



February 16, 2018

The Honorable Orrin G. Hatch
Chairman
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510 – 6200

The Honorable Ron Wyden
Ranking Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510 – 6200

Dear Chairman Hatch and Ranking Member Wyden,

On behalf of the nation’s Medicaid Directors, we are pleased to offer comments and insights into state activities to address the ongoing opioid epidemic, as well as areas where additional flexibilities can enhance state efforts.

The National Association of Medicaid Directors (NAMD) is a bipartisan, nonprofit, professional organization representing leaders of state Medicaid agencies across the country. Our members drive major innovations in health care while overseeing Medicaid, which provides a vital health care safety net for more than 72 million Americans. In 2009, Medicaid provided one out of every five dollars spent on substance use disorder (SUD) treatment, and the program is projected to account for 28% of all SUD service spending in 2020.¹

Medicaid Directors are key leaders in national efforts to address the opioid epidemic. Medicaid programs are focused on deploying comprehensive strategies to prevent addiction and provide high-quality, evidence-based treatment for all beneficiaries across all substance use disorders, including alcohol use disorder, opioid addiction and others. Several tools and flexibilities provided by Congress and the administration, such as Section 1115 demonstration waivers for SUD, have assisted these efforts, though additional targeted flexibilities in certain areas could further support states’ work on this critical issue.

¹ Substance Abuse and Mental Health Services Administration. National Expenditures for Mental Health Services and Substance Abuse Treatment, 1986–2009. HHS Publication No. SMA-13-4740. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013; Tami L. Mark et al., “Spending on Mental and Substance Use Disorders Projected to Grow More Slowly Than All Health Spending Through 2020,” *Health Affairs* 33, no. 8 (2014): 1407–1415, <http://content.healthaffairs.org/content/33/8/1407.full>.



Three specific actions Congress could take to support state strategies to address the opioid epidemic are:

1. Repeal or reform of the exclusion of federal match for Medicaid services provided in Institutions for Mental Disease (IMDs);
2. Reform of the SUD privacy protections at 42 CFR Part 2 to align with more modernized protections available under the Health Insurance Portability and Accountability Act (HIPAA), while maintaining safeguards prohibiting patient SUD records from being used in non-treatment related criminal, civil, or administrative proceedings; and
3. Additional federal investment in state infrastructure to develop, implement, and sustain cross-cutting opioid prevention and treatment strategies, inclusive of all relevant state agencies and partners.

We offer specific responses to the Committee's questions in the enclosed document. NAMD and our members are committed to working with the Committee and all other stakeholders to continue enhancing access to high-quality, evidence-based SUD care, and appreciate your consideration of state perspectives.

Sincerely,

A handwritten signature in blue ink that reads "Judy Mohr Peterson".

Judy Mohr Peterson
Med-QUEST Division Administrator
State of Hawaii
President, NAMD

A handwritten signature in black ink that reads "Kate McEvoy".

Kate McEvoy
State Medicaid Director
State of Connecticut
Vice President, NAMD

ENCLOSURE: NAMD Responses to Senate Finance Committee Questions on Promoting Effective Opioid Use Disorder Treatment



NAMD Responses to Senate Finance Committee Questions on Promoting Effective Opioid Use Disorder Treatment

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

A key priority of Medicaid Directors is exploring payment incentives and program models to promote integrated physical and behavioral healthcare. The strategies deployed to promote this goal include state interagency partnerships between Medicaid, behavioral health, and addiction agencies; value-based payment models to incentivize care coordination; and encouraging cross-cutting provider partnerships to transform practice environments. The common thread across these multilevel strategies is to break down programmatic silos and deliver comprehensive, whole-person care that addresses an individual's physical health, mental health, and substance use disorder needs.

Behavioral health integration strategies are already showing progress in improving care for individuals with chronic pain who may be at risk for SUD. These strategies are further incentivized by alternative payment models (APMs), which can take several forms – episodes of care, population-based payments, and enhanced payments for care coordination and practice transformation are a few of the APMs states are pioneering. APMs can also incentivize new approaches for leveraging technology to promote integrated care delivery, such as telehealth consults with pain management specialists. States are also targeting specific provider types with tailored incentive payments, such as linking enhanced payments to appropriate post-operative opioid prescribing.

Congress can provide additional tools for states' behavioral health integration work by enhancing federal investments in state delivery system reform infrastructure (including designing and implementing APMs), repealing the IMD exclusion to allow Medicaid to cover the full continuum of SUD care, and reforming 42 CFR Part 2's privacy protections with HIPAA.

