Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorders"
March 3, 2020

Kimberly Brandt
Principal Deputy Administrator for Policy & Operations
Centers for Medicare & Medicaid Services

The Honorable Frank Pallone, Jr. (D-NJ)

1. **A 2018 study showed that, despite being required by federal law, 40 percent of states may not provide Medicaid coverage for certain medication-assisted treatment (MAT) formats, such as injectable and implantable formats. According to the Government Accountability Office (GAO) report, the Centers for Medicare & Medicaid Services (CMS) has not investigated compliance of state Medicaid programs with federal requirements regarding MAT medications. The GAO report recommends that CMS investigate and ensure compliance of state Medicaid programs with federal requirements to cover MAT medications, and CMS concurred with this recommendation.** ***What is CMS doing to ensure that states are complying with federal law regarding Medicaid coverage for MAT?***

Response: CMS is committed to combating the opioid epidemic and ensuring that Medicaid beneficiaries have access to the Medication-Assisted Treatment (MAT) they need. All states reimburse for some form of medications for MAT. A review of Medicaid policies and data revealed that all states reimburse some form of buprenorphine, buprenorphine/naloxone for the treatment of opioid use disorder (OUD), oral naltrexone, and extended-release naltrexone, which can be used for the treatment of OUD or Alcohol Use Disorder (AUD), and that most states cover disulfiram and acamprosate for the treatment of AUD. Some states also reimburse for Medicaid covered services provided by opioid treatment program (OTP) providers, including reimbursement for buprenorphine and naltrexone.

States that offer the optional prescription drug benefit are currently required to cover all MAT drugs that meet the definition of "covered outpatient drug" and states will be required to cover all forms of MAT under a new mandatory benefit category beginning October 1, 2020. This provision will require coverage of methadone dispensed or administered by an OTP. This is required under section 1006(b) of the SUPPORT for Patients and Communities Act, signed into law on October 24, 2018, which amended sections 1902(a)(10) and 1905 of the Social Security Act to require state Medicaid plans to include coverage for MAT for categorically needy populations for the period beginning October 1, 2020, and ending September 30, 2025. Section 1006(b) requires coverage of all FDA-approved drugs, including methadone, and all FDA-licensed biological products to treat opioid use disorders, and all related counseling services and

behavioral therapy. To assist states in implementing this provision of the SUPPORT Act, CMS expects to release guidance for states on the new required benefit later this year.

The Medicaid Drug Rebate Program (MDRP) is a program that includes the Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and participating drug manufacturers that helps to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Under the MDRP, a drug manufacturer must enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. This requirement also applies to FDA approved drugs used for MAT provided the drug meets the definition of a "covered outpatient drug." Therefore, as with any other drug, if an MAT drug is labeled by a manufacturer that has signed a Medicaid National Drug Rebate Agreement, and the drug meets the definition of covered outpatient drug, then the drug is covered by the MDRP and is to be covered by state Medicaid programs. It should be noted, however, that states can use utilization management mechanisms such as prior authorization to assure appropriate use of covered outpatient medications. Medicaid drug coverage policies vary from state-to-state. For example, injectable drugs indicated for administration by a healthcare professional may be covered under the medical benefit in one state and through the pharmacy benefit in another.

CMS has also created a comprehensive approach to combat the opioid crisis that focuses on prevention, treatment, and data. In November 2017, CMS issued a State Medicaid Director Letter (SMDL) authorizing states to apply for 1115 waivers to receive federal financial participation for the continuum of services to treat addiction to opioids and other substances, including services provided to Medicaid enrollees residing in facilities that qualify as institutions for mental diseases, subject to CMS approval.[1] These SUD demonstrations often require that states take action to improve access to MAT in those settings as well as throughout their states. As of March 3, 2020, CMS had approved 1115 SUD demonstrations for 27 states and the District of Columbia.

Section 1003 of the SUPPORT Act requires CMS to conduct a demonstration project to increase SUD provider capacity. Consistent with this section, as well as in an effort to expand access to SUD treatment (including MAT) and/or recovery support services, CMS has awarded planning grants to 15 states to increase the capacity of Medicaid providers to provide these SUD treatment and recovery support services. These planning grants were awarded in September 2019 and are available for an 18-month period for states' initial assessment of the behavioral health treatment and recovery support needs of their state and to determine the extent to which providers are needed to address the SUD treatment and recovery support needs of Medicaid beneficiaries (including the types of such providers, geographic area of need, and sources of state data) in their states.

[1] *See* SMDL #17-003, *Re: Strategies to Address the Opioid Epidemic*, available at https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17003.pdf.

2. **One of the requirements of the SUPPORT Act was for Medicaid and CHIP Payment and Access Commission (MACPAC) to study how state utilization management policies may affect access to medication-assisted treatment, or MAT. MACPAC found a wide variation in state utilization management policies, but that it was difficult to assess the impact of these policies on access. It also found that utilization management for MAT may be more stringent than for other forms of treatment because of concerns about diverting controlled substances.** ***Can you tell us what, if any, efforts are underway at CMS to assess whether Medicaid utilization management practices delay access to care? Does CMS have plans to issue guidance or technical assistance to states to address their concerns about diversion while also ensuring beneficiaries have access to the treatment they need?***

Response: There is strong evidence that MAT provides substantial cost savings and leads to improved quality of life and health outcomes for individuals with SUDs. Many state Medicaid programs have implemented policies, such as prior authorization requirements, to help manage the prescribing and distribution of many medications, including medications used to treat SUD, as well as delivery of evidence-based behavioral therapies. HHS is committed to working with states to ensure MAT coverage policies do not inappropriately impact beneficiary access while also effectively reinforcing program integrity and clinically appropriate use of therapies.

As part of these efforts to monitor state policies, states are required, on an annual basis, to report on their Drug Utilization Review (DUR) programs, including on the nature and scope of their program interventions and operations and their adoption of new innovative DUR practices via the Medicaid Drug Utilization Review Annual Report Survey. In FY 2018, 28 states and the District of Columbia reported the adoption of innovative DUR practices, including dashboards, educational resources for beneficiaries, and provider outreach programs. Additionally, we are working to develop a proposed rule which would require minimum standards in Medicaid State Drug Utilization Review (DUR) programs, in part to help increase oversight of opioid prescriptions/dispensing in Medicaid.

Section 1004 of the SUPPORT Act also established drug utilization review standards to supplement existing requirements under section 1927(g) of the Social Security Act, in an effort to reduce opioid-related fraud, abuse, and misuse, and to expand existing DUR requirements. New requirements added by section 1004 of the SUPPORT Act include:

- Opioid prescription safety edits at the point of sale (POS) including automated claim reviews for subsequent opioid fills and fills exceeding state-specified maximum Morphine Milligram Equivalent levels
- Monitoring for co-prescribing of opioids and benzodiazepines and opioids and antipsychotics
- Monitoring and management of antipsychotic medication in children
- Identification of processes to detect fraud and abuse
- State Plan Amendment submission to provide for state compliance with the new DUR requirements
- Reporting of activities carried out annually via inclusion in the state's yearly DUR report already submitted pursuant to section 1927(g) of the Social Security Act.

Section 1004 of the SUPPORT Act required all states to implement the requirements outlined above by October 1, 2019, and to submit an amendment to their state plan no later than December 31, 2019 in order to describe how the state plans to address these provisions. In an effort to assist states in meeting this requirement, CMS issued guidance to states on August 5, 2019. The guidance may be accessed here: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib080519-1004.pdf. To date, all states have submitted an amendment to their state plan to describe how the state plans to address the new DUR requirements.

CMS has also created an Opioid Steering Committee, composed of CMS senior leadership and staff, to help coordinate opioid policy across the agency. Its meetings have included discussions about reducing barriers related to prior authorization and other utilization management practices, where appropriate, and implementation of the SUPPORT Act. Additionally, one of the State Opioid workshops organized by CMS focused specifically on MAT, including states' approaches to improving the availability and use of MAT through benefit, payment, and system design.

3. **Distribution methods of MATs are decided by the states. In some cases, to ensure immediate access for Medicaid beneficiaries, providers are required to purchase and store medications until administered. However, with injectable treatments costing as much as $1,200 per treatment, keeping a stock of MATs becomes a financial risk for providers, especially for smaller medical practices. Some state Medicaid policies restrict providers from choosing their alternative distribution methods (such as through a specialty pharmacy), though some states have removed such restrictions, leading to increased access. *Has CMS examined this issue and the impact it may have on access to treatment for Medicaid beneficiaries?***

Response: CMS is committed to ensuring Medicaid beneficiaries have access to the MAT they need.

Through technical assistance and support programs such as the State Opioid Workshop, which has provided state officials with the opportunity to share innovative practices designed to improve access to SUD treatment, we can help states to effectively design, deliver and pay for services to treat SUD for Medicaid beneficiaries. Additionally, the committee may also wish to confer with the Drug Enforcement Administration concerning how it regulates distribution and storage of controlled substances used for MAT.

The Honorable Michael C. Burgess (R-TX)

1. **Ms. Brandt, Section 5042 of the SUPPORT Act included the Medicaid Providers Are Required to Note Experiences in Record Systems to Help In-need Patients Act (better known as the Medicaid PARTNERSHIP Act). Beginning on October 1, 2021, the provision requires states to have a "qualified" prescription drug monitoring program (or PDMP) and for certain Medicaid providers to check the PDMP before prescribing a**

controlled substance to a beneficiary. To ensure states are prepared to comply with the requirement and to ease the burden for providers, we allowed states to claim 100 percent federal Medicaid matching funds during FY19 and FY20 for the costs related to ensuring the PDMP is "qualified."

A. With FY20 almost halfway over, can you tell me how many states have applied and been approved for the enhanced Medicaid matching funds for PDMP improvements?

a. What is the average amount that states are being approved for?

2. What are the guardrails or criteria that CMS is using when evaluating states' advance planning documents (APDs) to ensure states are strictly using these funds as Congress intended in Section 5042?

a. Anecdotally, we have heard that one state was approved for well over $40 million for a wide variety of health IT expenses, which I think is far more than Congress anticipated it would cost to get a state PDMP to the point where it is considered "qualified."

Response to 1-2: Under section 1944 of the Social Security Act, which was added by section 5042 of the SUPPORT Act, beginning October 1, 2021, states must have a qualified prescription drug monitoring program (PDMP) and must require that certain Medicaid providers check information about certain Medicaid beneficiaries' prescription drug history in the qualified PDMP before prescribing controlled substances to the beneficiary. Section 1944(f) of the Social Security Act also establishes a 100 percent federal matching percentage for fiscal years 2019 and 2020 for state expenditures to design, develop, or implement a qualified PDMP and to make connections to the qualified PDMP. In May 2019, CMS issued guidance for states on how to implement these new requirements and claim the 100 percent federal Medicaid matching funds.[2]

For the 100 percent federal matching percentage to apply, the PDMP must be qualified, which means it must satisfy the criteria described in sections 1944(b)(1) and (2) of the Social Security Act. Additionally, the state must have agreements in place with all contiguous states to share certain qualified PDMP data consistent with section 1944(f)(2) of the Social Security Act. A qualified PDMP must meet the following criteria:

1. The PDMP must facilitate access by covered providers to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible:
    a) Information regarding the prescription drug history of a covered individual with respect to controlled substances.
    b) The number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period.
    c) The name, location, and contact information of each covered provider who prescribed a controlled substance to the covered individual during at least the most recent 12-month period.

[2] Guidance available at: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/faq051519.pdf

2. The PDMP must also facilitate the integration of the information described in (1) into the workflow of a covered provider, which may include the provider's electronic prescribing system for controlled substances.

State expenditures on a qualified PDMP that can be matched at 100 percent could include expenditures on certain PDMP features that, in CMS's view, are consistent with the SUPPORT Act's description of qualified PDMPs. For example, potential expenditures, subject to CMS review, might include state expenditures to design, develop, or implement upgrades to the functionality of a state's current PDMP, to ensure that it meets the statutory definition of a "qualified" PDMP. CMS will not, however, match state expenditures on provider-administered or provider-owned systems under section 1944(f) of the Social Security Act. Section 1944 clearly requires that, to be federally matched at 100 percent, expenditures must be a state's expenditures on a PDMP administered by the state.

