CENTER FOR RURAL PENNSYLVANIA

City of Pittsburgh Testimony on Innovative Strategies to Curb the Overdose Crisis in Rural Pennsylvania

Contact: Joshua Schneider, Overdose Prevention Coordinator
Joshua.schneider@pittsburghpa.gov

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Testimony Provided By:

Joshua Schneider, BS, NRP
Overdose Prevention Coordinator
Office of Community Health and Safety, City of Pittsburgh
Joshua.schneider@pittsburghpa.gov

Laura Drogowski
Manager
Office of Community Health and Safety, City of Pittsburgh
Laura.drogowski@pittsburghpa.gov

Michael Lynch, MD
Medical Director, Pittsburgh Poison Center
Medical Director, UPMC Health Plan Substance Use Disorder Services
Assistant Professor, Division of Medical Toxicology, Department of Emergency Medicine
Divisions of Adolescent and Pediatric Emergency Medicine, Department of Pediatrics
University of Pittsburgh School of Medicine
lyncmj@upmc.edu

Executive Summary

A growing number of Pennsylvanians are dying from opioid overdoses and new strategies must be implemented that provide support for people who use drugs. Amid the COVID-19 pandemic, risk factors for substance use disorder have been exacerbated as individuals have become more isolated, have been stripped of support systems, and have seen health insurance and treatment plans disrupted. The growing presence of fentanyl has made the drug supply more potent which has increased the risk of opioid overdose, compounding other challenges. While there are many obstacles, there are also an abundance of evidence-based tools that promote sustained recovery and reduce harms associated with drug use.

Medication therapy for opioid use disorder, particularly buprenorphine, has been underutilized despite being the most effective treatment modality to address opioid use disorder. There are many barriers to this evidence-based treatment which are preventing widespread use, including many barriers in the criminal justice system. Programs such as the Pittsburgh Bureau of EMS Prehospital Buprenorphine Program overcome traditional barriers and expand access to populations who would otherwise go without care. With Pittsburgh's guidance, Emergency Medical Services (EMS) agencies across rural Pennsylvania can replicate this model, allowing paramedics to administer buprenorphine in the field and make connections to long-term treatment.

Telehealth services are another evidence-based means of delivering lifesaving opioid use disorder care. The UPMC Medical Toxicology Telemedicine Bridge Clinic (Bridge Clinic) has provided care to over 640 Pennsylvanians and serves as a model for telehealth services that expand access to opioid use disorder care, particularly in rural and low income communities. Audiovisual and audio-only telehealth services, such as those provided by the Bridge Clinic, are an evidence-based means of delivering lifesaving opioid use disorder care. The Bridge Clinic and similar models can continue to serve as an integral part of EMS buprenorphine induction program expansion, emergency department warm handoff processes, Single County Authority treatment engagement services, post-incarceration transitions of care, and other gaps in the existing substance use treatment infrastructure.

Not all people with opioid use disorder are ready, willing, or able to begin treatment. Mandatory treatment is ineffective and harmful, and we must make available other tools to improve the health and safety of people who use drugs. Rather than subjecting those who are not ready to begin treatment with punishment or incarceration, our aim should be to keep people safe, healthy, and alive until they are ready and fully invested in pursuing treatment. This is crucial because dead Pennsylvanians cannot recover. Syringe Service Programs (SSPs) provide access to safer substance use supplies and play an important role in preventing the transmission of blood borne infections. SSPs are safe, effective, cost saving, do not increase drug use or crime, and help participants get connected to treatment and other resources that aid recovery. Critically, people who access SSPs are five times more likely to enter treatment and substantially reduce or stop injection drug use.

The Center for Rural Pennsylvania and the Pennsylvania General Assembly can help support these efforts which would substantially improve care for people with opioid use disorder and help reduce the morbidity and mortality associated with the overdose crisis. Below are a list of recommendations and action items that the Center for Rural Pennsylvania can take to support these priorities which will improve the health, safety, and wellbeing of all rural Pennsylvanians.

Recommendations and Actions Items for the Center for Rural Pennsylvania

- Pursue and support efforts that authorize EMS providers to administer and dispense buprenorphine
    - Express support for ongoing pilot programs allowing EMS providers to administer buprenorphine for opioid withdrawal (Go to section)
    - Explore amendments to Act 37 of 2009 (EMS Systems Act) and/or Act 139 of 2014 that would authorize EMS providers to both administer and dispense buprenorphine thereby reducing barriers to evidence-based treatment (Go to section)
- Propose and support legislation that enable telehealth services to deliver lifesaving opioid use disorder care (Go to section)
    - Propose legislation that permits initial telehealth patient evaluation by both audiovisual and audio-only means to initiate treatment with controlled substances for substance use disorders that adheres to practice standards and complies with patient protection and confidentiality requirements
    - Propose legislation that requires reimbursement for telehealth services commensurate with in-person rates as has been passed in multiple other states to ensure ongoing access to care for individuals who face barriers to in-person treatment
- Work with providers currently offering low-threshold Medication for Opioid Use Disorder (MOUD) services to educate providers across Pennsylvania and encourage the expansion and creation of new low-threshold MOUD programs
    - Facilitate connections that help experienced MOUD providers offer technical assistance to those interested in providing low-barrier MOUD services
    - Encourage rural EMS agencies to adopt EMS-initiated buprenorphine programs (Go to section)
- Support legislation that legalizes harm reduction tools such as Syringe Service Programs (SSPs) and fentanyl test strips (Go to section)
    - Legalization of SSPs: SB 926 (Sen. Browne) and HB 2264 (Rep. Innamorato)
    - Legalization of fentanyl test strips: SB 845 (Sen. Kearney) and HB 1393 (Rep. Struzzi)

The Scope of the Opioid Overdose Crisis

Despite the large degree of resources and attention directed to the opioid overdose crisis, a growing number of Pennsylvanians are dying from opioid overdoses. After a steady decrease in overdose deaths following a 2017 peak, overdose deaths have continued to rise and are expected to reach new heights, with provisional data reports from the Centers for Disease Control and Prevention showing that more than 100,000 Americans died of a drug overdose during the 12-month period ending in April 2021.[1] Amid the COVID-19 pandemic, risk factors for substance use disorder have been exacerbated as individuals have become more isolated, have been stripped of support systems, and have seen health insurance and treatment plans disrupted. The growing presence of fentanyl has made the drug supply more potent which has increased risk of opioid overdose, compounding other challenges. For the 12-month period ending in June 2021, Pennsylvania reported that 5,312 people died of a drug overdose.[2] This level of mortality ranks second only to 2017 which prompted the declaration of a public health emergency, bipartisan legislative action, and an intense focus on increasing accessibility to lifesaving tools such as naloxone. We now find ourselves in similarly grave moment that demands further action be taken to stop an unacceptable level of pain and suffering in Pennsylvania communities.

Barriers to Evidence-Based Treatment

The primary approach to reducing morbidity and mortality among people who use drugs must be focused on increasing access to low barrier and evidence-based treatment, resources, and support. However, much of the focus in this area has been on mandatory treatment and treatment that encourages abstinence from drug use. Both mandatory treatment and abstinence-based treatment are ineffective, with more than 80% of patients returning to drug use.[3,4] This finding is especially impactful considering current practices of judges and drug court facilitators that force participants to choose between mandatory abstinence-based treatment or incarceration. Evidence shows that people are more likely to return to drug use following periods of forced abstinence and are even more vulnerable to overdose because of the resulting decreased tolerance to opioids.[5] Drug courts often prevent participants from accessing highly effective treatments for substance use disorder such as methadone or buprenorphine, with less than half of drug courts offering these therapies as an option for court-supervised treatment.[6] Parole and probation agencies may also decline to refer participants to treatment offering medication for opioid use disorder because of negative views of such medications,

[1] https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm
[2] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[3] Bart, Gavin. "Maintenance medication for opiate addiction: the foundation of recovery." *Journal of addictive diseases* vol. 31, 3 (2012): 207-25. doi:10.1080/10550887.2012.694598
[4] Vo, Anh T. "Assessing HIV and Overdose Risks for People Who Use Drugs Exposed to Compulsory Drug Abstinence Programs (CDAP): A Systematic Review and Meta-Analysis." *International Journal of Drug Policy* vol. 96 (2021). https://doi.org/10.1016/j.drugpo.2021.103401
[5] Merrall, Elizabeth L C et al. "Meta-analysis of drug-related deaths soon after release from prison." *Addiction (Abingdon, England)* vol. 105,9 (2010): 1545-54. doi:10.1111/j.1360-0443.2010.02990.x
[6] Matusow H., Dickman S.L., Rich J.D., Fong C., Dumont D.M., Hardin C. Medication assisted treatment in US drug courts: Results from a nationwide survey of availability, barriers and attitudes. *Journal of Substance Abuse Treatment.* 2013;44:473–480. doi: 10.1016/j.jsat.2012.10.004.

lack of knowledge about their effectiveness, and lack of information about where they are provided.[7,8] The National Academies of Sciences, Engineering, and Medicine determined that medication-based treatment is effective across all treatment settings studied to date and withholding or failing to have available medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment.[9]