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?

Several states are exploring options for coverage of alternative, non-pharmaceutical pain management therapies, such as acupuncture, massage therapy, physical therapy, yoga, group visits, and peer support groups for pain. However, the evidence base, potential utilization levels, and budgetary impacts of these alternative therapies has yet to be firmly established. In the absence of this evidence, states looking to cover these therapies are doing so via small-scale, targeted benefits. This approach allows states to track utilization and cost information which can inform future coverage policies and benefit design – particularly if states are able to link specific savings in other areas of their Medicaid programs to these alternative therapies.

Another barrier to more widespread utilization of non-pharmaceutical pain management therapies is the need for provider and patient education regarding these treatment options. Not all of these groups may be aware of the non-pharmaceutical therapies available, or may be skeptical that these therapies can be as effective as a pharmaceutical pain management approach. Again, the development of the evidence base could address these concerns.

Congress can support and accelerate state efforts to cover non-pharmaceutical pain management therapies by providing states with financial support to test these therapies. This support could be in the form of a demonstration model under the Center for Medicare and Medicaid Innovation (CMMI), or a time-limited federal match enhancement for specific non-pharmaceutical therapeutic approaches. Federal support for this testing environment would allow states to continue developing the evidence base for these therapies, including cost-effectiveness, and thereby support their broader adoption across the states. This evidence may also lead to states designing APMs to incentivize the use of non-pharmaceutical pain management therapies as part of their overall strategies to reduce opioid abuse.

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 to improve patient outcomes?

The IMD Exclusion

Seven states currently have authority from CMS to waive the IMD exclusion under an 1115 SUD demonstration – five under guidance from the previous administration, and two with updated guidance issued in November 2017. These states are using their demonstration authority to develop the full continuum of evidence-based SUD care in their delivery systems, modeled on



the American Society of Addiction Medicine (ASAM)'s Levels of Care criteria.² ASAM criteria represent the consensus for effective SUD treatment, and its care continuum includes intensive inpatient treatment and residential treatment options, both of which are difficult to provide in Medicaid under the IMD exclusion. These states, with federal support, are now able to leverage resources to not only provide low and high-intensity SUD treatment in IMD settings, but are also able to inject resources into their SUD provider communities to develop more community-based options, such as Medication-Assisted Therapy (MAT) in outpatient settings and recovery housing.

Further, as the SUD care continuum becomes more robust over the lifetime of the waiver, these states are likely to begin incorporating value-based purchasing arrangements and APM approaches to enhance the quality of SUD care provided. One approach states may take is to track an individual's discharge from a residential treatment facility into an outpatient MAT therapy, with payment incentives to encourage this care transition.

Waiver authority to develop SUD continuums of care, inclusive of IMD services, is a valuable tool for states. However, barriers remain to providing comprehensive care for individuals with co-occurring mental health and SUD needs. In some cases, an individual's SUD needs may be addressed with a shorter IMD stay, but their mental health needs may require a longer one. SUD waivers do not grant states the ability to cover mental health IMD stays in this scenario. Nor do the regulatory flexibilities under the Medicaid managed care rule – which allow up to 15 days of covered IMD services in a month – provide states with sufficient options to meet the needs of individuals with these co-occurring needs.

We encourage Congress to explore the viability of repealing the IMD exclusion entirely, recognizing the barriers it poses for robust SUD care and for the appropriate provision of mental health services. Should a comprehensive repeal not be possible, Congress could consider more targeted reforms to the IMD exclusion, such as waiving the exclusion entirely for Medicaid managed care delivery systems or codifying in statute the ability for states to cover 15 days of IMD services in a month, regardless of their delivery system design.

Patient Limit for Buprenorphine Prescribers

The Drug Addiction Treatment Act of 2000, modified by the Office of National Drug Control Policy Reauthorization Act of 2006, establishes the statutory parameters under which physicians may prescribe buprenorphine for MAT. The Substance Abuse and Mental Health Services Administration (SAMHSA) is the agency responsible for regulating these physicians. Currently,

² American Society of Addiction Medicine. "What are the ASAM levels of care?" <http://asamcontinuum.org/knowledgebase/what-are-the-asam-levels-of-care/>

SAMHSA rules cap an eligible prescriber at 30 patients, unless the prescriber obtains a waiver to lift the patient cap to 100 patients. Recent SAMHSA rulemaking allows prescribers who have the 100-patient waiver for one year or longer to apply for an additional waiver to lift their patient limit to 275 patients.

