

April 25, 2018

Senator Lamar Alexander  
Chairman  
Committee on Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

Dear Chairman Alexander:

**Our organization is writing to you regarding the Opioid Crisis Response Act of 2018 (S. 2680), which was marked up yesterday. On pages 2-3, I detail just some of our concerns regarding the original bill, as the marked-up bill is not yet available, and likely parts or most remain.**

But first, a few comments to start. Although there are Americans dying from opioids, the government (Congress, the U.S. Senate and the administration) often does not provide the best solution for these kinds of difficult situations. Too often, the government “solutions” are sweeping, not targeted, leaving innocent bystanders to suffer the consequences.

One of the consequences is a severe shortage of opioid medications for the sick and injured who are deprived of relief for their pain. As Jeffrey Singer, M.D., at the Cato Institute writes,

A recent story by Pauline Bartolone in the Los Angeles Times draws attention to some under-reported civilian casualties in the government’s war on opioids: hospitalized patients in severe pain, in need of painkillers. Hospitals across the country are facing shortages of injectable morphine, fentanyl, and Dilaudid (hydromorphone). As a result, trauma patients, post-surgical patients, and hospitalized cancer patients frequently go undertreated for excruciating pain.

Dr. Singer points out that this “crisis” is not an opioid crisis, per se. It’s a “fentanyl and heroin overdose crisis” which has not been helped by the DEA’s 25 percent reduction in 2017 and the 20 percent of reduction in 2018 of national opioid manufacturing quotas. Congress fails “to recognize that the deaths are the result of nonmedical users accessing dangerous and potentially tainted drugs in a black market caused by drug prohibition.” How many patients went to the street when opioids were not available?

Thus, while it may be tempting to pass legislation as a response to the “opioid crisis”—perhaps to give the appearance that the U.S. Senate and Congress are doing something—the passage of such legislation may be worse for Americans than ending drug shortages, encouraging simple physician education, and letting the situation solve itself over time—rather than building a costly and intrusive bureaucracy that will be difficult to shut down.

### **CCHF CONCERNS INCLUDE:**

- ETHICS - Research to develop “opioid sparing” methods may or may not be ethical, and we see no informed, written patient consent requirement for this activity. (14-15)
- WHERE IS CONSENT FOR DATA-SHARING? Comprehensive Opioid Recovery Centers must operate an interoperable health information system (34.4 - 34.6) and report data including health outcomes of the population of individuals who received services from the Center and “any other information that the secretary may require.” (35.4 - 35.24)
- HUGE TAXPAYER COST - \$1.5 billion (7), \$180 million (21), \$50 million (36), up to \$600 million (75), \$300 million (96), \$125 million (101), \$2.91 billion (116), plus \$200 million (131), \$269 million (149), PLUS an unknown “such sums as may be necessary” x 9.
- IMPROPERLY PRESCRIPTIVE - In the “alternatives to opioids” grants section, the grantees allow government to impose requirements on the practice of medicine and hospital operations (that will likely impact ALL patients)—and requires sharing of patient data with the government. This is not the proper business of government or Congress.
- BIG GOVERNMENT - Creates enormous new government grant program (economic and workforce impacts) in Sec. 407 to provide \$500,000 to \$5 million in grants/year to partnerships that serve certain individuals. How intrusive will partnerships be to try to identify all these individuals (e.g. “an individual who voluntarily confirms that the individual, or a friend or family member of the individual, has a history of opioid abuse or another substance use disorder” (63.4 – 63.8) Is there *fully-informed* consent?
- FALSE LIMITS - It limits the definition of “treatment provider” to a those who accept health insurance, which these patients may not use for privacy reasons. (52.7 – 52.16)
- BIG BROTHER - Development of monitoring systems for government reporting, including the use of electronic medical records. (93.3 – 93.11)
- DETAILED REPORTING – Funded states must report data “disaggregated by geographic location, economic status, and major racial and ethnic groups.” (93.12 – 94.12)
- ULTERIOR MOTIVE? Study on prescribing limits could lead to even more prescriptive government “solutions” and greater intrusions on private decisions. (104.18 – 106.2)

- TRACKING CITIZENS - See Sec. 392A “Enhanced Controlled Substance Overdoses Data Collection, Analysis, and Dissemination.” (111.1 – 113.23) For example “working to enable and encourage the access, exchange, and use of data.” (111.22 – 112.19)
- SURVEILLANCE OF PRESCRIPTION USE/PRESCRIBING - Embedding government surveillance (Prescription Drug Monitoring Program) into EHRs (118.13 - 118.22) to “prevent overdoses” through Sec. 392B despite significant overdoses arising from *non-medical use* of opioids, including fentanyl and heroin. The bill includes:
  - i. Encouraging all users to register and use the program (114.1 – 114.3)
  - ii. Real time access and access to any data updates (114.4 – 114.6)
  - iii. Notification mechanisms for potential misuse or abuse and detection of inappropriate prescribing practices (114.7 – 114.11)
  - iv. Encouraging PMP data to be used to create reports (114.12 – 114.24)
  - v. Integrating PMP into health information technology (115.1 – 115.5)
  - vi. Encouraging data-sharing with PMPs in other states (115.10 – 115.12)
  - vii. CDC can do research on substance abuse (115.22 – 115.25)
- UNCLEAR - It is unclear whether truly informed consent is required before displaying opioid misuse prominently in record. Can patient remove display later? (120.1 – 122.8)
- EVISCERATION OF PRIVACY - A plan to advance disclosure of substance abuse treatment without patient consent - a violation of current protective CFR 42, Part 2 (122.9 – 125.2)
- FAMILY SURVEILLANCE BASED ON PREGNANCY AND “TRAUMA” RISK - Massive collection and sharing of private data on parents who are pregnant or have a new baby (125.8 – 128.7), and on families with children who have or may in the future experience “trauma” in their life (131.8 - 149). Trauma is not defined.
- VIOLATED TWICE - First the trauma (if indeed there was “trauma”) and then the federal tracking system. The creation of a massive “Trauma Informed Care” Task Force of federal officials or appointees of 29 agencies/departments to build the surveillance system and a “national strategy” on data-sharing (135.14 – 135.21)
- UNCONSTITUTIONAL - Universal trauma screenings for students (142.11 – 142.17)

Thus, we do not support this proposal to tax Americans and embed the federal government further into the exam room and private medical decisions. Thank you for your consideration.

Sincerely,



Twila Brase, RN, PHN  
President and Co-founder