Instead, more emphasis should be placed on increasing access to evidence-based treatments such as Medication for Opioid Use Disorder (MOUD), particularly buprenorphine. People who take buprenorphine are more than twice as likely to stop nonmedical opioid use, have reduced risk of HIV and Hepatitis C, and are up to 50% less likely to die.[10,11,12,13] Treatment with buprenorphine also has larger societal benefits, including reduced crime and improved social functioning among people with opioid use disorder, in addition to a 42% annual reduction in healthcare costs.[4,14] Buprenorphine also has certain advantages over methadone. While methadone is a similarly effective treatment for opioid use disorder, it remains out of reach to many due to an array of regulatory barriers. In the United States, methadone is administered almost exclusively in stand-alone opioid treatment programs that people must commute to daily, requiring patients to stand in a line and be observed swallowing their medication. While some regulations have temporarily loosened during the pandemic, outpatient methadone treatment is rare and mobile programs are almost nonexistent. These factors are especially challenging for rural methadone patients who must travel significantly further to access this lifesaving medication. While barriers surrounding methadone must be addressed, buprenorphine can be prescribed by appropriately licensed providers in office-based outpatient settings offering a more realistic option to patients that reduces barriers to care.

While there are clear benefits to treating opioid use disorder with buprenorphine, many barriers still exist which prevent people from accessing this medication. The number of buprenorphine-prescribers is diminished by regulatory barriers such as the “X-waiver" which requires physicians to apply for a special waiver to prescribe buprenorphine. Lack of education and stigma surrounding buprenorphine, particularly among emergency department physicians where many people who use

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[7,] Friedmann PD, Hoskinson R, Gordon M, Schwartz R, Kinlock T, Knight Ket al. Medication-assisted treatment in criminal justice agencies affiliated with the Criminal Justice Drug Abuse Treatment Studies (CJ-DATS): availability, barriers, and intentions. Subst Abus. 2012;33(1):9–18

[8] Friedmann PD, Wilson D, Knudsen HK, Ducharme LJ, Welsh WN, Frisman Let al. Effect of an organizational linkage intervention on staff perceptions of medication-assisted treatment and referral intentions in community corrections. J Subst Abuse Treat. 2015;50:50–8

[9] National Academies of Sciences, Engineering, and Medicine 2019. Medications for Opioid Use Disorder Save Lives. Washington, DC: The National Academies Press. https://doi.org/10.17226/25310

[10] Medication for Opiate Addiction: The Foundation of Recovery. *J Addict Dis.* 2012 July; 31(3): 207-225.

[11] Bart G. Maintenance Weiss, R.D.; Potter, J.S.; Griffin, M.L. et al. Long-term outcomes from the National Drug Abuse Treatment Clinical Trials Network Prescription Opioid Addiction Treatment Study. *Drug and Alcohol Dependence* 150:112-119, 2015

[12] Tsui JI et al. Opioid agonist therapy is associated with lower incidence of hepatitis C virus infection in young adult persons who inject drugs. *JAMA Intern Med.* 2014 December; 174(12): 1974-1981.

[13] Schuckit MA. Treatment of Opioid-Use Disorders. *N Engl J Med.* 2016 July 28; 375: 357-368

[14] Tkacz J, Volpicelli J, Un H, Ruetsch C. Relationship between buprenorphine adherence and health service utilization and costs among opioid dependent patients. J Subst Abuse Treat. 2014 Apr; 46(4): 456-62

drugs seek care following an opioid overdose presents an additional barrier.[15] Many treatment programs have strict requirements for buprenorphine treatment, often discontinuing treatment if nonmedical opioid use is detected in a urine drug screen. These barriers are compounded for court-involved populations when considering previously stated criminal-legal barriers, thereby decreasing access to those who are at greatest risk of overdose. The pandemic has also made it more difficult to access treatment due to loss of health insurance and limited patient capacity of treatment clinics.

Increasing Access to Treatment through EMS Providers

Throughout the pandemic and over the past several years, Pittsburgh Public Safety professionals have served as the safety net for people in crisis. Ill-equipped to handle the needs of people struggling with complex social, physical, and mental health needs, Pittsburgh first responders have asked for additional tools to address these needs. The City of Pittsburgh Office of Community Health and Safety was created to integrate public health informed practices into public safety operations and to develop new ways to support vulnerable populations. Recent programs such as the AHN Street Outreach Team[16] and Pre-Arrest Diversion[17] have helped ensure that public safety professionals maximize every interaction with a person requiring additional assistance, recognizing that every public safety encounter is an opportunity to connect people with proper resources and find definitive solutions to the complex issues they face.

Emergency Medical Services (EMS) providers respond to a high number of opioid overdose calls and are a key access point to the healthcare system for people who use drugs. A large number of patients who engage with EMS following an overdose decline transport to the hospital, creating an access gap that leaves patients without any care beyond resuscitation with naloxone. In 2021, over 30% of Pittsburgh EMS patients declined transport to the hospital after experiencing an opioid overdose, approximately double the transport refusal rate for other call types.[18] While an emergency department is not always the optimal place for a person who has overdosed to receive care, it can act as a resource hub where patients can be connected to substance use treatment and social services. Patients who decline transport to the hospital cannot be connected to those resources. The majority of EMS agencies lack the ability to connect patients to other forms of care and patients who are not transported to the emergency department are often left at the scene with nothing more than a box of naloxone or a resource pamphlet.

Even patients who accept transport to the emergency department struggle to get connected with substance use treatment. While all Allegheny County emergency departments have the ability to administer buprenorphine and make a referral to community providers, most patients who present to the emergency department do not receive buprenorphine or linkage to longitudinal care.[19] An

[15] Hawk, Kathryn F et al. "Barriers and Facilitators to Clinician Readiness to Provide Emergency Department-Initiated Buprenorphine." *JAMA network open* vol. 35 e204561. 1 May. 2020, doi:10.1001/jamanetworkopen.2020.4561

[16] https://pittsburghpa.gov/press-releases/press-releases/4154 (Accessed February 9, 2022)

[17] https://pittsburghpa.gov/press-releases/press-releases/4174 (Accessed February 9, 2022)

[18] https://pittsburghpa.gov/publicsafety/overdose-dashboard (Accessed February 7, 2022)

[19] M. Lynch, MD, personal communication, July 28, 2021

evaluation of nearly 300 physicians and advanced practice clinicians in academic emergency departments found that 21% had high levels of readiness to prescribe buprenorphine in the emergency department and just 3.5% were X-waivered.[14] Additionally, a study found that only 16.6% of patients released from the emergency department obtained follow-up treatment within 90 days after an overdose.[20] It is imperative that we optimize every patient engagement which can be accomplished by giving EMS providers the ability to initiate buprenorphine treatment in the field and make direct referrals to longitudinal recovery resources.

Pittsburgh Bureau of EMS is eliminating barriers to treatment and connecting patients to recovery resources through its Prehospital Buprenorphine Program, a Pennsylvania Department of Health-approved pilot program that complies with all state and federal laws and regulations. This program allows paramedics to administer buprenorphine to a patient experiencing opioid withdrawal and connect that patient directly to a telemedicine clinic, allowing them to receive a buprenorphine prescription typically within 24 hours. This program circumvents traditional barriers because it offers medication at the point of EMS engagement, does not require transport to an emergency department, and offers low-threshold access to ongoing treatment through a simple phone call. To date, this pilot program has improved post-overdose withdrawal symptoms for all enrolled patients and has resulted in multiple patients continuing treatment. The prehospital buprenorphine-model is easily replicable and would be especially beneficial to rural EMS agencies where emergency department buprenorphine programs and substance use treatment providers are less abundant.

Pittsburgh Bureau of EMS Prehospital Buprenorphine Pilot Program

Pilot Procedure and Protocol

To provide Pittsburgh EMS patients with an alternative pathway to recovery, the Buprenorphine Administration for Opioid Withdrawal pilot protocol was developed allowing paramedics to administer buprenorphine to patients experiencing opioid withdrawal (Appendix A). This program is currently being piloted with three Pittsburgh Bureau of EMS Advanced Life Support (ALS) units in the South Pittsburgh community which consistently have the highest incidence of opioid overdose in the City of Pittsburgh. The Pennsylvania Department of Health Bureau of EMS recently approved an expansion of the pilot program to three additional ALS units covering the Pittsburgh's Northside and portions of the East End.

Patients who are eligible for treatment under this protocol must have experienced an opioid overdose that requires the administration of naloxone and are exhibiting signs of opioid withdrawal with a Clinical Opioid Withdrawal Scale (COWS) greater than or equal to eight (8). A patient is also eligible if they have a reported history of chronic opioid use and have a COWS greater than or equal to five (5) with no reported opioid use in the past 72 hours. Patients are excluded from treatment under this protocol if they have used methadone in the previous 72 hours, require emergency resuscitative interventions, are less than 18 years of age, incarcerated, pregnant, have an allergy to buprenorphine, or are not conscious, alert, and oriented.