These patient caps can impede access to MAT by limiting the number of patients a physician can treat. As noted in the ASAM criteria, outpatient MAT is a key component of effective SUD treatment. Congress should consider how it can modify relevant statute or work with SAMHSA to either lift the buprenorphine cap entirely, or to remove the year-long waiting period for prescribers to treat the maximum number of patients allowed. Congress could also consider allowing non-physician providers with appropriate training, such as Advanced Practice Registered Nurses (APRNs), to prescribe buprenorphine, thereby expanding MAT access. Congress can direct SAMHSA to ensure states have appropriate safeguards in place to ensure providers operating at their prescribing limit do so with proper oversight and accountability.

Other Changes to Support Appropriate Treatment

Effective SUD treatment is cross-cutting across medical and non-medical needs. To that end, Congress can support effective state interventions by making targeted statutory changes and encouraging federal agencies to develop appropriate regulatory structures. These could include, but are not limited to:

- Requiring Medicare to cover methadone for SUD treatment in outpatient clinic settings. Currently, Medicare only covers methadone for pain on an outpatient basis, and methadone to treat opioid addiction is only available in in-patient settings. Community-based methadone clinics are an important aspect of the SUD care continuum, but their lack of coverage under Medicare can create barriers to effective treatment for Medicaid beneficiaries who transition into Medicare coverage at age 65. While it is feasible to transition individuals stabilized on methadone to alternative medication-assisted treatments such as buprenorphine, such transitions require significant medical support and supervision, including in-patient hospitalization, and are not without risk of relapse.
- Directing CMS and the Department of Labor to develop regulations and guidance requiring Medicare Part D plans and private insurers to promote access to MAT drugs. While CMS has encouraged State Medicaid programs to reduce or eliminate access barriers to MAT drugs, including buprenorphine, by eliminating prior authorizations, Medicare Part D plans and private insurance have not followed suit.
- Allowing states to eliminate the restrictions on Medicaid coverage for individuals who are incarcerated in local jails or state prisons in order to begin or maintain MAT for

individuals entering the justice system. This change could also enhance state efforts to ensure individuals leaving the justice system are entered into care immediately upon discharge. Evidence shows that failures to make these care linkages shortly after reentry into the community leads to higher rates of relapse and recidivism.

- Should this flexibility not be available, Congress could direct CMS to develop regulations, guidance, and provide technical assistance resources for states to improve care transitions from the justice system into the community.
- Congress could also direct appropriate agencies to develop guidance on the effectiveness of initiating and/or maintaining MAT in justice settings.
- Directing the Drug Enforcement Administration (DEA) to finalize rules allowing mobile units to be used by credentialed providers to prescribe and dispense all opioid treatment medications. This rulemaking has been delayed, impeding state efforts to improve treatment access, particularly in rural areas.
- Allowing SAMHSA to certify mobile units as opioid treatment centers.
- Allowing mid-level practitioners (Physician Assistants, APRNs, Doctors of Pharmacy, etc.) to make administration and dosing decisions within opioid treatment programs without first obtaining an exemption from SAMHSA.

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?

The current statutory construct of the Medicaid drug rebate program (MDRP) requires states to cover all drugs approved as safe and effective by the Food and Drug Administration (FDA). States may place some drugs under a prior authorization process, though the products must still be available to beneficiaries able to meet these criteria. In exchange for mandatory coverage, states receive a mandatory rebate on these products. This includes all prescription opioids on the market.

The MDRP's requirements can limit the tools states have to design an opioid coverage policy. Given concerns around the number of prescription opioids on the market, their relative strengths, and the rate at which opioids are prescribed to Medicaid beneficiaries compared to other payers, states would benefit from the flexibility to more appropriately tailor their opioid coverage policies to meet the needs of their Medicaid populations.³ Congress could allow targeted exemptions to the MDRP's coverage requirements for opioids, allowing states the option to not cover all opioid products with a rebate agreement (inclusive of abuse-deterrent

³ Medicaid and CHIP Payment and Access Commission, June 2017 Report to Congress, Chapter 2. "Medicaid and the Opioid Epidemic." <https://www.macpac.gov/publication/medicaid-and-the-opioid-epidemic/>

formulations, which may be costly and have mixed evidence of effectiveness). Under this flexibility, states would independently determine if and how to cover opioid products, taking into account all available evidence for their safety and effectiveness and how such coverage policies interact with other components of the state's strategies to address the opioid epidemic.

