

February 16, 2018

The Honorable Orrin Hatch Chairman, Committee on Finance **United States Senate** Washington, DC 20510

The Honorable Ron Wyden Ranking Member, Committee on Finance **United States Senate** Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of the Bipartisan Policy Center, thank you for the opportunity to provide input on addressing the nation's opioid crisis and how the Medicare and Medicaid programs can effectively support pain management and prevent and treat substance use disorders. The Senate Finance Committee can play a pivotal role on this issue through its significant committee jurisdiction.

As directors of BPC's health program, the below recommendations reflect our current thinking on these issues as a starting point for discussion, and they do not necessarily represent the formal positions of BPC or its leaders.

First, we would make the following overarching points:

- 1) Use of evidence-based non-pharmacologic therapies for chronic pain (e.g., chiropractic services, physical therapy, acupuncture) should be encouraged, and coverage for them should be extended through the regulatory process wherever possible or through legislation where new statutory authority is required. A full review of the existing evidence base for non-pharmacologic therapies can inform where coverage limitations and patient cost-sharing may be limiting provider and patient options for alternative pain management. Ongoing work by the Patient Centered Outcomes Research Institute (PCORI) should also add to our understanding of the comparative clinical effectiveness of various treatment modalities.
- 2) All evidence-based medication-assisted treatments (MAT) for opioid use disorder (OUD) - buprenorphine, methadone, naltrexone - should be covered for Medicare and Medicaid beneficiaries. Consistent with value-based insurance design, to the extent that patient cost-sharing can be waived for these treatments, the more likely that they will be utilized.
- 3) Medicare Part D plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans should adopt utilization management techniques and should also bear some financial risk for poor patient-related outcomes. The Comprehensive Addiction and Recovery Act of 2016 made some positive steps forward including providing the Centers for Medicare and Medicaid Services (CMS) with new authority to establish a voluntary drug utilization management program targeted to beneficiaries "at risk for prescription drug abuse or misuse" for standalone Medicare PDPs and MA-PD plans. CMS is

- currently finalizing its proposed ruleⁱ on the implementation of this new authority for plan year 2019, which Congress should continue to monitor.
- 4) Congress and CMS should ensure that, where appropriate, evidence-based, National Quality Forum (NQF)-endorsed opioid quality measures are included across the Medicare and Medicaid programs. Stakeholder input should be gathered to ensure an appropriate balance is struck between use of these measures which reflects the seriousness and extent of the national opioid epidemic and the burden placed on providers to collect the data and report on these measures.

Responses to the Committee's Questions:

1. How can Medicare and Medicaid payment incentives be used to promote evidencebased care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUDs?

Providers often lack knowledge or training in the appropriate prescription of opioids or the availability of alternatives. Medicare and Medicaid can promote use of evidence-based guidelines by clinicians through a variety of ways, including development and dissemination of educational materials; provision of accurate, timely, and actionable information on inappropriate provider prescribing and beneficiary utilization; and inclusion of evidence-based measures in various payment and delivery programs.

Congress should encourage or direct CMS to add an appropriate NQF-endorsed quality measure on opioids as part of its measure sets for alternative payment models, the Merit-Based Incentive Payment System, and for Medicare Advantage STAR ratings. There are currently three endorsed measures. iii

2. What barriers to non-pharmaceutical therapies for chronic pain currently exist in Medicare and Medicaid? How can those barriers be addressed to increase utilization of those non-pharmaceutical therapies when clinically appropriate?

Barriers to non-pharmaceutical therapies (such as acupuncture, cognitive behavioral therapy, and pain management coaching) for chronic pain include lack of knowledge about these alternatives among providers, lack of reimbursement or coverage for these therapies, and the need for a stronger evidence base on the long-term effectiveness of these therapies, particularly among special populations.

a. Medicare

 Many non-pharmaceutical therapies for chronic pain are not a covered service under Medicare. With recent changes in Medicare Advantage as enacted as part of the Bipartisan Budget Act of 2018, MA plans may be able to cover nonpharmaceutical therapies for those with chronic conditions (unclear until regulations or other guidance is released). While someone with chronic pain may qualify for supplemental services depending on whether it is a result of a chronic disease, supplemental services could be covered. The Senate Finance Committee could clarify that chronic pain would qualify as a chronic condition under the new law if the non-pharmaceutical therapy can be reasonably expected to improve or maintain health or functional status.

- 2. Congress or the CMS Innovation Center could clarify that within alternative payment models such as patient-centered medical homes or accountable care organizations where providers bear risk for financial and quality outcomes, providers could subcontract for non-pharmaceutical pain management modalities that would not otherwise be covered but can be reasonably expected to improve or maintain health or functional status.
- 3. The Innovation Center at CMS could be encouraged or directed to develop a risk-based model explicitly targeted for patients with OUD. With the cost of an opioid overdose ranging from \$58,500 to \$92,400,^{iv} this has potential to increase quality of care and bring down cost. A demonstration could be structured to permit both pharmaceutical and non-pharmaceutical therapies for those who have presented in an emergency room with an overdose, or who have been screened as at high-risk for overdose.
- 4. For instances when coverage of non-pharmaceutical therapies exists but there are utilization management barriers (e.g., co-payments), *CMS could add a category of opioid addiction to the list of conditions eligible for the Medicare Advantage Value-Based Insurance Design Model*.¹

b. Medicaid

- 1. Medicaid agencies and managed care organizations (MCOs) should be *encouraged to cover evidence-based non-opioid services for the treatment of pain and to share best practices* with other states on their approaches for ensuring appropriate use within federal and state budget constraints.
- 2. Congress could consider *developing a new state option known as an Emergency Non-Pharmaceutical Pain Treatment Option for States*, which could be codified through Title 19 or through a new Social Security Act subtitle on Emergency Non-Pharmaceutical Pain Treatment Coverage. Under this state option, eligible patients (e.g., those with prior overdose or identified as at risk of overdose based on screening) could be eligible for non-pharmaceutical pain management therapies, provided the therapy did not add to the federal share of Medicaid costs over a 10-year budget window.

3

¹ For more information see: https://innovation.cms.gov/initiatives/vbid/.

3. How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs while promoting efficient access to appropriate prescriptions?

a. Medicare

- 1. Eliminating Financial Barriers *Medicare PDPs and MA-PD plans could be required to waive co-payments for the cost of medication-assisted treatment.*Encouraging or requiring naloxone coverage on PDP formularies could also help to ensure access to this life-saving emergency treatment.
- 2. Alternative Payment Models Congress or CMS could develop a model for bundled payment for providing medication-assisted treatment to those addicted to opioids. This is line with the legislative proposal in the President's FY19 budget, *Provide Comprehensive Coverage of Substance Abuse Treatment in Medicare.*^v
- 3. Alternative Care Delivery Models Access to mental health and substance abuse services is a challenge for many populations, including those living in rural and underserved areas. Telehealth is a promising tool for providing substance abuse treatment services and support to populations living in geographic regions that have difficulty assessing care. CMS should expand existing efforts to increase coverage of telehealth services to include those related to opioid-related prevention, screening, assessment, and treatment.

b. Medicaid and Other State Programs

1. *Improve Prescription Drug Monitoring Programs (PMDPs)*. PMDPs are state-run electronic databases that collect data from pharmacies on controlled prescription drugs (including opioids) that are dispensed to patients. PMDPs help clinicians and pharmacists intervene early with patients if there are signs of misuse. They can also help state Medicaid programs, state licensing boards, and public health agencies identify unusual patterns that require intervention.

Currently, every state, the District of Columbia and territory of Guam has a PDMP, 39 states require providers to access PDMPs under certain circumstances; and 43 states share data with other states, with six others are working toward these agreements. However, these programs remain underutilized. While the vast majority of primary care physicians are aware of their state PMDP, only about half of used it, and many did not use it routinely. Barriers to usage include the burden and time associated with clinician access and the lack of integration of PMDPs with the electronic health records (EHRs) now being used by nearly 90 percent of physicians in the United States, which has a significant negative impact on work flow. Other issues include the lack of interoperability across state PDMP databases, variability among data standards used (which hinders usability of the data across states), lack of accessibility, and the lack of real-time response to

support clinical decision-making. To address these issues, we recommend the following:

Congress could direct the secretary of HHS – by a date certain, with an interim report due to Congress by a date certain – to work with states, stakeholder organizations, and other experts to reach agreement on and adopt a common set of private-sector consensus data interchange standards to support interoperability between PDMPs and EHRs and interoperability across PDMPs. This could improve reporting and use among clinicians and ensure the benefits of these systems is more fully realized. These standards should include adoption of a minimum data set and standard transaction format for submission of data and data transport standards that support real-time reporting. Options and considerations:

- a. Provide incentives to states, such as a permanent (or temporary)² enhanced administrative match for the cost of establishing and updating their programs;
- b. Create model agreements and best practices for states which may include:
 - i. Mandatory use of PDMPs, including access for managed care organizations (MCOs);
 - ii. Interdepartmental agreements between state professional licensing boards (pharmacy, nursing, and physician), health departments, and law enforcement agencies;
 - iii. Data tools to assess prescribing practices and patient misuse.
- 2. Provide for an enhanced federal administrative match under Medicaid. The enhanced match rate could be linked to standards developed by the secretary of HHS, as outlined above.
- 3. Require or incentivize states to waive co-payments for medication-assisted treatment, including provider visits.
- 4. Create a limited benefit for example, under managed care organizations that covers treatment for OUD and SUD for uninsured individuals who do not qualify for Medicaid. These individuals would not be eligible for any Medicaid-covered services except those directly related to treatment. This would be similar to current-law options under which states may cover certain screenings and treatments for uninsured individuals who do not qualify for Medicaid. This could be a permanent or temporary state option. For example, this option could be made available to states when the president has declared a national public health emergency. Eligibility for the treatment could be limited to those who present in an emergency department with a drug overdose or could be more broadly available to anyone who is screened and determined to be at risk for overdose. This is similar to a county-sponsored program in Jacksonville, Florida. The

5

² For example, the enhanced administrative match could be available only in times of national emergencies declared by the president; or a state of emergency declared by a governor. Another approach would be to set time limits, such as 12-24 months.

payment model for this treatment program could be an episode-based payment bundle that sets a prospective payment amount for the treatment (e.g., a fixed payment for a 90-day or longer episode of care for outpatient treatment). Value-based incentives could be incorporated, e.g. a specified percentage at risk for achievement of success based on no emergency room visits for opioid overdose during treatment or a 90-day period post treatment.

- 5. Use Medicaid to provide incentives to states to enact legislation requiring use of e-prescribing for controlled substances. This could be done as a requirement, by increasing FMAP, or by directing the secretary of HHS to develop an expedited process for waivers designed to address opioid use with preference in states that require e-prescribing.
- 4. Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?

CMS' proposal in its 2018 Medicare Advantage and Part D Draft Call Letter to limit initial opioid prescriptions for acute pain to seven days is a good start. It should be noted that even with a seven-day limit, particularly with an opioid prescribed for use multiple times daily, opioid addiction can occur. VIII CMS' proposal that PDPs prohibit dispensing of any prescription that is more than 90 morphine milligram equivalents is also appropriate.

In addition, for Part D plans, consideration should be given to:

- 1. Eliminating the opioid-only "consent" restriction. Plans should be able to implement full opioid restriction for a beneficiary that meets stringent criteria under the CMS-mandated opioid care management processes without prescriber consent. Beneficiaries who receive a drug coverage denial already have access to a well-established appeals process, which includes the availability of independent clinical review.
- 2. Shortening the waiting period for Medicare PDPs to impose limited access restrictions. CMS has recently proposed an allowance for PDPs to restrict at-risk patients to certain prescribers and/or pharmacies; this restriction is designed to prevent "doctor-shopping" or the use of multiple emergency department visits to inappropriately obtain opioids that are more likely to be abused or diverted, while still ensuring that a beneficiary has access to medically necessary medication. However, the current six-month waiting period is too long for a beneficiary who is truly at risk of developing an addiction or opioid use disorder. Congress could encourage or direct CMS to shorten this period, e.g., to 60 days.

5. How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?

As recommended by the Government Accountability Office, CMS should identify providers who may be inappropriately prescribing large amounts of opioids and require plan sponsors to report actions they take when they identify such providers. ^{ix} At a minimum Part D plans should ensure these providers have the CDC's Guidelines for Prescribing Opioids for Chronic Pain and develop a follow-up mechanism to ensure provider adherence to these guidelines.

The Committee could consider *requiring mandatory training for clinicians with high opioid prescribing patterns*. Failure to participate in the program by a date certain could limit coverage of prescription opioids in Part D or Medicaid.

