U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General *Washington, DC 20530*

The Honorable Brett Guthrie
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Guthrie:

Please find enclosed responses to questions arising from the appearance of the Drug Enforcement Administration Deputy Assistant Administrator Matthew Strait before the House Committee on Energy and Commerce Health Subcommittee, on June 21, 2023, at a hearing titled "Responding to America's Overdose Crisis: An Examination of Legislation to Build Upon the SUPPORT Act." We apologize for the delay in providing these responses.

We hope this information is helpful. Please do not hesitate to contact this office if we may provide additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to the submission of this letter from the perspective of the Administration's program.

Sincerely,

Matthew Hanson
Deputy Assistant Attorney General

Enclosure

cc:

The Honorable Larry Bucshon
Vice Chair
House Committee on Energy and Commerce Health Subcommittee
U.S. House of Representatives
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
House Committee on Energy and Commerce Health Subcommittee
U.S. House of Representatives
Washington, DC 20515

Attachment 1—Additional Questions for the Record

The Honorable Earl L. "Buddy" Carter

1. **Question: Mr. Strait, I have been hearing that pharmacies lack clarity around buprenorphine suspicious orders and are limiting their orders, which is affecting patient access at the pharmacy counter. Is DEA aware of this issue and is there any clarity that can be provided around the risk of buprenorphine diversion as compared to other controlled substances such as opioids themselves?**

   Response: DEA is committed to ensuring adequate access to medication for opioid use disorder. As you know, practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result the Consolidated Appropriations Act (CAA) signed by President Biden on December 29, 2022. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823. As a result of this legislation, on November 28, 2023, DEA published the guidance document DEA-DC-078 titled "Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)." This guidance document, among other things, notes that some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation. The guidance further explains that the CAA expanded patient access to medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine than prior to the date the CAA was signed.

   After this guidance was published, DEA sent an email notifying various associations that represent manufacturers and distributors, practitioners, boards of pharmacy, and others of its publication on DEA's website. DEA also posted the guidance on the DEA guidance portal on the Diversion website.

   Additionally, DEA, the Department of Health and Human Services (HHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA) published a joint letter on medications for opioid use disorder (MOUD) in February 2024. DEA, HHS, and SAMHSA are committed to ensuring safe and ready access to MOUD, especially in rural or underserved areas where treatment options have been limited. With the passage of the CAA, there was an immediate and significant increase in the number of practitioners with federal authority to prescribe schedule III MOUD products (e.g., buprenorphine single entity and combination products containing buprenorphine and naloxone) for patients with OUD. As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. In this letter, DEA is asking its registrants to ensure an adequate and uninterrupted supply of MOUD products when appropriately prescribed and asks distributors to examine any quantitative thresholds they established to ensure that individuals with OUD are able to access buprenorphine. Expanding access to MOUD is one

more way to assist patients with OUD during the Opioid Public Health Emergency.

The Honorable Ann Kuster

1. **Question: During your testimony you answered questions about the permanent scheduling of fentanyl related substances. Can you please clarify the Administration's position about scheduling of fentanyl related substances?**

   Response: The permanent class-wide scheduling of fentanyl related substances is DEA's top legislative priority. DEA supports the Biden/Harris legislative proposal transmitted to Congress on September 2, 2021 that would permanently make all unscheduled fentanyl-related substances (FRS) Schedule I drugs with a streamlined process for the Department of Health and Human Services (HHS) to recommend removal or rescheduling of FRS that are subsequently found to not have a high potential for abuse. The emergence of new fentanyl-related substances (FRS) is an on-going threat to Americans. With relative ease, clandestine chemists are able to create new synthetic compounds by simply altering the chemical composition of controlled substances to create new synthetics that have similar opioid effects and potential lethality. The Administration and Congress worked together to temporarily close this loophole by making all fentanyl-related substances Schedule I drugs, which carry additional reporting requirements and penalties. However, this measure expires on December 31, 2024. The Administration has submitted a legislative proposal to permanently schedule FRS to Congress as part of the Biden-Harris Detect and Defeat Proposal[1] and continues to encourage Congress to pass it. Permanent class-wide scheduling of FRS will ensure that the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances can be applied to persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle FRS.

