Governors Discover One??Size??Fits??All Regs Can Be a Straitjacket. Same's True with Pain Prescription Limits.

By Jeffrey Singer — April 1, 2020

Last week Arizona Governor Doug Ducey exercised his best judgment, aiming to expand the scope of the health care workforce during the COVID-19 public health emergency. And yet health care practitioners lack the same ability, based upon their knowledge and their patients’ circumstances, to use their best judgment when treating pain.

On March 23 Arizona Governor Doug Ducey sent a letter [1] to Seema Verma, Administrator of the Centers for Medicare and Medicaid Services, informing her the state was opting out of Medicare regulations that require Certified Registered Nurse Anesthetists to be supervised by a physician. This is aimed at expanding the scope of the health care workforce during the COVID-19 public health emergency. The following day the governor issued an executive order to that effect, causing Arizona to join 17 other states that allow CRNAs to practice independently. This was made possible by a 2001 Bush Administration rule that made the supervision requirement optional [2], deferring to the judgment of the states and their state licensing boards.

As the governor of a state, Ducey exercised his best judgment, based upon the knowledge available to him as well as the specific needs and characteristics of his particular state, to determine the risks and benefits of the action. And yet health care practitioners lack the same
ability, based upon their knowledge and their patients’ circumstances, to use their best judgment when treating pain.

The 2016 guidelines [3] for the treatment of acute and chronic pain issued by the Centers for Disease Control and Prevention, like Medicare’s CRNA regulation, were always meant to be optional. In fact, in its opening section, the guidelines state:

- Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient’s clinical situation, functioning, and life context.

The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care (emphasis added).

That didn’t stop governors and state legislatures from enacting strict restrictions [4] on opioid prescribing by health care practitioners. The majority of states have statutory limits on the dosage and quantity of opioids a provider can prescribe to a patient in pain. Some states direct or authorize state entities to set these limits instead of spelling them out in the law.

These constraints were enacted despite major criticism [5] from medical professionals and the American Medical Association that the CDC guidelines lack [6] a strong basis in the evidence. In late 2018, then??Commissioner Scott Gottlieb of the Food and Drug Administration announced plans [7] to consult the National Academy of Science, Engineering and Medicine to develop evidence based guidelines for the treatment of pain. In April 2019 the CDC issued a clarification [8] of the 2016 guidelines, claiming these guidelines were misinterpreted and misapplied, and two of the guidelines’ authors wrote in the New England Journal of Medicine [9]:

- We need better evidence in order to evaluate the benefits and harms of clinical decisions regarding opioid prescribing, including when and how to reduce high-dose opioids in patients receiving them long term. The CDC developed the guideline on the basis of the best available evidence, with input from a multidisciplinary group that included experts in pain management as well as representatives of patients and the public. In situations for which the evidence is limited, it is particularly important not to extend implementation beyond the guideline’s statements and intent. And yet in some cases, the guideline has been misimplemented in this way.

In May 2019 the Department of Health and Human Services released a report [10] from its Pain Management Best Practices Interagency Task Force. The report stated in its Executive Summary:

- The Task Force recognizes the utility of the 2016 Guideline for Prescribing Opioids for Chronic Pain released by the CDC and its contribution to mitigating unnecessary opioid exposure and the adverse outcomes associated with opioids. It also recognizes unintended consequences that have resulted following the release of the guidelines in 2016, which are due in part to misapplication or misinterpretation of the guideline, including forced tapers and patient abandonment.
Among its conclusions:

- **An emphasis on an individualized, patient-centered approach for diagnosis and treatment of pain is essential to establishing a therapeutic alliance between patient and clinician…** The choice of medication should be based on the pain diagnosis, the mechanisms of pain, and related co-morbidities following a thorough history, physical exam, other relevant diagnostic procedures and a risk-benefit assessment that demonstrates that the benefits of a medication outweigh the risks (emphasis in the original).

Nevertheless, state-based restrictions remain in place, straitjacketing health care practitioners who want to relieve their patients’ pain.

The COVID-19 pandemic provides many lessons for policymakers. Many lessons reveal how complicated, inflexible, one-size-fits-all regulations stifle swift and effective responses to changing circumstances. As the federal government temporarily relaxes numerous regulations in response to the public health crisis, state and local policymakers are using their newfound freedom to make risk-benefit decisions that fit their specific needs.

Hopefully this experience will cause state leaders to free clinicians to exercise their best judgment in treating their patients in pain once again.

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**Links**

[3] https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm