American Pharmacists Association

March 31, 2023

Scott A. Brinks
Diversion Control Division
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

RE: Docket No. DEA–407 & Docket No. DEA–948: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation & Expansion of Induction of Buprenorphine via Telemedicine Encounter

Submitted via https://www.regulations.gov/ for Docket No. DEA–407 & Docket No. DEA–948

Dear Mr. Brinks:

The American Pharmacists Association (APhA) is pleased to submit comments on the Drug Enforcement Administration's (DEA) notices of proposed rulemaking entitled "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation" & "Expansion of Induction of Buprenorphine via Telemedicine Encounter." Our comments are separated by each proposed rulemaking below.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

DOCKET NO. DEA-407: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation
DEA's NPRM **requests** comments on whether the NPRM "Expansion of Induction of Buprenorphine via Telemedicine Encounters" should be combined with this rulemaking when publishing a final rule on these proposals. **APhA supports combining both rulemakings in a final rule as both address telemedicine prescribing pursuant to 21 U.S.C. 802(54)(G).**

DEA regulations in effect prior to the public health emergency (PHE) required that a patient receive at least one in person visit with a practitioner before a controlled substance could be

prescribed. During the PHE, DEA invoked temporary emergency authority to permit telemedicine prescribing of controlled substances without this in-person visit requirement.

The NPRM states "[t]his rule is designed to ensure that patients do not experience lapses in care. It is also designed to ensure continuity of care under the current telehealth flexibilities in place [during] the COVID-19 public health emergency." **APhA recommends ensuring there are no disruptions to patient access to needed medications as DEA finalizes these proposals as we approach the end of the COVID-19 PHE on May 11, 2023. If DEA is unable to finalize these proposed rules prior to the end of the PHE, APhA recommends DEA continue to allow the temporary emergency authorities currently in effect that permit telemedicine prescribing without an in-person requirement until DEA is able to review all comments submitted to these dockets and finalizes these proposals.**

A. Part 1300: Definitions

DEA is proposing to clarify the definition of a "telemedicine relationship established during the COVID-19 [PHE]." This clarification would allow a six-month transition period for practitioner/patient relationships established during the COVID-19 PHE using these telehealth prescribing flexibilities to transition to the use of the telehealth prescribing authorities in this proposed rule. APhA appreciates DEA proposing a transition period to ensure there are no disruptions to patient care and access to medications. However, APhA is concerned that pharmacists and other health care providers may need more than six-months to ensure their systems and processes are updated to comply with these new requirements once the PHE ends on May 11, 2023. **APhA recommends DEA consider a reasonable transition period to ensure pharmacists and other health care providers have systems and processes in place to ensure compliance with DEA's finalized telemedicine rules.**

Part 1306: Prescriptions

DEA's proposal would require all telemedicine prescriptions to indicate on the face of the prescription or within an electronic prescription that it was issued via a telemedicine encounter. In addition, the Centers for Medicare & Medicaid Services (CMS) also defines codes used to identify the type of telehealth visit.

NCPDP recommends that during a telemedicine encounter prescribers should mark place of service codes on the prescription to indicate the prescription was provided via telehealth. Code 02 designates a telehealth visit provided outside of a patient's home. Code 10 designates a telehealth visit provided in a patient's home. Using these best practices would help ensure prescribing practitioners provide the information a pharmacy will need to determine that a telemedicine visit occurred.

APhA recommends the use of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Implementation Recommendations Document, which provides best practices for telehealth prescribing.

Thirty-Day Schedule III-V Supply Limit

DEA's proposal would initially limit prescriptions for Schedule III-V controlled substance medications issued to a patient to a 30-day supply through telemedicine. For a patient to continue to receive a Schedule III-V controlled substance medication, DEA would require a patient to have an in-person medical evaluation with the prescribing practitioner to continue receiving a prescription for a Schedule III-V controlled substance.

DEA proposes two alternatives to an in-person medical evaluation, which include: a qualifying telemedicine referral from a practitioner who conducted the in-person medical evaluation, or an in-person medical evaluation with another practitioner with an interactive video link with the prescribing practitioner.

It would create a significant workflow and administrative burden for a pharmacist to pro-actively confirm the type of evaluation that was conducted for each controlled substance prescription and whether a patient fulfilled the requirement to see a practitioner in person for a controlled substance prescription beyond a 30-day initial supply to continue prescribing to a patient. Without verification that the in-person evaluation was conducted, APhA has concerns that this could lead patients to seek alternative pharmacy locations to fill their controlled substance prescription without an in-person evaluation after the initial 30-day supply.

Accordingly, APhA requests that DEA confirm how a prescribing practitioner will communicate to a pharmacist/pharmacy that an in-person medical evaluation was conducted.