2. **Question: For over a year, the Bureau of Justice Assistance has been developing new guidelines to assist jail administrators, correctional officers, and jail-based clinicians in the detection and management of opioid withdrawal for individuals in custody. What is the status of those guidelines? Will the guidelines include non-pharmacological options/drug-free options that have been approved by the FDA for opioid withdrawal management? If not, why?**

   Response: In June 2023, BJA released the "Guidelines for Managing Substance Withdrawal in Jails: A Tool for Local Government Officials, Jail Administrators, Correctional Officers, and Health Care Professionals" (the Guidelines). The Guidelines were developed in partnership with the National Institute of Corrections (NIC), and in collaboration with Advocates for Human Potential, Inc., the American Society of Addiction Medicine, and the National Commission on Correctional Health Care. BJA and NIC also worked with an expert committee of medical and criminal justice

[1] FACT SHEET: Biden-Harris Administration Announces New Actions to Counter the Scourge of Fentanyl and Other Synthetic Drugs | The White House

professionals, who included addiction specialists, correctional health care providers, and jail administrators, to guide the development process. The Guidelines provide guidance on use of FDA approved pharmacological options for management of opioid withdrawal within correctional settings. It does not provide guidance on non-pharmacological options or potential adjunctive treatments for opioid withdrawal, some of which have received FDA market authorization but not FDA approval, because of concerns that including guidance regarding adjunctive therapies would be misinterpreted as justification to not provide pharmacological options.

DEA respectfully directs any additional questions on these guidelines to the Bureau of Justice Assistance.

The Honorable Paul Tonko

1. **Question: I am thankful for DEA's actions in this space but believe more needs to be done going forward. Regardless of DEA's stated goal to expand buprenorphine access, prior enforcement actions and fear of future investigations are contributing to a reduction in access so multiple and repeated clear communications are warranted even if it seems redundant. When will DEA issue additional guidance that sends a strong message to the community that DEA wants access to addiction medication in every community?**

   Response: DEA is committed to ensuring adequate access to medication for opioid use disorder. As you know, practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result of legislation recently passed by Congress. On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act (CAA), 2023, which included provisions to expand patient access to medications for OUD. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823. The intent of the legislation was to expand patient access to medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine than in previous years.

   On January 20, 2023, DEA published the guidance document DEA-DC-65 titled *DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders*. This guidance document clarifies that neither the Controlled Substance Act (CSA) nor DEA regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can order and dispense.

   On November 28, 2023, DEA published the guidance document DEA-DC-078 titled "Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)." This guidance document, among other

things, notes that some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation.

After this guidance was published, DEA sent an email notifying various associations that represent manufacturers and distributors, practitioners, boards of pharmacy, and others of its publication on DEA's website. DEA also posted the guidance on the DEA guidance portal on the Diversion website. We will continue to reach out and pursue additional opportunities to raise awareness on having medications for OUD available in communities. Moreover, we look forward to working with the Committee on ensuring that distributors, pharmacists, and providers are aware of their role in providing this critical treatment.

Finally, DEA, the Department of Health and Human Services (HHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA) published a joint letter on MOUD in February 2024. DEA, HHS, and SAMHSA are committed to ensuring safe and ready access to MOUD, especially in rural or underserved areas where treatment options have been limited. With the passage of the CAA, there was an immediate and significant increase in the number of practitioners with federal authority to prescribe schedule III MOUD products (e.g., buprenorphine single entity and combination products containing buprenorphine and naloxone) for patients with OUD. As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. In this letter, DEA is asking its registrants to ensure an adequate and uninterrupted supply of MOUD products when appropriately prescribed and asks distributors to examine any quantitative thresholds they established to ensure that individuals with OUD are able to access buprenorphine. Expanding access to MOUD is one more way to assist patients with OUD during the Opioid Public Health Emergency.

2. **Question: Will DEA provide additional clarification to distributors, pharmacists and providers so that they better embrace their role to expand access to addiction treatment?**

Response: DEA is committed to ensuring adequate access to medication for opioid use disorder. On November 28, 2023, DEA published the guidance document DEA-DC-078 - titled "Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)." As you know, practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result of legislation recently passed by Congress. On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act (CAA), which included provisions to expand patient access to medications for OUD. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823. This guidance document, among other things, notes that some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation. The intent of

the legislation was to expand patient access to medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine than in previous years.

After this guidance was published, DEA sent an email notifying various associations that represent manufacturers and distributors, practitioners, boards of pharmacy, and others of its publication on DEA's website. DEA also posted the guidance on the DEA guidance portal on the Diversion website. Moreover, we look forward to working with the Committee on ensuring that distributors, pharmacists, and providers are aware of their role in providing this critical treatment.

Additionally, the joint DEA/HHS/SAMHSA letter on MOUD as noted in the response to question 1 above was a critical effort to ensure DEA registrants understand the Administration's commitment to ensuring access to MOUD to those who need it.