To make sure states are meeting all of the requirements included in section 1944 of the Social Security Act and are truly eligible for the enhanced match rate, CMS requires applications to, at a minimum:

- Include State's Requests for Proposals (RFPs) (HHS sole source requirements and guidance may apply), contracts, IAPDs, or other documentation (as applicable) to demonstrate that the system will be a qualified PDMP as defined in 1944(b) of the Social Security Act, because it will facilitate access by a covered provider to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible:
    - Information regarding the prescription drug history of a covered individual with respect to controlled substances.
    - The number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period (note that data on "prescribed" medication and "filled" medication may be two data sources).
    - The name, location, and contact information (or other identifying number selected by the state, such as a national provider identifier issued by the CMS National Plan and Provider Enumeration System) of each covered provider who prescribed a controlled substance to the covered individual during at least the most recent 12-month period.
- Demonstrate that the qualified PDMP will facilitate the integration of the information described above into the workflow of covered providers, which may include the provider's electronic prescribing system for controlled substances.
- Demonstrate that the state has documented that it has in place agreements with all contiguous states that meet the criteria described in section 1944(f)(2) of the Social Security Act, or has submitted preliminary information about these agreements and attested that the agreements will be in effect before the state claims any enhanced federal matching funds under section 1944(f) of the Social Security Act.

To date, 14 states have received approval from CMS for enhanced Medicaid matching funds for PDMP improvements. The average approval is just over $11 million, with the majority of states being approved for amounts ranging from $2 million to $5 million. It should be noted that several states that received higher Medicaid matching funds have used these funds to make technology investments that may benefit other states as well, including investments in a data hub

for PDMP data, which could allow prescribers to check the prescriptions their patients have received in other states.

The Honorable Gus M. Bilirakis (R-FL)

1. ***Ms. Brandt – Considering the incredible potential for continuous monitoring of patients taking opioids to save lives and billions of dollars for Medicare, is CMS considering continuous monitoring as a standard of care for all patients taking opioids in the hospital?***

    A. ***Would CMS support a federal study examining the cost benefit of continuous monitoring for all patients taking opioids in the hospital?***

Response: Opioids have been the cornerstone therapy used for the management of post-operative moderate and severe pain. But as with all medications, they are accompanied by potential complications or adverse reactions. It is well accepted that opioids increase the risk of post-operative respiratory depression in certain populations (e.g. those who are obese, or have sleep apnea), but more healthcare and training institutions are promoting anesthesia without opioids and analgesia as a way to reduce complications—including respiratory depression—for all populations.

In 2014, CMS issued a Survey and Certification Memorandum to update guidance for hospital medication administration requirements which reflect the need for patient risk assessment and appropriate monitoring during and after medication administration, particularly for post-operative patient receiving intravenous (IV) opioid medications. The guidance states that hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-15.pdf). Hospitals must have policies and procedures related to the use of high-alert medications, such as IV opioids for post-operative patients, that include the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods.

This memorandum also includes a discussion of recommendations of patient safety organizations for best practices related to the use of IV opioid medications, including sedation assessment, frequency of monitoring and use of technology-supported monitoring, such as continuous pulse oximetry and/or capnography linked to clinical staff notification devices. These recommendations were highlighted in the guidance in what is called “blue boxes”. Although adoption of these “blue box” best practices is not required, hospitals are strongly encouraged to review these practices and consider whether to adopt them. Each patient’s situation is unique and hospitals and physicians are best suited to determine the appropriate monitoring needed.

If surveyors find that a hospital does not have adequate policies and procedures on the use and monitoring of high-alert medication, the hospital could be cited for a deficiency under the survey, and the hospital would be required to address this deficiency.

The Honorable Larry Bucshon (R-IN)

1. **A crucial tool available to the federal government to curtail the opioid epidemic and prevent addiction is to encourage access to safe and effective opioid alternatives to manage acute and chronic pain. Even though some alternatives, such as high frequency spinal cord stimulation, have been shown to reduce opioid usage by nearly 70%, current Medicare policies make it difficult or financially disadvantageous for hospitals to offer these alternatives to patients. As you know, Section 6082 of the SUPPORT for Patients and Communities Act (PL No: 115-271) passed in October 2018 directed CMS to review and adjust Medicare payment for evidence-based non-opioid therapies (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) by January 1, 2020, with a goal of correcting any misaligned payment incentives that incentivize the use of opioids over appropriate alternatives. I remain both concerned and disappointed that the agency declined to make payment adjustments for any therapies proven to reduce opioids and concurrently reduce pain in your 2019 and 2020 Hospital Outpatient Prospective Payment System (OPPS) rulemakings, and made a payment adjustment for only one therapy in the ambulatory surgical care setting.**

   In the CY2020 OPPS Final Rule, CMS stated that they "have not found compelling evidence for other non-opioid pain management alternatives to warrant separate payment." I am aware that at least some prospective, published, peer-reviewed studies were, in fact, submitted by stakeholders.