6. What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?

Promote Real-time Information on Medicare Individuals Identified by State PDMPs - By a date certain, for example, plan year 2021, require PDPs and MA-PD plans to contract with pharmacies that have integrated EHRs and PDMPs and can communicate in real-time. Most major chain drug stores have done this, and the secretary of HHS could issue guidelines for a different approach for smaller independent pharmacies to either integrate EHRs and PDMPs or develop a plan to limit access to opioids for at-risk Medicare patients (e.g., those prescribed both benzodiazepines and opioids, which puts them at higher risk for overdose). For those individuals identified, plans could be required to report to the prescriber for referral to screening and treatment. Hopefully this would already have been done in states that require prescribers to check PDMPs, although states vary as to the circumstances in which the physician is required to check.

7. What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?

One study has recommended that *states authorize Medicaid, Medicare, the Veterans Administration, Department of Defense, Indian Health Service, workers' compensation carriers, and private third-party health care payers to access PDMP data for their enrollees, with patient protections to assure, for example, that data sharing does not result in coverage or pricing changes.* Xi States are already doing this to some degree. Pharmacy benefit managers could also be allowed to access the data as agents of the third-party payers for whom they manage benefits. Below is an excerpt from the report on the rationale for this recommendation:

"Access to PDMP data can provide third-party payers with the ability to identify and contact prescribers whose prescribing practices expose enrollees to unnecessary risks; identify enrollees who are obtaining high-risk prescriptions, contact their prescribers, create prescription limitations, and monitor compliance thereafter; and identify pharmacies where dispensing may put enrollees at risk. Such access may provide valuable information to inform internal policies that address opioid-use disorders associated with prescribed opioids. Careful consideration of enrollee protections is essential to protecting patients' rights and guarding against abuse. Current Status: Thirty-six states and one territory authorize some combination of third-party payers to access PDMP data. Seven states provide access to Medicare and five states to commercial third-party payers. Washington State authorizes Medicaid and Workers Compensation to access the PDMP data in bulk."

The legislative proposal in the president's FY19 budget to require coverage of all medication-assisted treatments in Medicaid is a sound one. The proposal requires that state Medicaid programs cover all Food and Drug Administration-approved medication-assisted treatments (MAT) for opioid use disorder, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from opioid use disorder. [\$865 million in savings over 10 years]

Medicaid programs are also implementing a range of policies to regulate and reduce prescription opioid use: xiii

These include:

- patient review and restriction in fee-for-service or managed care or both (as of 2015, all states and DC); xiv
- preferred drug lists (as of 2012, 48 states and DC);xv
- prescription drug monitoring programs (PDMPs) (as of 2014, 31 states and DC had access to PDMP data);^{xvi}
- prior authorization requirements (as of 2016, 44 states and DC); and
- quantity limits on opioid dispensing (as of 2016, 46 states)xvii

While Medicaid programs are required to cover certain services, such as medicallynecessary inpatient hospital, outpatient hospital, and physician services, many other services used in substance use disorder treatment are at state discretion, including counseling, licensed clinical social work services, targeted case management, medication management, and peer and recovery supports.

States are tailoring their efforts to expand substance use disorder benefits and the number of enrollees eligible for this care through various mechanisms, including through Section 1115 waivers (e.g., Virginia) and the health homes option (e.g., Vermont). **viii,xix**

8. What human services efforts (including specific programs or funding design models) appear to be effective in preventing or mitigating adverse impacts from OUD or SUD on children and families?

An August 2017 SAMHSA report found that one-in-eight children live in a family where one or both parents have a substance use disorder. Further, approximately 70 percent of women entering substance use disorder treatment services have children. Infortunately, our substance use disorder treatment system rarely accommodates families even though the outcomes for women are better if women can be with their children. Further, other services, in addition to treatment, are necessary to improve outcomes for at-risk families. These services include employment, housing, and parenting skills, to name a few.

Such programs can be funded through increased funding to the states through SAMHSA. A few specific programs are: Connecticut's *Pay for Success Family Stability Project*, Boston Medical Center's *SoFar Clinic* for mothers in recovery and their children, and *Project Respect*, a treatment program for women also at Boston Medical Center.³

Thank you for your commitment to addressing the nation's opioid crisis through policies under the jurisdiction of the Senate Finance Committee that can be advanced in a bipartisan and fiscally responsible manner. Thank you again for the opportunity to submit comments; we look forward to continuing to work with you on this important effort.

Sincerely,

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³ For more information, see: http://www.ct.gov/dmhas/lib/dmhas/adpc/(6) family recovery project.pdf, https://www.bmc.org/pediatrics-primary-care/sofar, and https://www.bmc.org/pediatrics-primary-care/sofar, and https://www.bmc.org/obstetrics/project-respect.

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