[20] Kilaru AS, Xiong A, Lowenstein M, et al. Incidence of Treatment for Opioid Use Disorder Following Nonfatal Overdose in Commercially Insured Patients. *JAMA Netw Open.* 2020; 3(5):e205852. doi:10.1001/jamanetworkopen.2020.5852

During a patient encounter, the paramedic manages the patient's chief complaint per appropriate protocol and screens the patient for inclusion and exclusion criteria once stable, conscious, alert, and oriented. The paramedic then assesses the patient using the COWS and determines their appropriate score. If the patient is eligible for treatment under this protocol, the paramedic provides counseling on buprenorphine induction and assesses the patient's interest in receiving the therapy. If the patient consents to receiving buprenorphine, the paramedic contacts medical command via radio or cell phone. Then, they give a report to medical command who will make a final determination as to whether the patient is appropriate for buprenorphine therapy. If necessary, the paramedic has the option to contact medical command via iPad video conference to perform a telehealth consultation and may use their discretion based on situational factors.

With a recommendation from medical command to administer buprenorphine, the paramedic gives the patient with water to moisten their mouth and administers 16 mg buprenorphine underneath the patient's tongue (sublingual or "SL"). The paramedic may also administer 4 mg ondansetron as needed ("PRN"). After ten minutes, the paramedic reassesses the patient and is permitted to re-dose with 8 mg buprenorphine SL if symptoms worsen or persist. The maximum dose of buprenorphine under this protocol is 24 mg.

Connection to Longitudinal Recovery Resources

After the medication has been administered, the paramedic will determine whether the patient is interested in scheduling a follow up appointment with the UPMC Medical Toxicology Telemedicine Bridge Clinic (Bridge Clinic) where they can get rapid access to a buprenorphine prescription. Alternatively, if the patient did not meet criteria for buprenorphine administration, the paramedic may still assess the patient's interest in being referred to the Bridge Clinic after this determination has been made.

If the patient is interested in continuing care through the Bridge Clinic, the paramedic will contact Pittsburgh Poison Center to schedule an appointment. Pittsburgh Poison Center is used as a link to the Bridge Clinic because the Poison Center is available 24/7 whereas the Bridge Clinic is open Monday-Friday 8am-5pm. The paramedic will provide the patient's name, date of birth, address, and phone number and the patient will be registered in the UPMC system. The patient will then receive a call from the Bridge Clinic to schedule an appointment, typically within 24 hours of the EMS interaction. Most patients can schedule an appointment and speak with a provider within the same day.

The Bridge Clinic is a telehealth service utilized by patients and providers throughout Pennsylvania to provide patients with rapid access to initial medical addiction treatment evaluation and buprenorphine prescription when appropriate. The Bridge Clinic is meant to provide easy access to medication for individuals who may have had a lapse in care or those who are waiting to onboard with another treatment provider. Patients typically use the service to receive an initial prescription and are then referred to the UPMC Western Psychiatric Hospital or another Center of Excellence. The Bridge Clinic has shown excellent outcomes with 96% of scheduled patients filling a buprenorphine prescription within 30 days of the telemedicine visit and 77% filling two or more prescriptions. Some patients require multiple visits to the bridge clinic due to significant barriers to accessing local in-person care highlighting the need for greater investment and proliferation of low-barrier/low-threshold treatment options for

patients with substance use disorder. This advent would be especially useful for rural Pennsylvanians who may have diminished access to treatment for substance use disorder.

Relevant State and Federal Laws and Regulations

Buprenorphine is a Schedule III controlled substance and the prescription, dispensing, and administration of buprenorphine is governed by the Controlled Substances Act. Under the Controlled Substances Act, medical providers may prescribe controlled substances if they have registered with the Drug Enforcement Administration (DEA), have obtained a DEA number, and are permitted to do so under the laws of the state in which they practice.[21] In order to prescribe a controlled substance, the DEA holds that a physical examination of a patient must be performed by the prescriber or another medical professional acting under the prescriber's direction.[22] In the context of prescribing buprenorphine to treat opioid use disorder, prescribers must apply for an X-waiver.[23] However, federal regulation states that providers may dispense, but not prescribe, a one-day supply of narcotic drugs without an X-waiver to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment.[24] Such emergency treatment may be carried out for up to three days which will soon be extended under the Easy MAT for Opioid Addiction Act, a bill recently signed into law allowing providers to dispense up to a three-day supply of buprenorphine without an X-waiver.[25]

To address legal ambiguities regarding the ability of EMS providers to administer controlled substances, Congress passed the Protecting Patient Access to Emergency Medications Act (PPAEMA). This law permits EMS providers to administer controlled substances to "ultimate users receiving emergency medical services" outside the physical presence of a medical director or other authorizing medical authority, so long as certain conditions are met. The administration of controlled substances by EMS must be authorized by State law pursuant to a "standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority." The controlled substance may also be administered under a verbal order that is "issued in accordance with a policy of the agency and provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient to ensure the proper care and treatment of a specific patient." [26] In the case of the Pittsburgh EMS Prehospital Buprenorphine Program, medication is administered only after EMS providers receive a patient specific order from a medical command physician. Additionally, the protocol authorizing paramedics to administer buprenorphine was implemented only after approval from the Pennsylvania Department of Health was given with recommendations from the Pennsylvania Emergency Health Services Council and the Regional EMS Council, EMS West.

