A BILL TO DETER DEPARTURE OF PROVIDERS FROM PAIN MANAGEMENT

Date: July 2019

Be it enacted by the Senate and House of Representatives of the United States of America in Congress Assembled.

SEC. 1.
Title: Deterring Departure of Providers From Pain Management Act

SEC. 2.
Explanation of terminology:

(a) Medical provider means any physician, physician assistant, nurse, nurse practitioner, pharmacist or other medical practitioner licensed at any time since January 1, 2010, to prescribe or dispense Scheduled opioid medications.

(b) Chronic, non-cancer pain means “pain lasting longer than 90 days that is not associated with active cancer or outcomes of the treatment of cancer.”

(c) Acute pain means “pain of duration less than 90 days, attending injury or disease assessed by a licensed healthcare provider to be temporary in nature, including pain attendant to surgery or other medical interventions.

(d) Non-terminal means “not assessed by a licensed healthcare provider as likely to result in death of the patient.”

(e) Medically established need means “any measure or program of patient therapy developed by a healthcare provider who is licensed to prescribe Scheduled opioid medications.”

(f) AMA means American Medical Association.

(g) CDC means the US Centers for Disease Control and Prevention and subsidiary Centers and organizations.

(h) FDA means US Food and Drug Administration and subsidiary Centers and organizations

(i) VHA means the US Veterans Health Administration

(j) HHS/CMS means the US Department of Health and Human Services, Centers for Medicare and Medicaid Services and subsidiary Centers and

organizations

(k) NIH means US National Institutes of Health and subsidiary organizations

(l) Opioid means a class of drugs that are pharmaceutical-grade medicines available legally by prescription and used for control of pain. This Bill does not apply to nor is it intended to modify, any law concerning illegal, drugs such as heroin or illegally manufactured or imported synthetic opioids such as fentanyl.

(m) MMED means “Morphine Milligram Equivalent Dose”, an estimate of the pharmacological strength of drugs in the class of opioids, relative to morphine.

(n) Legacy patient means “any patient who has been treated previously by a licensed healthcare provider in a therapy plan that includes any medication or medications among the class of opioids.”

SEC. 3.
Purpose of this Bill: To deter the departures of providers from pain management practice by amending and redirecting Federal policy and regulation pertaining to prescribing opioid medications to patients with acute or chronic pain, as applied by CDC, FDA, NIH, and HHS/CMS.

SEC. 4.
No additional funding is required for this Bill. Enforcement and administration of this Bill will not be modified.

SEC. 5.
Enactment Date: 30 days following signature by the President.

WHEREAS: The US CDC issued a Guideline in March 2016 for prescription of opioids to adults with chronic non-cancer pain; and

WHEREAS: The CDC Guideline has been challenged broadly by many medical professional associations, individual researchers and practitioners on grounds including unacknowledged anti-opioid bias on the part of the CDC writers, failure to establish consistent standards of research quality, failure to address the natural variability in individual genetic profiles affecting patient metabolism for opioid analgesics; and consequent harms to both legacy and new patients due to withholding of opioid therapy, coerced tapers, consequent withdrawal symptoms, and under-treatment of pain; and

WHEREAS: Regulatory over-reach referenced to or grounded upon the

2016 CDC Guideline has interfered with doctor-patient relationships and usurped physicians' authority to manage treatment regimens which include prescribing opioids for pain; and

WHEREAS: Thousands of new and legacy patients with medically documented needs for management of acute, chronic, non-cancer and non-terminal pain are being denied the only pharmaceutical products in the formulary that are effective for many of them; and

WHEREAS: It is now known definitively that the declared National crisis in opioid addiction and overdose deaths is driven almost entirely by illegal street drugs rather than by medically prescribed opioids; and

WHEREAS: When managed and used by medical providers and patients for medically established needs, opioids have for decades been known to be safe and effective pharmaceuticals for controlling acute and chronic pain; and

WHEREAS: The American Medical Association affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the 2016 CDC Guideline and that such care may be medically necessary and appropriate; and

WHEREAS: In violation of the intent of the CDC Guideline, both Federal and State drug enforcement agencies have seized upon the Guideline as a standard for assessing when providers are "over prescribing" opioids to their patients; criminal investigations of providers have ruined medical practices by prominent announcements in public media, attempting to coerce practice employees to disclose provider misbehavior, seizing and freezing access to patient records, and in some instances seizing civil assets -- often for months before cases are brought to court ; and

WHEREAS: The hostile regulatory environment created by such sanctions is prompting hundreds of providers, practices, and hospitals to cease prescribing opioid analgesic medications or to depart from practice entirely; and

WHEREAS: There is documented proof from data published by CDC that rates of opioid prescribing by healthcare providers are unrelated to rates of overdose-related mortality from all sources – including legal prescriptions, diverted prescriptions and illegal street drugs; and

WHEREAS: The US Congress made the CDC Guidelines mandatory for medical practice in the Veterans Health Administration in the budget resolution bill of December 2015 -- three months before CDC publication. VHA interpreted the Guideline to require that all patients being treated

with opioid pain relievers must be tapered to zero; many patients are now offered Tylenol or Ibuprofen at high doses after surgery, creating risks of liver or kidney failure; and

WHEREAS: Due to over-regulation of opioid supplies and insurance providers' application of "high prescriber" alerts toward providers and pharmacies, National chain pharmacies are failing to stock adequate supplies of prescription opioids and turning away patients presenting valid prescriptions written by licensed healthcare providers.

SECTION 6

IT IS THEREFORE DIRECTED upon CDC, NIH, FDA, and HHS/CMS that

(a) **Section 6.1**

It is henceforth Federal policy and practice for regulation of prescription opioid pain relievers, that no Federal Agency shall apply MMED (Morphine Milligram Equivalent Dose) thresholds as anything more than non-mandatory guidance; further, that -- in the absence of other indications of verifiable harms to patients -- no medical provider shall be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal investigation, prosecution, civil liability or other penalties or practice limitations, solely as a consequence of prescribing opioids at quantitative levels above any fixed numeric MMED threshold, including those of the 2016 CDC Guideline.

(b) Section 6.2

The 2016 CDC Guideline on Prescription of Opioids to Adults With Chronic Pain is hereby withdrawn, pending rewrite by an Inter Agency Task Force to be led by the NIH Office for Pain Policy, for completion on or before May 31, 2021. This rewrite shall be conducted in a publicly transparent process that includes patients and/or their advocates as voting members of the writers group.

(c) Section 6.3

Section 131 of the "Veterans Administration Mission Act" of 2018 is hereby repealed; within two years of enactment of this Act, VHA is directed to withdraw and rewrite its "Opioid Safety Initiative" and all Clinical Practice Guidelines associated therewith, to reflect Federal policy changes directed above.

(d) Section 6.4

Within 30 days of enactment of this Act, HHS/DHS is directed to rescind January 2019 Medicare Part D and Medicare Advantage rule changes which authorize insurance providers to require pharmacies to conduct "safety edits" for prescriptions which exceed numerical MME thresholds.

(e) Section 6.5

Within 30 days of enactment of this Act, VHA, HHS/CMS, and FDA are directed to publish letters to all medical providers licensed under their respective healthcare systems, conveying the mandatory changes of Federal regulatory policy above. These letters shall further be disseminated to all State Medical Boards, Pharmacy Boards, Departments of Health, Medicaid programs, Insurance Boards, and State Attorney Generals.

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