Hearing on "Opioids"
Kim Brandt, Principal Deputy Administrator
Centers for Medicare & Medicaid Services
Energy & Commerce Health Subcommittee
April 11, 2018

Additional Questions for the Record

The Honorable Michael C. Burgess, M.D.

1. **Virtually every stakeholder group that I have met with agrees that the IMD exclusion should be repealed as part of Congress ensuring Medicaid patients have access to a continuum of care. Many things have changed since the 1960s when this payment rule was adopted and now it is widely recognized that residential treatment is appropriate for some beneficiaries with substance use disorder. A full repeal of the IMD exclusion is still cost-prohibitive, with the Congressional Budget Office pegging the price tag of that policy at about $60 billion. But before us we have a targeted proposal that would remove a barrier to care and allow care in an IMD for up to 90 days in a 12 month period. This allows for longer treatment periods for all beneficiaries, not just selected subpopulations. Do you agree that a partial repeal of IMD is a good first step to ensuring that Medicaid beneficiaries receive the care they need? If so, how quickly so you think states will be able to react to this change?**

Answer: CMS is committed to making sure the right patient is getting the right treatment in the right setting. As you may know, a 90 day limitation could trigger the Mental Health Parity and Addiction Equity Act for some providers and insurers. However, the White House has announced the Administration's support for legislative changes to the IMD exclusion.[1] In the meantime, CMS has implemented a bold new policy that encourages States to submit demonstration projects for CMS approval under which Medicaid could cover services for patients in an IMD that would ordinarily not be covered by Medicaid. As discussed at the hearing, from October 31, 2017 through May 8, 2018, CMS has approved demonstration projects in six states[2], and these states can receive federal financial participation for the continuum of services to treat addictions to opioids and other substances, including services provided to Medicaid enrollees with a substance use disorder (SUD) who are short-term residents in residential and inpatient treatment facilities that meet that definition of an IMD. While I am unable to respond on behalf of states' ability to react to such change, CMS has had and is having discussions with other states about approving similar flexibilities in other demonstrations. We look forward to working with the Committee and Congress on this issue.

[1] https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/
[2] The states as of 5/8/2018 are: Louisiana, New Jersey, Utah, Indiana, Kentucky, and Illinois.

2. **I was pleased to see you mentioned in your testimony CMS's efforts to keep moving forward on Transformed Medicaid Statistical Information System. I am glad to hear that 49 states, DC, and Puerto Rico are reporting data now through this system. More accurate and timely Medicaid data is important for helping us combat the opioid crisis and it's important for improving Medicaid's role as a payer overall. As you know, Ranking Member Pallone and I, along with our counterparts in the Senate, sent the Administrator a letter on March 16th asking about the agency's progress implementing Transformed Medicaid Statistical Information System. I look forward to a formal response to that letter in coming days, but I want to ask about a comment in your testimony. You noted T-MSIS includes data on prescription opioids, and CMS is thinking about how to work with states in innovative ways to use this data in a way that will augment efforts to combat opioid misuse. Certainly, there is bipartisan interest in understanding how CMS is overseeing drug spending in the Medicaid program – whether it's the Medicaid drug rebate program, or the role of opioids, or other issues. While I know the data is imperfect, could CMS start releasing some sample data so Congress and the public have better information?**

Answer: CMS has made significant progress with its federal T-MSIS information technology (IT) platform, and CMS is continuing to work on T-MSIS data quality and technical compliance as a priority for 2018. CMS continues to focus on improving the quality and completeness of the state submissions, technical compliance and building the agency's Medicaid and CHIP data analytic capacity. We look forward to making data more widely available as quality improves.

3. **To help move the ball forward on this Medicaid data initiative, what does it take to boost CMS plans to use for program oversight efforts – do you need more resources and staff to move faster on this?**

Answer: CMS is dependent upon the 50 states, the District of Columbia, and the U.S. territories to submit complete, accurate, and current T-MSIS data on a monthly basis, which complicates CMS's ability to ensure a robust and accurate data set. Additionally, states need to consider how changes to their systems could adversely impact the T-MSIS dataset on timeliness or data quality, and work with CMS to protect against degradation of data during implementation of changes to state systems. This will be an ongoing effort requiring states prioritize T-MSIS data quality and technical compliance, as we work to improve the completeness and accuracy of state-submitted data and stabilize this new system and data set.