3. **Question: How and when will DEA communicate directly to pharmacies and pharmacists that perceived "limits" should not result in denying a prescription fill as long as the need is legitimate?**

Response: DEA does not establish quantitative thresholds or place limits on the volume of controlled substances, including buprenorphine, that DEA registrants can distribute or order and dispense. Rather, it is important to note that registrants are required to design and operate a system to detect *suspicious orders* of controlled substances including MOUDs. The definition of "suspicious order" may include, but is not limited to, an order of unusual size, an order that deviates substantially from a normal pattern, and an order of unusual frequency. The guidance clarified that the registrants' obligation to report suspicious orders of controlled substances to DEA still applies to MOUDs, but increased quantity alone may not render an order suspicious after giving due consideration to the effect of the CAA.

DEA is committed to ensuring adequate access to medication for opioid use disorder, and has issued a number of guidance documents and letters in this area as noted in the responses to questions 1 and 2 above. On January 20, 2023, DEA published the guidance document DEA-DC-65 titled *DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders*. This guidance document clarifies that neither the Controlled Substance Act (CSA) nor DEA regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can order and dispense.

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provisions to expand patient access to medications for OUD. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823. This guidance document, among other things, notes that some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation. The intent of the legislation was to expand patient access to medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine than in previous years.

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Additionally, the joint DEA/HHS/SAMHSA letter on MOUD as noted in the response to question 1 above was a critical effort to ensure DEA registrants understand the Administration's commitment to ensuring access to MOUD to those who need it.

4. **<u>Question</u>: Given reports of prescribers and patients running into barriers getting buprenorphine prescriptions appropriately filled at pharmacies throughout the country, would the DEA consider issuing guidance encouraging DEA-registered manufacturers or distributors to start separately tracking buprenorphine from other opioids and monitoring it differently since red flags for opioid analgesics may be much less relevant when applied to buprenorphine?**

   <u>Response</u>: DEA is committed to ensuring adequate access to medication for opioid use disorder. On November 28, 2023, DEA published the guidance document DEA-DC-078 titled "Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)." As you know, practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result of legislation recently passed by Congress. On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act (CAA), which included provisions to expand patient access to medications for OUD. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823. This guidance document, among other things, notes that some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation. The intent of the legislation was to expand patient access to medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine than in previous years.

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5. **Question: The combination products have a different risk profile because they contain naloxone. Would DEA consider guidance to distributors allowing them to treat combination products differently?**

   Response: DEA commissioned a report from IQVIA on buprenorphine prescribing trends. The report was completed in September 2024 and is pending clearance for posting on DEA's website. The objectives of this project are to assess trends in buprenorphine treatment before and after January 2023 to evaluate the impact of the waiver removal, and to potentially identify gaps in treatment.

6. **Question: If someone is concerned about reaching a threshold or perceived limit, who can they talk to DEA to seek clarity?**

   Response: DEA registrants and the public can contact their local DEA field office if there is concern on reaching a threshold or perceived limit.

   In addition, DEA is aware of some pharmacies reporting issues obtaining buprenorphine from their distributors, either because the pharmacy order exceeded threshold amounts established by the distributor, or the order was deemed suspicious by the distributor. DEA does not establish quantitative thresholds or place limits on the volume of controlled substances, including buprenorphine, that DEA registrants can distribute or order and dispense. It is also worth noting that the federal Bureau of Prisons facilities have also been advised by distributors of "thresholds" being met and have had to work with distributors.

7. **Question: The DEA issued a proposed rule on suspicious order monitoring over 2 years ago. Does DEA plan to finalize the rule, and if so, when? This rule will provide additional guidance and clarification to registrants and may help with access to buprenorphine.**

   Response: DEA published a Notice of Proposed Rule Making (NPRM) on November 2, 2020. This NPRM had a 60-day public comment period. DEA reopened the comment period on February 25, 2021. DEA has reviewed the public comments and continues to work through the rulemaking process.

8. **Question: Is there a way to provide guidance to distributors allowing them to increase their thresholds by a specific percentage for buprenorphine combination products?**

   Response:

On January 20, 2023, DEA published guidance entitled "DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders." The guidance can be found here. This guidance clarifies that neither the CSA nor DEA regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can order and dispense. DEA has notified associations representing manufacturers and distributors, practitioners, boards of pharmacy, and others of this guidance. The guidance also has been posted on the DEA Diversion website.