[21] United States Code, 21 CFR §1306.04(a).
[22] Federal Register, 66 FR 21182.
[23] United States Code, 21 USC §823(g) (2)
[24] United States Code, 21 USC §1306.07 (b).
[25] United States Code, 21 CFR 1306.07(b)
[26] United States Code, 21 USC §823(j) (4).

To administer controlled substances, the PPAEMA holds that EMS agencies must be registered with the DEA. EMS agencies not registered with the DEA that are associated with a hospital "may use the registration of the hospital to administer controlled substance." [27] Pittsburgh Bureau of EMS is not registered with the DEA, however, agency medical command services, including the provision of controlled substances, are provided by the UPMC Prehospital Care Program which is registered with the DEA. An EMS agency may deliver controlled substances from a registered location of the agency (e.g., UPMC Prehospital Care Program) to an unregistered location of the agency (e.g., Pittsburgh EMS Headquarters) if the EMS agency "designates the unregistered location for such delivery." [28] EMS agencies may also store controlled substances "at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or in an emergency medical services vehicle used by the agency that is travelling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or otherwise actively in use by the agency under circumstances that provide for security of the controlled substances." [29]

Prehospital buprenorphine programs have successfully operated within the confines of the law in both Camden, NJ and Contra Costa County, CA. Future programs created in the Commonwealth of Pennsylvania can follow the lead of Pittsburgh Bureau of EMS and model themselves after these two programs which have set a precedent and have demonstrated the legal ability of EMS agencies to successfully administer buprenorphine in accordance with state and federal laws and regulations.

Opportunities for Replication of the Prehospital Buprenorphine Model

The Pittsburgh Bureau of EMS Prehospital Buprenorphine Program is the first program of its kind in the Commonwealth of Pennsylvania and only the third known program in the United States. While this intervention is novel among EMS providers, it has long been utilized in the emergency department setting and has been shown to be safe and effective. A prehospital buprenorphine program in Camden, NJ, the first such program in the United States, published early data demonstrating its safety and efficacy at both reducing withdrawal symptoms in the immediate aftermath of an overdose and helping patients get connected to long-term treatment with the goal of entering sustained recovery.[30] Pittsburgh Bureau of EMS has shown similar results in the very early stages of the program with all patients experiencing improvement in withdrawal symptoms immediately following administration of buprenorphine and more than half of patients engaging with recovery resources. No adverse events have been reported.

The Pittsburgh Bureau of EMS Prehospital Buprenorphine Program is authorized by the Pennsylvania Department of Health Bureau of EMS under a one-year pilot which will continue through

[27] United States Code, 21 USC §823(j) (3).
[28] United States Code, 21 USC §823(j) (5).
[29] United States Code, 21 USC §823(j) (6).
[30] Carroll, Gerard G, et al. "Buprenorphine Field Initiation of ReScue Treatment by Emergency Medical Services (Bupe FIRST EMS): A Case Series." Prehospital Emergency Care: Official Journal of the National Association of EMS Physicians and the National Association of State EMS Directors, U.S. National Library of Medicine, 4 May 2020, pubmed.ncbi.nlm.nih.gov/32208945/.

November 2022. At that point, the Department of Health will review the outcomes of the pilot program and has the option to establish a statewide protocol, affording any ALS EMS service in Pennsylvania the opportunity to implement such a program. Statewide protocols for EMS providers are typically released every other year, with the most recent slate of protocols taking effect in the final months of 2021. Should the Department of Health wish to implement a statewide protocol prior to a scheduled release of updated protocols, they may have the option to introduce a new statewide protocol on an emergency basis, however, consultation with the Bureau of EMS on this matter is recommended. Pennsylvania EMS agencies wishing to obtain authorization of their own pilot program must submit a proposal to and obtain approval from their Regional EMS Council, the Statewide Medical Advisory Committee, and the Bureau of EMS.[31,32]

The City of Pittsburgh stands ready to assist other Pennsylvania EMS agencies in replicating its prehospital buprenorphine program. The City of Pittsburgh is already working with municipalities across the United States, providing a range of technical assistance to EMS agencies and advising how the prehospital buprenorphine model can be best adapted to various EMS systems given best practices and lessons learned. Patients with opioid use disorder served by rural EMS agencies stand to see significant benefits from the implementation of prehospital buprenorphine programs. Previously stated barriers to MOUD are exacerbated in rural areas. EMS providers regularly interact with patients that are not served by traditional healthcare services, allowing care to reach those most vulnerable patients who would otherwise go without care. Providing an alternative pathway to treatment will increase the likelihood that this patient population will be connected to care and begin down the road to sustained recovery.