For the success of T-MSIS, CMS recognizes the need to devote staff and resources to this initiative so we can meet our collective goals of high-quality, timely Medicaid and CHIP data, especially early on in the program. It is worth noting that States, in addition to CMS, must staff and resource this initiative appropriately. In order to help ensure States give appropriate priority to T-MSIS, CMS has conveyed the importance of T-MSIS in quarterly meetings with State Medicaid Directors, as well as other communications with them. In terms of the Federal resources devoted to this initiative, Administrator Verma supported increased funding for contractor resources to bolster support for Medicaid and CHIP IT investments, data analytics, data quality oversight, and technical assistance to states. In Fiscal Year 2018, CMS has obligated

$15 million in contract funding to support development, operations and maintenance efforts, as well as state technical assistance. CMS expects to maintain a strong commitment in this area.

4. **MACPAC and CMS have highlighted research that shows that patients enrolled in Medicaid have a higher risk of opioid overdose than patients covered by other payers. As a physician, I understand many Medicaid patients may have chronic conditions and long- term pain that can skew what the data looks like. I believe CMS and states share my concern over the vulnerability of Medicaid patients emphasized in these reports. Can you explain what CMS is doing to conduct oversight of state Medicaid programs and partner with them to drill down on the areas of vulnerability and protect patients who may be at risk of opioid misuse or overdose?**

Answer: While the Federal government establishes general guidelines for Medicaid, states design, implement and administer their own programs. States are required to report on their providers' prescribing patterns, including prescription opioids, as part of the Medicaid Drug Utilization Review (DUR) program. This is a two-phase process that is conducted by the state Medicaid agencies. During the first phase, (prospective DUR), the state agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, contraindications, incorrect dosage, and clinical misuse or abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care.

The President's FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

5. **The Medicaid PARTNERSHIP Act will allow state flexibility in how states design their PDMP programs. However, it also ensures that PDMPS are a part of Medicaid provider's clinical workflow, which is critically important, given that a 2014 national survey "found that 53 percent of primary care physicians used their state's program at least once, but that many did not use it routinely." If more physicians and pharmacists were checking the PDMP would you expect the number of unsafe prescriptions of opioids to decrease?**

Answer: PDMPs can certainly play an important role in the response to the opioid crisis. In 2016, forty-nine states (98%) reported having a PDMP in their state. Twenty-six states (53%) have some ability to query the PDMP database, while the remaining twenty-three states (47%) do not have the ability to do so. Only 13 states (27%) require that prescribers access the patient history in the database prior to prescribing restricted (controlled) substances. As of the close of this reporting period, Missouri reported to be the only state that was not implementing a PDMP, although in July 2017 the Governor signed an executive order to implement a PDMP. While 19 states (39%) report that they also have access to Border States PDMPs, thirty-six states (73%) indicated that they face a range of barriers that hinder their ability to fully access and utilize the

database to curb abuse.[3]

There is evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry[4], with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the implementation of its PDMP, New York saw a 75 percent decrease from 2012 to 2013, in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs.[5]

The CMS Quality Improvement Organization (QIO) Program has made an effort to record and post information about individual state PDMPs. The purpose of these short recordings is to promote use and increase understanding of the similarities and differences between state PDMPs.[6]

6. **Representative Tonko's bill would allow states to use federal Medicaid dollars to pay for treatment of prisoners 30-days prior to release back into the community. So, for example an inmate with substance use disorder Medicaid would pay for the first Vivitrol shot and subsequent shots would be given after release. I understand that the incarcerated population needs to be part of our opioid discussion, but I am worried about states just shifting costs to CMS. It seems like we can do better coordination under current law, without spending billions of Medicaid dollars more on prisoners. For example, Pennsylvania has a program where the state Department of Corrections pays for the first shot of Vivitrol and then after release, if the inmate is eligible for Medicaid, Medicaid picks up the costs for subsequent shots. If Pennsylvania can figure out how to do this, why can't other states under current law?**

7. **There are currently non-incarcerated people who may be low-income and uninsured, and some may even be Medicaid eligible. For example, a study in San Diego concluded that nearly 80% of more than 13,000 uninsured patients in in hospital emergency departments over 11 months were eligible for some form of government insurance. Shouldn't we prioritize non-criminals first? Wouldn't it make sense to prioritize a low-income, but uninsured group and help facilitate their enrollment into Medicaid first?**

Answer to #6 and #7: CMS is committed to making sure patients get the right care, in the right setting. We are also committed to working with states to find innovative and efficient ways to provide care to those eligible for Medicaid coverage. States need the flexibility to operate their Medicaid programs in the way that best meets their needs. CMS is willing to work with

[3] https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf
[4] https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank
[5] https://www.cdc.gov/drugoverdose/policy/successes.html
[6] https://qioprogram.org/prescription-drug-monitoring-program-state-videos

interested states to help them share best practices and offer better guidance around these issues, and we look forward to continuing to work with you and the Committee on possible solutions.

8. **Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid-related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study (which I would like to submit for the record), "reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies." I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR bill for example. Does the Administration believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?**

Answer: This Administration agrees that reducing the number of unsafe prescriptions of opioids is an important part of combatting the opioid crisis. Last month, President Trump highlighted the Administration's commitment to tackling the opioid crisis by announcing a goal of cutting the number of opioid prescription fills by one-third within three years.[7]

To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize several medical management techniques, including quantity limits. As of FY 2016, thirty-seven states have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and thirty-nine states have similar edits in place to limit the quantity of long-acting opioids.[8] To increase oversight of certain prescription opioids, states have the option of amending their Preferred Drug Lists and Non-Preferred Drug Lists to require prior authorization for certain opioids. In addition, the President's FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

There is also evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry[9], with limited exceptions. The mandatory duty to consult the PDMP affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the

[7] https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/

[8] https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf

[9] https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank

implementation of its PDMP, New York saw a 75 percent decrease from 2012 to 2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs[10].

Lock-in programs are one of many valuable tools available to states in their efforts to address the opioid epidemic and could also be valuable for Medicaid managed care programs. Under current law[11], states are able to implement lock-in requirements for enrollees who have utilized Medicaid services at a frequency or amount that is not medically necessary, according to guidelines established by the state. These limitations may be imposed for "a reasonable period of time." Almost all Medicaid agencies have a Lock-In or Patient Review and Restriction Program in which the state identifies potential fraud or misuse of controlled drugs by a beneficiary.

CMS is happy to work with the Committee and provide technical assistance on the legislation you are considering.

9. Last fall, CMS released its 2016 Drug Utilization Review report. The report noted that 26 Medicaid agencies have access to PDMP data. States can use PDMP data to manage the overutilization of opioids and detect fraud, waste, and abuse. On the other hand, 23 state Medicaid agencies report that they do not have access to PDMP data. Given how some states have seen PDMPs help protect patients and reduce reliance on opioids, I think that this bill helps those states equip the Medicaid agency with an important tool that can be used to fight this epidemic. Can you describe how Medicaid agency officials would use PDMP data to combat opioids?

Answer: PDMPs are one of many valuable tools available to states in their efforts to address the opioid epidemic. Currently, 49 States have implemented a PDMP, and 13 States require prescribers to check the PDMP before prescribing controlled substances. We encourage States and providers to take advantage of these programs, and we are making efforts to improve the interoperability of these valuable programs.

States which allow Medicaid programs to access PDMP data may enhance the states' drug utilization review program oversight activities. Successful collaborative initiatives to reduce prescription opioid abuse in Oklahoma and Washington included promoting full access to PDMP data for monitoring and data research purposes.