9. **Question: A recent large-scale national study showed that only 56% of pharmacies across the country stock buprenorphine, and indicated that dispensing regulations imposed by the federal government may be contributing to the lack of access at retail pharmacies. What regulatory barriers exist that prevent pharmacies from stocking buprenorphine, and has the DEA given any guidance to pharmacies on this issue?**

Response: DEA is committed to ensuring adequate access to medication for opioid use disorder. We understand the issue of pharmacy stocking to be complex (i.e., the multidistrict litigation noted in question 3 above, insurance reimbursements, and many other factors). As you know, practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result of legislation recently passed by Congress. On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act (CAA), which included provisions to expand patient access to medications for OUD. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823. On November 28, 2023, DEA published the guidance document DEA-DC-078 titled "Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)." This guidance document, among other things, notes that some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation. The intent of the legislation was to expand patient access to medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine than in previous years.

After this guidance was published, DEA sent an email notifying various associations that represent manufacturers and distributors, practitioners, boards of pharmacy, and others of its publication on DEA's website. DEA also posted the guidance on the DEA guidance portal on the Diversion website.

Additionally, DEA, the Department of Health and Human Services (HHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA) published a joint letter on MOUD in February 2024. DEA, HHS, and SAMHSA are committed to ensuring safe and ready access to MOUD, especially in rural or underserved areas where

treatment options have been limited. With the passage of the CAA, there was an immediate and significant increase in the number of practitioners with federal authority to prescribe schedule III MOUD products (e.g., buprenorphine single entity and combination products containing buprenorphine and naloxone) for patients with OUD. As access to treatment increases, it is understood that the use of MOUD products will likely increase at the same time. In this letter, DEA is asking its registrants to ensure an adequate and uninterrupted supply of MOUD products when appropriately prescribed and asks distributors to examine any quantitative thresholds they established to ensure that individuals with OUD are able to access buprenorphine. Expanding access to MOUD is one more way to assist patients with OUD during the Opioid Public Health Emergency.

10. **Question: Since granting opioid treatment program designations to all BOP facilities, how many inmates have received methadone treatment and what challenges with implementation have you heard back from BOP?**

    Response: As of September 2024, 95 individuals in BOP custody are receiving methadone treatment for OUD. According to BOP, every individual in BOP custody who qualifies for methadone treatment is receiving it. Implementation challenges have largely been administrative. In our experience, the rules for regulation of methadone for OUD were not written with the unique circumstances of corrections in mind. Despite this, BOP successfully worked with DEA to certify 100 percent of its facilities as OTPs by February 2024, and methadone is available at every BOP location.

    Updates to 42 CFR part 8 (February 2024) clarified an exemption for correctional facilities to provide methadone for OUD without OTP certification when the patient has a primary diagnosis other than OUD. This update has greatly reduced the logistical challenges BOP has faced in this area.

    When providing methadone to a patient in BOP custody, BOP also must consider the patient's ability to access methadone upon release. With only about 2,000 OTPs throughout the United States, BOP patients might be unable to access methadone upon release, resulting in the need to consider alternative OUD medications

    DEA respectfully directs any additional questions on this issue to the Federal Bureau of Prisons.

11. **Question: In addition to certifying all BOP facilities as opioid treatment programs, it's important that state and local correctional facilities also have capacity for providing access to medications for opioid use disorder. What guidance is DEA providing to field offices and local and state law enforcement to encourage and support local and state correctional facilities seeking opioid treatment program certification?**

    Response: The Substance Abuse and Mental Health Services Administration (SAMHSA) is the Federal authority that certifies opioid treatment programs (OTP).

Once an OTP is certified and has state authority, they may apply for a DEA registration as a narcotic treatment program (NTP). DEA directs this question to SAMHSA regarding the issuing of guidance pertaining to OTP certification. We would be pleased to work with SAMHSA and state and local correctional facilities on this issue.

12. **Question: How and when will DEA communicate to pharmacies and pharmacists that in an age of essentially universal Prescription Drug Monitoring Programs (PDMP) where controlled substance prescription fills in multiple states are immediately accessible, denying a prescription fill based upon pharmacy distance from a home address or legal, evidence- based, legitimate prescriptions from a telehealth provider operating within existing regulations is not acceptable or consistent with DEA's mission and goals?**

    Response: The Controlled Substances Act has no restrictions on where a patient can fill a prescription for a controlled substance. However, state laws or regulations may exist that can restrict or further define the specific circumstances under which filling a controlled substance prescription can occur. Consistent with federal regulation, DEA constantly informs pharmacists that they have a corresponding responsibility when filling a prescription to ensure that it was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of practice.