The Pennsylvania Legislature can facilitate the proliferation of prehospital buprenorphine programs in rural Pennsylvania by fulling embracing MOUD. While Pittsburgh's prehospital buprenorphine program grants patients easy access to a buprenorphine prescription, patients are still required to fill the prescription themselves thereby creating additional barriers. Patients may lack access to transportation or insurance, preventing them from filling the prescription. Creating a mechanism that allows EMS providers to, not just administer, but dispense buprenorphine to patients will further reduce barriers and increase the number of patients who continue treatment following an EMS engagement. The Center for Rural Pennsylvania should pursue and support efforts that authorize EMS providers to administer and dispense buprenorphine. By expressing their support for ongoing EMS-initiated buprenorphine pilot programs to the Pennsylvania Department of Health, the Center for Rural Pennsylvania Board of Directors will encourage state health officials to fully authorize these programs and adopt a statewide protocol. The Center for Rural Pennsylvania should also work with the Pennsylvania Department of Health Bureau of EMS and the Pennsylvania Emergency Health Services Council to explore amendments to Act 37 of 2009 (EMS Systems Act) and/or Act 139 of 2014 to statutorily authorize EMS providers to administer and dispense buprenorphine to patients experiencing opioid withdrawal, thereby reducing barriers to evidence-based treatment.

Telehealth Utilization Improves Engagement in Opioid Use Disorder Care

The COVID-19 public health emergency posed numerous challenges to the delivery of evidence-based care. Among those challenges has been disruptions in-person care which served to exacerbate

[31] http://pehsc.org/resources/regional-ems-councils/
[32] http://pehsc.org/wp-content/uploads/2014/10/Research-and-Pilot-Program-Protocol.pdf (Page 4)

existing barriers and inequities that rural and other communities experience. The expansion of available telehealth services has helped to offset those challenges and barriers including improved access to evidence-based, lifesaving addiction care. Remote management of opioid use disorder including medication therapy with buprenorphine has been implemented in the management of patients from rural communities with good outcomes even prior to the pandemic.[33,34]

Temporary waivers of both federal and state regulations which have been supported by the PA legislature have allowed for initial care for patients with opioid use disorder to be provided through audiovisual and audio-only telehealth platforms that abide by all statutory and ethical requirements for delivering quality care.[35] The UPMC Medical Toxicology Telemedicine Bridge Clinic (Bridge Clinic) is an example of such a service. Implemented in collaboration with PA Department of Drug and Alcohol Programs in April 2020, the Bridge Clinic has provided care to more than 640 patients from all backgrounds including rural communities. Patients evaluated on the same day as presentation are seven times more likely to engage in care than patients who are forced to wait two or more days making the urgency of accessibility critical in responding to the growing need for care.[36]

The model of a telemedicine bridge clinic integrated with existing in-person substance use treatment programs throughout the Commonwealth offers an innovative and evidence-based solution to many of the barriers that patients seeking opioid use disorder care face, particularly in rural communities where access to specialized treatment providers can be significant delayed and distant from a person's home. In order to maintain this service which has demonstrated improved connection to treatment beyond the public health emergency, we urge the legislature to pass legislation that permits prescribing of controlled substances following an initial telehealth visit that complies with specialty standards and patient protections. Our Bridge Clinic has found that 90% of patients either require or prefer audio-only visits as currently permitted through public health emergency measures so we encourage the ongoing allowance of audio-only visits in order to meet patients where they are and take technological and internet access considerations into account. As an example, West Virginia has established that audio-only visits are sufficient to establish a physician-patient relationship. Finally, we recommend that telehealth reimbursement parity be passed as it has in many other states to ensure that these services remain viable and available to patients who need them most. Only seven states including PA do not have private payer telehealth reimbursement laws (Appendix B).[37]

[33] Weintraub E, et al. Expanding access to buprenorphine treatment in rural areas with the use of telemedicine. The American Journal on Addictions. 2018; 27: 612-617

[34] Zheng W, et al. Treatment outcome comparison between telepsychiatry and face-to-face buprenorphine medication-assisted treatment (MAT) for opioid use disorder: A 2-Year retrospective data analysis. J Addict Med. 2017; 11(2): 138-144

[35] Drug Enforcement Administration (DEA), Department of Justice. 2009. Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. Interim final rule with request for comments. Fed Regist.74(64):15595-625.

