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Dear House and Senate Opioid Legislation Conferees:

The Pew Charitable Trusts is an independent nonpartisan, nonprofit research and policy organization. Our work to address substance use disorders focuses on developing and supporting policies that 1) reduce the inappropriate use of prescription drugs while ensuring that patients have access to effective pain management and 2) expand access to effective treatment for substance use disorders, including through increased use of medication-assisted treatment (MAT).

Pew urges you to include the following key provisions in final opioid legislation: expanding the proposal that would allow Medicare plan sponsors to use patient review and restriction (PRR) programs to include all controlled substances in Drug Enforcement Administration (DEA) schedules II through V, allowing nurse practitioners and physician assistants to prescribe buprenorphine for the treatment of opioid dependence, and increasing the maximum number of patients a qualified physician may treat with buprenorphine at a given time (i.e., the patient caps). The importance of these components is described in detail below.

DEA Schedules Included in Proposed Medicare PRRs

Section 705 of S. 524, the Comprehensive Addiction and Recovery Act (CARA) would authorize the use of PRRs by Medicare plan sponsors. These programs can play an important role in preventing prescription drug misuse and diversion by assigning patients who are at risk for substance use disorders to pre-designated pharmacies and prescribers to obtain drugs that are subject to abuse. PRRs also include important protections to ensure beneficiaries have continued access to effective and safe pain management.

While Pew strongly supports inclusion of section 705 of CARA in the final legislation, the section only addresses controlled substances in, or within the same class or category of drugs as, DEA schedule II. **Pew urges conferees to expand section 705 of CARA to include controlled substances in DEA schedules II through V, which would encompass opioids, benzodiazepines, muscle relaxants, and other frequently misused drugs.** Alternatively, Pew would support a provision that allows the Secretary of the Department of Health and Human Services (HHS) to determine controlled substances that are frequently misused or diverted for inclusion in PRRs. A similar provision is included in section 3141 of the House-passed 21st Century Cures Act. Expanding the scope of these programs to include controlled substances beyond DEA schedule II would allow plan sponsors the flexibility to address current and future patterns of drug misuse. It would also reduce potential beneficiary harm by allowing designated providers to monitor and coordinate the use of all controlled substances. The primary rationale for expanding PRRs beyond schedule II is that concomitant use of other scheduled drugs is an independent risk factor and predictor of outcomes. Indeed, the Centers for Disease Control and Prevention (CDC) reports that in nearly a third of opioid overdose deaths, benzodiazepines (drugs in DEA schedule IV) were also cited as a contributing cause of death.[i]

This recommendation is supported by results of a survey Pew conducted of 38 Medicaid fee-for-service PRRs.[ii] All responding PRRs require beneficiaries to receive from designated providers prescription drugs that extend beyond those included in DEA schedule II. Fifty percent of programs require patients to receive DEA schedules II through V from designated providers, and 42 percent include in their program all controlled prescription drugs as well as non-controlled drugs identified as frequently subject to misuse or diversion, such as those used to treat human immunodeficiency virus. Eight percent of programs include DEA schedules II through IV. In order for PRRs to effectively coordinate care and protect patients from harmful amounts of opioids, all controlled substances should be included in PRR legislation.

Buprenorphine Prescribing Authority for Nurse Practitioners and Physician Assistants

H.R. 4981, the Opioid Use Disorder Treatment Expansion and Modernization Act, would amend the Controlled Substances Act to include nurse practitioners and physician assistants among the practitioners that may receive a waiver to prescribe buprenorphine. **Pew strongly supports extending buprenorphine prescribing authority to nurse practitioners and physician assistants as a critical step to expanding access to MAT for the treatment of opioid use disorders.** Expanded prescribing authority is especially important in rural areas. A study published in 2015 found that the majority of U.S. counties had no physician who had obtained a waiver to prescribe buprenorphine, resulting in more than 30 million people living in counties without access to this treatment.[iii]

It is important to note that nurse practitioners and physician assistants can already prescribe prescription opioids in nearly every state, including DEA schedule II narcotics, in almost every state. They may also prescribe buprenorphine for pain, but not for treatment of opioid dependence. With the additional training proposed in H.R. 4981, nurse practitioners and physician assistants would be well prepared to help more patients access high-quality treatment, especially in areas where physicians are not readily available.

Unfortunately, while H.R. 4981 provides this prescribing authority, it also includes a provision that would greatly diminish the bill's intent to expand treatment availability to more patients. The legislation mandates that, in states where the nurse practitioner or physician assistant is required to work in collaboration with or under the supervision of a physician, the overseeing physician must also hold a buprenorphine waiver (i.e., be a "qualifying physician") in order for the nurse practitioner or physician assistant to obtain a waiver. This requirement would apply to every state for physician assistants and would be applicable in all but 21 states and the District of Columbia for nurse practitioners.[iv]

Fewer than three percent of physicians are waivered to prescribe buprenorphine for opioid use disorder.[v] The low percentage of physicians who have obtained a waiver is a primary reason that it is critical that buprenorphine prescribing authority be expanded to other providers. However, as the legislation is written, the vast majority of otherwise qualified nurse practitioners and physician assistants would be ineligible to receive a waiver to prescribe buprenorphine simply because their collaborating or supervising physician does not have a waiver. Pew believes this provision is counterproductive and strongly urges conferees to strike the word "qualifying" in subclause (III) of H.R. 4981, which lists the requirements for nurse practitioners and physician assistants seeking to obtain a buprenorphine waiver.

Patient Caps for Buprenorphine Prescribers

The sponsor of the original DATA 2000 legislation, Senator Hatch, and twelve other senators stated in a letter to HHS Secretary Burwell in 2015 that, "This law arbitrarily capped the number of addicted patients a physician can treat at any one time to 30 through the first year and, if requested and certified, permits expansion to 100 patients thereafter."[vi] With the exception of buprenorphine, there are no federal limits on the number of patients a practitioner may treat using any other office-based medication, including the narcotic analgesics most often involved in drug overdoses. These limits are arbitrary and the accumulation of real-world evidence demonstrates that buprenorphine is safe and effective when used properly. **Pew strongly urges conferees to raise the buprenorphine patient caps**.

Health care practices vary widely in their capacity to treat patients with opioid use disorder. For example, a specialized clinic with a long history of treating opioid use disorder and a significant number of support staff can provide high quality care to many more patients than a solo primary care provider. Given this variation, there is no reliable way to arrive at a single number for how many patients practices are capable of appropriately managing when providing buprenorphine treatment. It is critical that practitioners treating patients with buprenorphine be able to refer them to counseling and other appropriate ancillary services, which is required in current law. Pew believes that adherence to clinical guidelines, requirements for referral services in the current statute, and additional prescriber training are sufficient mechanisms to ensure that patients receive appropriate care. In addition, Pew supports the proposal in S. 1455, the TREAT Act, to require that prescribers seeking to treat more than 100 patients fully participate in state prescription drug monitoring programs.

Pew recognizes that concerns have been raised by some stakeholders about eliminating the caps entirely, including concerns that it could result in suboptimal care for some patients. We suggest increasing the current 100-patient cap to 500, which physician specialists and other prescribers meeting certain requirements would be able to apply for one year after receiving an initial waiver. This would recognize the wide variation in clinical practices and ensure that practitioners with the most expertise and capacity, such as specialists, are able to treat an increased number of patients.

Pew also urges conferees to increase from 30 to 100 the initial limit on the number of patients a waivered practitioner may treat in the first year, as S. 1455 would do. The number of Americans with an opioid use disorder far exceeds existing capacity to provide these individuals with MAT.[vii] Increasing this initial limit would allow specialists with extensive training and capacity to treat more patients immediately. However, Pew strongly supports maintaining the current two-tier patient cap framework, modified as recommended. This approach would better respond to the urgent need to increase capacity and be less burdensome than the three-tier system proposed in the "Sense of Congress" section of H.R. 4981, which would delay clinicians' ability to offer MAT services to additional patients.

Finally, Pew urges conferees to ensure that any change in the law related to the patient caps maintain the current authority of the HHS Secretary to change these thresholds through regulation. Pew also recommends that the final legislation remove specific provisions requiring additional recordkeeping and reporting for waivered providers and instead direct HHS to solicit stakeholder feedback on any proposed changes of this nature. This approach would allow these activities to be consistent with recognized treatment guidelines and account for future changes in practice patterns.

While the policies above would be significant improvements, Pew also urges the conferees to include substantial new funding to support effective treatment. Opioid use disorders are treatable diseases, but only if there is adequate funding and the resources to ensure that people have access to MAT.

Pew appreciates the opportunity to comment and urges conferees to include these key components in the final legislation to reduce the misuse and diversion of prescription drugs through the use of PRR programs and to expand access to effective treatment for substance use disorders through increased use of MAT.

Sincerely,

Cynthia Reilly, MS, BS Pharm
The Pew Charitable Trusts

CC:
The Honorable Patty Murray, The Honorable Lamar Alexander, The Honorable Ron Wyden, The Honorable Orrin Hatch, The Honorable Fred Upton, The Honorable Frank Pallone, The Honorable Chuck Grassley, The Honorable Patrick J. Leahy, The Honorable Bob Goodlatte, and The Honorable John Conyers

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[iii] Rosenblatt RA, Andrilla CHA, Catlin M, & Larson EH (2015). Geographic and specialty distribution of US physicians trained to treat opioid use disorder. *The Annals of Family Medicine*, *13*(1), 23-26

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[v] Rosenblatt RA, Andrilla CHA, Catlin M, & Larson EH (2015). Geographic and specialty distribution of US physicians trained to treat opioid use disorder. *The Annals of Family Medicine*, *13*(1), 23-26

[vi] Hatch OG, et al (2015). Correspondence to Health and Human Services Secretary Sylvia Burwell, accessed May 18, 2016, http://www.kirk.senate.gov/pdfs/HeroinLetter.pdf

[vii] Jones CM, Campopiano M, Baldwin G, & McCance-Katz E (2015). National and state treatment need and capacity for opioid agonist medication-assisted treatment. *American Journal of Public Health*, *105*(8), e55-e63