There is also evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry[12], with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the implementation of its PDMP, New York saw a 75 percent decrease from 2012 to

[10] https://www.cdc.gov/drugoverdose/policy/successes.html
[11] 42 CFR 431.54(e)
[12] https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank

2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs[13].

10. I have a question pertaining to the Medicaid Pharmacy Home Act, which requires states to have a provider/pharmacy assignment program for patients whom the state identifies as potentially misusing or abusing controlled drugs. In 2012, CMS highlighted the importance of these "lock-in" programs as an element of a robust state Medicaid controlled prescription drug program. This past October, CMS released its annual Drug Utilization Review report. The report notes that while 48 states are currently using lock- in programs, some states make lock-in programs optional for managed care organizations. Lock-in programs are effective in reducing overprescribing and in states like Pennsylvania and New York the program has resulted in reducing patient harm and saved money due to curbing unnecessary utilization. The Pharmacy Home Act codifies a requirement that requires Medicaid managed care plans have a similar program. Can you think of a reason why managed care organizations should not be asked to use this important tool?

11. I want to address a point that my colleague brought up about lock-in programs being used to theoretically deny Medicaid beneficiaries prescription drugs they need or restrict access. Not only do I see that the bill exempts populations for the program such as beneficiaries in hospice, but I am aware of a 2016 Pew Charitable Trust Report which showed that 38 of 41 states surveyed operate a similar program. If lock-in programs really are meant to restrict access and deny people drugs they medically need, why is it that both Republican and Democratic states are using them? I think such critiques are misleading smokescreens. We are here to adopt proven technological solutions that help protect patients and ensure they get the care they need. If members and stakeholders want to be thoughtful and have constructive improvements to the draft proposal, we certainly welcome them.

Answer to #10 and #11: Under current law[14], states are able to implement lock-in requirements for enrollees who have utilized Medicaid services at a frequency or amount that is not medically necessary, according to guidelines established by the state. These limitations may be imposed for "a reasonable period of time." Almost all Medicaid agencies have a Lock-In or Patient Review and Restriction Program in which the state identifies potential fraud or misuse of controlled drugs by a beneficiary.

Lock-in programs are one of many valuable tools available to states in their efforts to address the opioid epidemic and could also be valuable for Medicaid managed care programs. The President's FY 2019 Budget includes a proposal that would allow CMS to make lock-in programs mandatory within the Medicare Part D program.

12. In your testimony, you discussed Medicare's Overutilization Monitoring Program which helps plans identify at-risk beneficiaries so plans can take appropriate clinical steps to prevent opioid misuse or overdoses. Does this program also share this data

[13] https://www.cdc.gov/drugoverdose/policy/successes.html
[14] 42 CFR 431.54(e)

with state Medicaid programs so they can ensure the best care for beneficiaries who are dually enrolled in Medicare and Medicaid?

a. If yes, can you explain how the process works to get this information to state programs and how quickly this process works?
b. If no, can you please have your staff look into the feasibility of sharing this data with state programs and get back with the Committee?

Answer: Each Medicaid drug management program has its own criteria and requirements for reviewing and addressing recipients who may be at-risk for prescription drug abuse or misuse and its own interventions. Furthermore, Medicaid programs are not required to comply with section 1860D-4(c)(5) as Part D drug management programs are.
Currently, Medicare's Overutilization Monitoring System does not provide information to state Medicaid programs. However, we are always looking for ways to improve the coordination of care between beneficiaries who are dually enrolled in Medicare and Medicaid. To date, states have not requested this information from us. State Prescription Drug Monitoring Programs likely include much of the same information.

13. In your testimony, you describe how Medicare Part D plans receive the quarterly pharmacy risk assessments which list pharmacies identified by CMS at high risk. Does CMS also share this data with state Medicaid programs to help ensure the best care for patients who are dually enrolled in Medicare and Medicaid?

a. If not, would CMS be willing to look at how it might be possible to share this data with state programs and get back with the Committee?