   A. What is the level of evidence that CMS requires to be found "compelling"?

      a. **Transparency is required to ensure that stakeholders have a meaningful opportunity to comment on CMS' review. I urge CMS to create a clear standard that would remove barriers to accessing alternatives to opioids. The statute has been effective for almost a year and a half and CMS has proceeded through a proposed rule and two final rules, but has failed to articulate a reasonable or appropriate standard consistent with the statute.**

Response: Better pain management is one of the five pillars included in HHS's 5-Point Strategy to respond to the opioid crisis, and CMS has taken a number of steps towards achieving this goal. For example, in January, CMS finalized a decision to cover acupuncture for Medicare patients with chronic low back pain. Acupuncture is a treatment in which practitioners stimulate specific points on the body, most often by inserting thin needles through the skin. As with other complex diseases, CMS recognizes the importance of having treatment options which allow for an integrated approach that is tailored to the needs and preferences of Medicare patients.

Section 6082 of the SUPPORT Act required CMS to review current payment policies for evidence-based non-opioid alternatives for pain management "with a goal of ensuring that there are not financial incentives to use opioids instead," and to revise payment where needed to reduce financial incentives to use opioids instead of non-opioid alternatives for pain management.

As part of its review process, CMS examined peer-reviewed literature and other information submitted from stakeholders as well as Medicare claims data. As stated in the CY 2020 OPPS final rule, evidence that current payment policy provides a payment incentive for using opioids instead of non-opioid alternatives should align with available Medicare claims data.

CMS has already started evaluating our policies and making changes where appropriate. For example, CMS examined the impact of Medicare's bundled payment for all "surgical supplies"—including certain drugs, *such as hospital-administered drug products intended to alleviate postsurgical pain*—on utilization of non-opioid alternatives in both the hospital outpatient department and the ambulatory surgical center (ASC) setting.

We found that in the ASC setting, bundling payments for non-opioid pain management drugs that function as a supply was correlated with decreased utilization of non-opioid alternatives. However, we did not see a similar trend in the hospital outpatient department; in fact, we observed the opposite effect in this setting. These findings, along with stakeholder feedback and other peer-reviewed evidence, informed our decision to finalize a policy beginning in 2019 to pay separately for non-opioid pain management drugs that function as a supply when used in a covered surgical procedure performed in the ASC setting. Additionally, for calendar year 2020, CMS evaluated continuous peripheral nerve blocks and neuromodulation alternatives to determine if the current packaging policy represented a barrier to access. For each product, CMS examined the most recently available Medicare claims data. All of the alternatives examined showed consistent or increasing utilization in recent years, with no products showing decreases in utilization.

CMS will continue to analyze the issue of access to non-opioid alternatives in the hospital outpatient department and the ambulatory surgical center settings for which payment policy should be revised to allow separate payment as appropriate. In addition, CMS provided guidance[3] to states seeking to promote non-opioid options for chronic pain management, and encourages Medicare Advantage plans to consider benefit designs for supplemental benefits that address medically-approved non-opioid pain management and complementary and integrative treatments.[4] CMS also implemented Section 6021 of the SUPPORT Act, by including information on non-opioid pain management in the 2020 Medicare & You Handbook.

2. During the hearing you referenced ongoing work with the HHS Inter-Agency Pain Management and Best Practices Task Force related to the implementation of Sec. 6082. This Task Force was established under the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), and, in the SUPPORT Act, the Task Force was tasked

[3] https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf
[4] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf

with creating an Action Plan under Sec. 6032. The Task Force's Action Plan is, by statute, separate from CMS' mandate to review and adjust payments, as appropriate, under Sec. 6082. While I am encouraged that the Task Force is moving forward, I am concerned that the Task Force's involvement in CMS' review and adjustments of payments, which was not required by Sec. 6082, only serves to further delay meaningful change to remove financial barriers to alternatives to opioids, particularly in light of the fact that CMS has already missed Congress' deadline.