APhA also has concerns for patients with logistical challenges to meet the in-person requirement for controlled substance prescriptions beyond a 30-day supply. Certain patient populations may have unmet patient needs, such as those who live in rural areas, without access to transportation, the physically disabled, and who do not have paid time off work or access to child-care to attend an in-person appointment.

APhA requests that DEA consider the unintended consequences and equity of the in-person requirement for these and other patient populations.

Prescription Drug Monitoring Program (PDMP) Requirements

This proposed rule would require practitioners prescribing pursuant to § 1306.31 to review the

PDMP data for the state where a patient is located, where available, for the last year. APhA supports this requirement.

To avoid unnecessary administrative burdens or costs with this requirement, APhA recommend DEA consider using the National Association of Boards of Pharmacy's (NABP) InterConnect, which allows participating state PMPs to be linked, providing a streamlined process to support DEA's goal of combating drug diversion and misuse nationwide.

DEA Request for Additional Comments on FDA-Approved Medications
DEA is requesting comments on whether this proposed rule should limit the issuance of prescriptions for controlled substance medications to the FDA-approved indications contained in the FDA-approved labeling for those medications. APhA believes patients should not face additional barriers for prescription medications for legitimate medical needs if current clinical literature would support off-label use for those medications.

DOCKET NO. DEA-948: Expansion of Induction of Buprenorphine via Telemedicine Encounter
This proposed rule would increase patient access to buprenorphine treatment for opioid use disorder (OUD). DEA is proposing to expand the circumstances under which registered practitioners would be authorized to prescribe buprenorphine for OUD via telemedicine, including an audio-only telemedicine encounter meeting the requirements of 42 CFR 410.78(a)(3). In states that prohibit prescribing of controlled substances based on an audio-only evaluation, this proposed regulation would not authorize prescribing of buprenorphine for OUD. DEA's proposed rule would only authorize audio-only OUD prescribing in states that authorize OUD buprenorphine prescribing based on an audio-video interaction.

However, there are 11 states that allow pharmacists to prescribe controlled substances Schedule III-V, including buprenorphine for patients with OUD, pursuant to varying collaborative practice agreements or state protocols. Those states include: California, Idaho, Massachusetts, Montana, Nevada, New Mexico, North Carolina, Ohio, Tennessee, Utah, and Washington state.

For the last three years, DEA has allowed telemedicine prescribing of controlled substances, including buprenorphine, without this in-person visit requirement. **Therefore, APhA recommends removing the in-person medical evaluation for buprenorphine. This drug is medically necessary to treat OUD and this requirement could deter patients from seeking care if they encounter barriers to access due to the need for an in person visit with a prescribing practitioner.**

Wholesaler Barriers to Buprenorphine in Pharmacies
Wholesaler "suspicious order" enforcement of obscure, but often fixed ratios of controlled substances, such as buprenorphine dispensed by pharmacies, prevent or limit access for patients to these life-saving medications. Pharmacists often fear the unknown actions by wholesalers to limit or discontinue access to these controlled substances. Thus, pharmacies will often either not stock these medications or turn patients away to avoid skewing their ratios.

Wholesalers will not disclose formal ratios but will discuss preferences in the 20% controlled to 80% noncontrolled range. Other actions the pharmacy takes to maintain good patient care and prevent diversion are not considered in this program. DEA states they do not set ratios, yet the operating assumption of wholesalers is that ratios must not be exceeded for any reason. As prescribing of buprenorphine increases to meet gaps in treatment, pharmacies that fill increasing numbers of prescriptions face having their supplies cut off if they exceed their wholesaler's limits. Removing buprenorphine from this program would remove a barrier to pharmacies to stock buprenorphine. Overall, greater transparency in this program would help pharmacies maintain their supplies of controlled substances.

Accordingly, APhA recommends removal of buprenorphine from the suspicious order monitoring program for controlled substances to remove barriers to pharmacy access to this medication to increase patient access to treatment for OUD through pharmacies. APhA also requests DEA clarification on wholesaler ordering ratios.

Conclusion
APhA appreciates the opportunity to respond to DEA's NPRM's entitled "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation & "Expansion of Induction of Buprenorphine via Telemedicine Encounter." Under the COVID-19 PHE, healthcare providers have operationalized approaches to effectively use telemedicine to provide continuity of care for patients who need it. APhA requests DEA consider the unintended consequences of changes to current telehealth prescribing as they finalize these proposed rules prior to the end of the public health emergency on May 11, 2023, as these proposed rules are more restrictive than the current exception DEA has allowed for telehealth prescribing during the PHE. If you have any questions, please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Interim Executive Vice President and CEO