    In addition, the formal rulemaking process on telemedicine is ongoing and because DEA's role is to determine the details of a permanent telemedicine system, it would be inappropriate to comment on the rulemaking process. We will adhere to the process, procedures, and steps for formal rulemaking.

13. **Question: What are DEA's plans to further communicate with regulated industries (e.g., pharmacies) to alleviate expressed concerns about stocking and dispensing buprenorphine?**

    Response: DEA is committed to ensuring adequate access to medication for opioid use disorder. As you know, practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result of legislation recently passed by Congress. On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act (CAA), 2023, which included provisions to expand patient access to medications for OUD. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823. On November 28, 2023, DEA published the guidance document DEA-DC-078 titled "Prescribing Buprenorphine under the Mainstreaming Addiction Treatment Act (the MAT Act) for Opioid Use Disorder (OUD)." This guidance document, among other things, notes that some pharmacies have been reluctant to fill prescriptions for buprenorphine and some wholesalers have limited distribution based on perceptions or fears that filling prescriptions or distributing buprenorphine may generate an investigation. The intent of the legislation was to expand patient access to

medications for OUD by eliminating regulations that limited access to medications. Therefore, it is expected that this will result in more prescribing of buprenorphine and dispensing of greater amounts of buprenorphine than in previous years.

After this guidance was published, DEA sent an email notifying various associations that represent manufacturers and distributors, practitioners, boards of pharmacy, and others of its publication on DEA's website. DEA also posted the guidance on the DEA guidance portal on the Diversion website.

14. **Question: Does DEA have a mechanism for identifying the scope of the issue of buprenorphine stocking or for tracking and monitoring buprenorphine orders separately from other controlled medications?**

    Response: For certain controlled substances, including buprenorphine, DEA registrants are required to report to the Automated Reports and Consolidated Ordering System (ARCOS). DEA can separate out data by drug class and by dosage forms. DEA also can gather data on the controlled substances that have been transferred from manufacturers and distributors to pharmacies, hospitals, practitioners, and others.

    A system does not currently exist for pharmacies to report stock outages or lack of availability for controlled substances that are necessary to treat patients.

15. **Question: What does the DEA need from Congress to address this issue? Are there areas where DEA believes it cannot act and require a legislative response from Congress?**

    Response: DEA continues to address the factors that are limiting buprenorphine prescriptions. We are happy to work with Congress to address this issue.

16. **Question: In response to the 2023 House report language, what steps is DEA taking to publicize its suspicious orders guidance? How is the DEA communicating its guidance to field staff?**

    Response: On January 20, 2023, DEA published guidance entitled "DEA-Registered Manufacturer and Distributor Established Controlled Substance Quantitative Thresholds and the Requirement to Report Suspicious Orders." The guidance can be found here. This guidance clarifies that neither the CSA nor DEA regulations establish quantitative thresholds or place limits on the volume of controlled substances DEA registrants can distribute or order and dispense. DEA has notified associations representing manufacturers and distributors, practitioners, boards of pharmacy, and others of this guidance. The guidance also has been posted on the DEA Diversion website.

17. **Question: Is DEA aware of examples of problems with stocking and dispensing**

buprenorphine? If yes, what barriers are involved?

Response: DEA is committed to ensuring adequate access to medication for opioid use disorder. As noted above, DEA does not have a system that tracks the stocking and dispensing of buprenorphine. Additionally, stakeholders have indicated to DEA that insurance reimbursements negatively impact the stocking and dispensing of buprenorphine.

To better understand barriers and associated challenges with access to buprenorphine, the Office of the Chief Medical Officer at the Substance Abuse and Mental Health Services Administration and the Office of the Assistant Secretary of Health, on behalf of HHS, convened a Policy Priority Roundtable on Buprenorphine Access and Availability in Pharmacy Settings. This meeting was supported and facilitated by representation from many operational divisions of HHS, and other federal partners including DEA and the Office of National Drug Control Policy.
This meeting occurred virtually on August 11, 2022, and August 12, 2022, with participants that included distributors, pharmacy executives from the major chains, individual pharmacists, practitioners, and individuals with lived experience with OUD. The purpose of this meeting was to identify barriers associated with buprenorphine access and availability in pharmacies and develop solutions to address the barriers. SAMHSA published a summary report which can be viewed here.

As you know, practitioners may now prescribe buprenorphine for opioid use disorder (OUD) without a DATA-2000 waiver, as a result of legislation recently passed by Congress. On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act (CAA), which included provisions to expand patient access to medications for OUD. Specifically, the CAA amended the Controlled Substances Act to eliminate the "DATA-Waiver requirement," which had been codified in 21 U.S.C. 823.

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