The federal government can also support state efforts to ensure appropriate opioid prescribing by continuing to update and refine the Centers for Disease Control and Prevention (CDC)'s opioid prescribing guidelines.⁴ These guidelines send a strong signal to the prescriber community, advance the national conversation on appropriate prescribing, and have helped empower states to set reasonable, evidence-based opioid prescribing limits. Congress could direct the CDC to periodically update these guidelines and provide state Medicaid programs with technical assistance resources to implement the guidelines.

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

One of the most useful tools available for monitoring prescribing rates across providers is a state's Prescription Drug Monitoring Program (PDMP). While PDMP design and which entities have access to PDMP data are at the discretion of the state, Congress could support states fully leveraging their PDMPs by directing the Department of Health and Human Services to develop and disseminate guidance on effective PDMPs. Potential elements of this guidance could include:

- Strategies to ensure all appropriate entities, including Medicaid, health systems, managed care entities, and providers, have access to PDMP data. This could include practices for sharing proactive PDMP reports to these entities, rather than awaiting specific queries or data requests.
- Common data elements and user-friendly methods for accessing PDMP data.
- Strategies to ensure all prescribing providers submit timely data to the PDMP. This should address steps states can take to integrate PDMPs into electronic health records (EHR), how to delegate PDMP submission responsibilities to appropriate provider staff, facilitate training on PDMP submissions, and other practices to ensure PDMP data submission does not unduly intrude on a provider's ordinary workflow.
 - This work may require input or rulemaking from the Office of the National Coordinator (ONC).

⁴ Centers for Disease Control and Prevention. "CDC Guideline for Prescribing Opioids for Chronic Pain." <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>

- Strategies to promote inter-state sharing of PDMP data to effectively track opioids prescribed by out-of-state providers for Medicaid beneficiaries.
- Strategies to ensure PDMP data is used only to support treatment decisions, and not to initiate or substantiate criminal, civil, or administrative proceedings which discourage individuals from entering treatment.

Congress can also explore ways to support states in their provider education efforts and best practices for informing providers of their prescribing levels. Some states have found that traditional education tools may not always be effective and are exploring other options – particularly those focused on peer-to-peer education between providers. This may include targeted specialty consults via telemedicine, such as Project ECHO, or partnering with local public health agencies to identify “physician champions” to educate their peers and colleagues.⁵ Should these education and outreach efforts not produce the desired results, states may opt for targeted disenrollment of providers who are unable to reduce inappropriately high rates of opioid prescribing.

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

Promoting effective and timely sharing of data across SUD care teams requires statutory repeal or reform of 42 CFR Part 2. This outdated statute, first established in the 1970s in a world where SUD treatment and medical understanding of addiction was very different than it is today, creates serious barriers to SUD treatment. Part 2 statute and SAMHSA regulations create more stringent privacy protections for patient SUD data than for other sensitive health data protected by modern HIPAA rules. Specifically, Part 2 requires patient consent each time a new provider would need access to the patient’s SUD medical records, rather than HIPAA’s generalized consent.

The lack of alignment between Part 2 and HIPAA creates challenges across the healthcare system, from state Medicaid agencies to managed care plans and down to individual provider practices. While SAMHSA has worked to modernize Part 2 regulations, its most recent rulemaking earlier this year still explicitly prohibits disclosure of Part 2 data for purposes of diagnosing, treating, or referring patients to SUD treatment (including care coordination and case management) without patient consent. This prohibition inhibits the integration of SUD care into primary care and other care models, poses unnecessary administrative costs on states,

⁵ Robert Wood Johnson Foundation. “Project ECHO.” <https://www.rwjf.org/en/how-we-work/grants-explorer/featured-programs/project-echo.html>

plans, and providers, and can result in patient harm or death due to lack of full access to relevant SUD data.

Congress should prioritize repeal or reform of 42 CFR Part 2 to align SUD privacy protections with HIPAA, while maintaining appropriate protections for patient SUD information – namely prohibiting such information from being used to initiate or substantiate criminal, civil, or administrative proceedings. In doing so, individuals with SUD can realize the benefits of integrated care approaches without fear of adverse impacts on their families and livelihoods for seeking treatment.

In addition to the necessary changes to 42 CFR Part 2, we again call attention to the potential for federally-developed best practice guidance for PDMPs, discussed above.

Congress could also encourage and support the work being done through the Medicare-Medicaid Coordination Office (MMCO) and its contractors to facilitate Medicaid access to Medicare Part D opioid prescribing data. MMCO's technical assistance resources to states in this area are another helpful tool in tackling the opioid epidemic, and should be maintained and enhanced going forward.