A. Could you please describe the work the Task Force is pursuing, where they are in the process, if there will be opportunity for stakeholder input, and whether it will be completed in time for changes to be made in the CY 2021 OPPS rulemaking?

a. Given the three months that have passed since the date payments should have been adjusted, which follows statutory enactment by almost a year and a half, in addition to the proposed rule and two final rules issued in the meantime, CMS' ongoing failure to articulate a standard is inexcusable.

Response: CMS worked with the HHS Pain Management Best Practices Inter-Agency Task Force (PMTF), a federal advisory committee established by section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (P.L. 114-198), to review available data and to develop criteria for revisions to payment for opioid alternatives that are effective for pain relief or in reducing opioid use. In May 2019, the PMTF published a final report that includes numerous recommendations for agencies across the Administration.[5] We have reviewed the recommendations and will continue to examine ways to incorporate them into our policies when appropriate. In June 2019, CMS held a public meeting with the PMTF to discuss payment and coverage policies for chronic and acute pain, service delivery models, access to therapies and medical devices, and other issues outlined in section 6032 of the SUPPORT Act. The PMTF sunset following that meeting. In September 2019, CMS issued a Request for Information to seek feedback from the public regarding ways for CMS to address the opioid crisis, including payment and coverage policies in Medicare or Medicaid that have enhanced or impeded access to non-opioid treatment of acute or chronic pain. We are in the process of reviewing the responses we received, and we will use them to inform our policies to build an Action Plan that will build upon our efforts in to combat the opioid crisis.

As we work to make our nation's healthcare system work better for patients and the providers who care for them, CMS will continue to listen closely to its many stakeholders. The standard rulemaking process, including for the Medicare Outpatient Prospective Payment System, includes gathering extensive feedback from patients, providers, plans, and other industry stakeholders during a 60-day public comment period. These comments provide critical insight from those who implement our policy changes on the front line, and we take this feedback into consideration in our work across the agency.

The Honorable Markwayne Mullin (R-OK)

[5] Final Report available at: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

1. **Ms. Brandt - The SUPPORT Act included a provision I championed which requires the use of e-prescribing for controlled substances in Medicare Part D. We worked hand in hand with CMS when drafting the law, and per CMS' request, we moved back the implementation date to January 1, 2021, allowing more than enough time for rulemaking or guidance to be developed.**

    A. Can you commit that CMS will be prepared to FULLY implement e-prescribing for prescription opioids, as required by statute, by January 1, 2021?

        a. If the answer is no – why not?

Response: Section 2003 of the SUPPORT Act requires prescriptions for controlled substances covered under Medicare Part D to be submitted electronically by prescribers, unless a waiver applies, by January 1, 2021. We recognize the importance of electronic prescribing of controlled substances (EPCS) and the statutory mandate. CMS is working hard to make sure plans have the resources and support they need to implement these new requirements and we encourage all prescribers to conduct EPCS as soon as is feasible for them. We understand that implementing EPCS takes additional time and resources for prescribers. We also recognize that the current public health emergency for the COVID–19 pandemic presents additional EPCS challenges for some prescribers. As part of the CY 2021 Physician Fee Schedule proposed rule (CMS-1734-P) issued on August 3, 2020, we proposed to require all prescribers to conduct electronic prescribing of Schedule II, III, IV, and V controlled substances under Medicare Part D using the NCPDP SCRIPT 2017071 standard by January 1, 2022, except in circumstances in which the Secretary waives the requirement. We believe that requiring EPCS by January 1, 2022 strikes the balance between not providing too large of a burden on providers and helping ensure that the benefits of EPCS are leveraged expeditiously.

In addition, on July 30, 2020, we issued a Request for Information (RFI) soliciting input from stakeholders around implementation of Section 2003—in particular, whether CMS should include exceptions to the EPCS and under what circumstances, and whether CMS should impose penalties for noncompliance with this mandate in its rulemaking, and what those penalties should be. The RFI seeks input from stakeholders, including prescribers that we do not directly regulate under MA, and/or Part D, and who are not enrolled in Medicare or Medicaid. Requiring EPCS by January 1, 2022 would allow time to receive and consider the important feedback from the RFI that is necessary for implementation of the EPCS requirements.