gain a great deal of useful information from such databases, and their role in safe opioid prescribing cannot be overstated. By reviewing this information from the outset and frequently afterward, prescribers are able to ensure that a patient's controlled substance history is consistent with his or her current prescribing record and treatment. And because the opioid crisis affects people of all kinds, we agree wholeheartedly that prescribers should consult PDMPs across the board and not "differentially based on assumptions about what they will learn about different patients." *Id.* at 136.

- Likewise, we do appreciate and agree with the CDC's position that prescribers should give only the "lowest effective dosage of immediate-release opioids" and for "no longer than needed." Proposed Guidelines at 4. We hope that the CDC means what it says here and that "lowest effective dosage" is taken seriously. For the reasons discussed above, we hope the recommendation is interpreted to include the physical quantity of opioids prescribed as well.

- Lastly, we agree with the CDC's continuing efforts to remind prescribers and others that these Guidelines are recommendations, not national standards of care. *See*, *e.g.*, Proposed Guidelines at 12; *see also*, *e.g.*, Kurt Kroenke et al., *Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report*, 20 PAIN MED. 724, 726 (2019) ("The guideline[,] … at times, has been implemented without flexibility, perhaps without full awareness of the guideline's precise content and intent."). As the Federation of State Medical Boards has acknowledged, "successful implementation of state medical board pain policy varies among jurisdictions." FED'N OF STATE MED. BDS. OF THE U.S., INC., MODEL POLICY FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN (May 2004), https://bit.ly/3LysbRE. Especially given that the Proposed Guidelines would remove caps on appropriate dosage and prescription lengths, the hardest hit communities must continue to have discretion to take approaches that more aggressively resist opioid abuse. *See*, *e.g.*, James G. Hodge, Jr., et al., *From Opioids to Marijuana: Out of the Tunnel and into the Fog*, 67 U. KAN. L. REV. 879, 887 (2019) ("Multiple states [have] overhauled their opioid prescribing guidelines and capped supplies for first-time prescriptions.").

We appreciate the opportunity to provide input as the CDC considers how best to fulfill its responsibilities to ensure that these guidelines meet the needs of the American people. Ultimately, the opioid crisis remains one of the preeminent tragedies facing our country today. So we look forward to the CDC's continued attention to the issues raised in these comments, and we welcome further opportunities to discuss the ways our States are responding—on the community level—to the realities of opioid abuse.

Sincerely,

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