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?

As we have alluded to throughout these comments, states are employing a host of strategies, practices, and interventions to address the opioid epidemic. Medicaid is a key payer of SUD treatment services, and states are striving to maximize Medicaid policy levers and financial incentives to enhance access to evidence-based, high-quality SUD treatment. Examples of effective state strategies include:

- Using SUD 1115 waivers (including a waiver of the IMD exclusion) to develop the full continuum of SUD care, modeled on ASAM criteria. These care continuums are designed to ensure individuals receive care at the right level, whether it be intensive outpatient treatment, low-intensity residential treatment, outpatient MAT, or community-based recovery options.
- Employing pharmacy management tools, such as:
 - Implementation of the CDC opioid prescribing guidelines;
 - Putting 3- or 7-day limits on opioid prescriptions for acute pain, with appropriate exceptions processes when there is a medical need in an individual's care plan;
 - Setting morphine milligram equivalent limits for all non-cancer, non-terminally ill individuals;

- Using prescription data to lock in high-risk individuals to one prescriber for all opioids and one pharmacy to fill opioid prescriptions.
- Tying APMs and value-based purchasing arrangements to the provision of SUD for applicable populations.
 - Specific strategies include enhanced payments to hospitals for appropriate post-surgical or post-emergency department discharge prescribing of opioids and/or opioid addiction treatments, such as providing a buprenorphine prescription for individuals treated in emergency departments for an opioid overdose.
 - State investment in specific statewide care models, such as the hub-and-spoke framework in Vermont, rely in part on innovative payment arrangements.⁶
- Partnering with sister state agencies, local health departments, provider associations, and other relevant partners to promote provider education on appropriate opioid prescribing and SUD treatment options.
 - Some states are using prescriber report cards derived from PDMP data to ensure providers are aware of their opioid prescribing levels and how they compare to their peers.
- Exploring coverage of alternative, non-pharmacological pain management therapies.
- Facilitating data sharing via PDMPs, integrating PDMPs into EHRs, and leveraging public health data to create a fully informed picture of the opioid epidemic and drive targeted interventions.
 - Some states are developing or have already deployed public-facing data dashboards to display this information in an easily-used format.
- Leveraging Medicaid and public health dollars, including standing orders at pharmacies, to ensure first responders are supplied with naloxone to reverse opioid overdoses.
- Developing peer supports, recovery coaches, and other support services to reduce incidents of overdose and promote stable recovery for individuals with SUD.

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?

State leaders recognize that addressing the opioid crisis requires a holistic, collaborative approach. Medicaid agencies, with their coverage and payment levers, are a key partner in this effort, but not the only partner. Evidence shows that addiction can be impacted by more than

⁶ State of Vermont Blueprint for Health. “Hub and Spoke.” <http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke>

just medical factors, requiring states to consider how to address issues such as a lack of stable housing and employment as part of their opioid strategies.

State opioid task forces are often driven by strong leadership from Governors and/or state legislatures. They include not only Medicaid, but all key state agencies and partners – corrections agencies, public health, law enforcement, behavioral health and addiction agencies, housing agencies, employment agencies, foster agencies, and others. Those states with the resources and ability to build a culture of collaboration across these varied partners are seeing notable strides in developing and implementing comprehensive strategies.

Private partners, including private insurers and endowments, are also valuable allies for states in addressing the opioid epidemic. States can combine funding opportunities and relationships with these private groups alongside various federal funding streams to support strategies and interventions that address all the factors driving the opioid epidemic.

Some states are leveraging Medicaid and its partners to implement targeted programs for certain high-risk groups. One example is the Colorado Special Connections program, which engages pregnant women with SUD and directs them into treatment services, along with continued supports for one year postpartum.⁷ The program prioritizes linking eligible pregnant women into MAT coverage during their pregnancies. It also facilitates access to key services and supports for infants with neonatal abstinence syndrome through its postpartum services.

A similar commitment to collaboration across federal agencies would serve to enhance state efforts. This collaboration must manifest in concrete and complementary federal laws, regulations, and policies. For example, public housing policies under the U.S. Department of Housing and Urban Development (HUD) do not always support evidence-based best practices for SUD treatment. HUD policies, despite its current guidance, can make obtaining and retaining stable housing for individuals with SUD challenging. Consistency in this and other areas will support state efforts, particularly when states are leveraging partnerships across many public and private social and health agencies.

⁷ Colorado Department of Health Care Policy and Financing. “Special Connections.” <https://www.colorado.gov/pacific/hcpf/special-connections>