Answer: Pharmacy Risk Assessments, provided quarterly to Medicare Part D plans by the Medicare Drug Integrity Contractor (MEDIC), are not currently provided to state Medicaid programs because there could be privacy and security concerns related to sharing the content of these assessments with all state Medicaid programs. However, we are always looking for ways to improve the coordination of care between beneficiaries who are dually enrolled in Medicare and Medicaid.

14. The National Association of Boards of Pharmacy reports that 39 states already mandate use of PDMPs. What has your experience been in using PDMPs to combat the opioid crisis? What is your sense on how providers and dispensers view the usefulness of PDMPs?

Answer: PDMPs are one of many valuable tools available to states in their efforts to address the opioid epidemic. Currently, 49 States have a PDMP, and 13 States require prescribers to check the PDMP before prescribing controlled substances. We encourage States and providers to take advantage of these programs, and we are making efforts to improve the interoperability of these valuable programs.

Many States have seen promising results from the use of PDMPs. For example, in New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a

mandatory duty to consult the Prescription Monitoring Program Registry[15], with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the implementation of its PDMP efforts, New York saw a 75 percent decrease from 2012 to 2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs.[16]

The CMS Quality Improvement Organization (QIO) Program has made an effort to record and post information about individual state PDMPs. The purpose of these short recordings is to promote use and increase understanding of the similarities and differences between state PDMPs.[17]

15. **Numerous studies have found that Medicaid enrollees have excessive burdens of chronic pain and are at a much higher risk of substance use disorders compared to populations with other types of insurance. Similar studies have found that Medicaid enrollees are thus at heightened risk for prescription opioid misuse and were five to six times as likely to die from opioid-related overdose compared to populations with other types of insurance. Because of this, according to the authors of one such study, which I quote: "reducing the number of unsafe prescriptions of opioids in the Medicaid population should be a priority for any drug control policies." I believe that we have several bills before us today that will help achieve that goal. Our Pharmacy Home Bill, our PDMP Bill, and our DUR bill for example. Do you believe that these policies will help to advance the important goal of reducing the number of opioids in the Medicaid population?**

Answer: This Administration agrees that reducing the number of unsafe prescriptions of opioids is an important part of combatting the opioid crisis. Last month, President Trump highlighted the Administration's commitment to tackling the opioid crisis by announcing a goal of cutting the number of opioid prescription fills by one-third within three years.[18]

To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize several medical management techniques, including quantity limits. As of FY 2016, thirty-seven states have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and thirty-nine states have similar edits in place to limit the quantity of long-acting opioids. To increase oversight of certain prescription opioids, states have the option of amending their Preferred Drug Lists and Non-Preferred Drug Lists to require prior authorization for certain opioids. In addition, the President's FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase

[15] https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank
[16] https://www.cdc.gov/drugoverdose/policy/successes.html
[17] https://qioprogram.org/prescription-drug-monitoring-program-state-videos
[18] https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/

oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

There is also evidence that use of a PDMP can reduce potentially problematic prescribing. In New York State, all prescribers writing a prescription for a Schedule II-IV controlled substance have a mandatory duty to consult the Prescription Monitoring Program Registry[19], with limited exceptions. The mandatory duty to consult the PDMP provision affords practitioners with current, patient-specific controlled substance prescription information intended to inform the practitioner of controlled substance utilization by their patient at the point of prescribing. Following the implementation of its PDMP, New York saw a 75 percent decrease from 2012 to 2013 in the number of patients who use multiple prescribers and pharmacies for controlled prescription drugs[20].

Lock-in programs are one of many valuable tools available to states in their efforts to address the opioid epidemic and could also be valuable for Medicaid managed care programs. Under current law[21], states are able to implement lock-in requirements for enrollees who have utilized Medicaid services at a frequency or amount that is not medically necessary, according to guidelines established by the state. These limitations may be imposed for "a reasonable period of time." Almost all Medicaid agencies have a Lock-In or Patient Review and Restriction Program in which the state identifies potential fraud or misuse of controlled drugs by a beneficiary.

CMS is happy to work with the Committee and provide technical assistance on the legislation you are considering.

16. The Medicaid HUMAN CAPITAL Act would provide enhanced funding for states to recruit highly-experienced Medicaid directors, Chief Information Officers, and Chief Financial Officers. In Mr. Douglas's testimony, he discusses the importance of strengthening Medicaid's role as a payer in combatting opioid misuse. He notes "Congress should implement policies that support state recruitment and retention of strong Medicaid executive leadership," because as he explains, a stable and strong state leadership will be best equipped to respond to the opioid crisis and further public health crises." In your opinion, is it helpful to improving Medicaid's role in addressing the opioid epidemic and other public health challenges by helping states secure the most talented, innovative, and experienced leadership possible?

Answer: In order to have a well-run Medicaid program, states need to have good staff, and we appreciate the great work being done by our state partners. Every state is different, and CMS has typically deferred to states to determine the incentives that would be most appropriate for recruiting and retaining staff.

17. I am interested in the draft that proposes a demonstration project to increase provider capacity in Medicaid for treating substance use disorder. States could apply to use the funds to recruit or train current or new providers. However, I do

[19] https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/#_blank
[20] https://www.cdc.gov/drugoverdose/policy/successes.html
[21] 42 CFR 431.54(e)

have several concerns with the idea. Given all the funds that Congress has authorized to support provider capacity such as GME as well as grants from HRSA, SAMSHA, and CDC. Is this idea duplicative? I am also unclear why we would start a new program when those are well established and have staff that understand workforce capacity. Can you comment on that?

Answer: One of the core components in our efforts to address the opioid epidemic is making sure beneficiaries have adequate access to treatment. We have already approved several substance use disorder demonstration projects and in order to bolster States' flexibility and we are actively encouraging more states to apply.

Effectively combatting the opioid crisis will require collaboration across the Federal government. The goal should be to establish collaborative, complementary roles while avoiding duplication and overlap. CMS is committed to working with our partners across HHS, the Administration, and Congress to address this epidemic.

The Honorable Leonard Lance

1. **The 2019 Call Letter states that Part D beneficiaries with cancer-related pain are excluded from the 'Overutilization Monitoring System.' Can you please clarify how CMS intends to also exclude patients diagnosed with conditions beyond cancer but that are cancer-like in their association with extreme pain?**

Answer: Through rulemaking (CMS-4182-F), CMS finalized regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) to further reduce the number of beneficiaries who may potentially misuse or overdose on opioids while still having access to important treatment options. The final approach builds on and integrates with the Overutilization Monitoring System (OMS), as also discussed in the 2019 Call Letter.

Through this final rule, CMS has established a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries." Specifically, under drug management programs, Part D plans will engage in case management of potential at-risk beneficiaries, through contact with their prescribers, when such beneficiary is found to be taking a specific dosage of opioids and/or obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Sponsors may then limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" to a selected prescriber(s) and/or network pharmacy(ies) or through beneficiary-specific claim edits after case management with the prescribers for the safety of the enrollee.

CMS developed clinical guidelines with stakeholder input that will be used to identify potential at-risk beneficiaries. The clinical guidelines for 2019 are expanded OMS criteria, which take into consideration the level of opioids used and the number of opioid prescribers and opioid dispensing pharmacies.

Also, we finalized the definition for exempted beneficiary: An exempted beneficiary, with respect to a drug management program, will mean an enrollee who: (1) has elected to receive hospice care or is receiving palliative or end-of-life care; (2) is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) is being treated for active cancer-related pain.

CMS will report potential at-risk beneficiaries who meet the minimum criteria of the clinical guidelines to sponsors through the OMS. To the extent CMS data shows a beneficiary meeting the exclusion criteria, they would not be listed in the OMS report. Sponsors may have more current data or obtain information through the case management and notification processes to further exempt beneficiaries. The case management process may also identify other beneficiaries with extreme pain due to other conditions where the prescriber asserts that the use is medically necessary, including patients diagnosed with conditions beyond cancer but that are cancer-like in their association with extreme pain if deemed medically necessary. These beneficiaries would not be subject to a limitation on access to coverage for frequently abused drugs.