[36] Roy PJ, Choi S, Bernstein E, Walley AY. Appointment wait-times and arrival for patients at a low-barrier access addiction clinic. J Subst Abuse Treat. 2020 Jul;114:108011. doi: 10.1016/j.jsat.2020.108011. Epub 2020 Apr 22. PMID: 32527508

[37] State Telehealth Laws & Reimbursement Policies Report - CCHP (cchpca.org) (Accessed 2/9/2022)

Harm Reduction Measures Improve the Health & Safety of People Who Use Drugs

While MOUD is an effective method of overdose prevention and reduction, not all people with opioid use disorder are ready, willing, or able to begin treatment. Having established that mandatory treatment is ineffective and harmful, we must make available other tools to improve the health and safety of people who use drugs. Rather than subjecting those who are not ready to begin treatment with punishment or incarceration, our aim should be to keep people safe, healthy, and alive until they are ready and fully invested in pursuing treatment. This is crucial because dead Pennsylvanians cannot recover. These efforts are part of a larger strategy to address the mortality and morbidity of the overdose crisis known as harm reduction. Harm reduction is a set of practical strategies and ideas aimed at reducing the negative consequences of drug use. This concept recognizes that drug use is not always preventable and instead seeks to make drug use safer through a spectrum of strategies including safer use, managed use, abstinence, meeting people "where they're at" and addressing physical and mental health conditions associated with drug use.

A Syringe Service Program (SSP) is one harm reduction strategy that provides safe injection supplies, counseling, and linkages to care to people who use drugs. Nearly three decades of research show that SSPs are safe, effective, do not increase drug use or crime, and play an important role in reducing the transmission of viral hepatitis, HIV, and other infections. [38,39] Without access to sterile syringes, people are more likely to reuse and share needles, putting them at risk for contracting HIV, Hepatitis C, and other bacterial and blood borne infections. SSPs are cost effective; the estimated lifetime cost of healthcare for a person living with HIV is $400,000 while a new sterile syringe costs only 10 cents. HIV and Hepatitis C infections are rising in Pennsylvania and increasing access to sterile syringes will result in less infections and taxpayer money saved. SSPs also reduce the number of improperly discarded syringes by taking back used syringes and distributing biohazard sharps containers. Critically, people who access SSPs are five times more likely to enter treatment and substantially reduce or stop injection drug use.[40] SSP-based health services are also shown to reduce emergency department utilization among people who inject drugs.[41]

SSPs are not currently authorized by state law, however, both Allegheny County and Philadelphia have authorized the practice through local ordinance. SSPs in both counties have help to curb HIV and Hepatitis C infections and connect participants to treatment, however, Pennsylvania's 65 other counties do not have access to these critical resources. There are several pieces of legislation moving through the legislature that members of the Center for Rural Pennsylvania Board of Directors

[38] Aspinall, E. J., Nambiar, D., Goldberg, D. J., Hickman, M., Weir, A., Van Velzen, E., . . . Hutchinson, S. J. (2014). Are needle and syringe programmes associated with a reduction in HIV transmission among people who inject drugs: a systematic review and meta-analysis. Int J Epidemiol, 43(1), 235- 248. doi:10.1093/ije/dyt243

[39] Bernard, C. L., Owens, D. K., Goldhaber-Fiebert, J. D., & Brandeau, M. L. (2017). Estimation of the cost-effectiveness of HIV prevention portfolios for people who inject drugs in the United States: A model-based analysis. PLoS Med, 14(5). doi:10.1371/journal.pmed.1002312

[40] Hagan, H et al. "Reduced injection frequency and increased entry and retention in drug treatment associated with needle-exchange participation in Seattle drug injectors." *Journal of substance abuse treatment* vol. 19,3 (2000): 247-52. doi:10.1016/s0740-5472(00)00104-5

[41] Pollack, Harold A et al. "The impact of needle exchange-based health services on emergency department use." *Journal of general internal medicine* vol. 17,5 (2002): 341-8. doi:10.1046/j.1525-1497.2002.10663.x

should support to increase resources for people in rural areas of the Commonwealth. SB 926 introduced by Senator Browne and HB 2264 introduced by Representative Innamorato and sponsored by Representative Struzzi would legalize SSPs statewide.

There are also parallel efforts to decriminalize fentanyl test strips, a harm reduction tool that allows individuals to test substances for the presence of fentanyl. Alongside the increase in opioid overdoses and opioid overdose deaths, fentanyl, a powerful synthetic opioid that can quickly cause respiratory depression, was present in 77% of Allegheny County overdose deaths in 2020 and is increasingly present in the drug supply.[42] Fentanyl can be mixed with many substances and is especially dangerous when fentanyl is mixed with non-opioid substances such as cocaine where the individual using drugs may not realize that fentanyl is present as an additive. A study published in the International Journal of Drug Policy found that people were likely to change their drug use behavior if they used fentanyl test strips and the study concluded that fentanyl test strips "represent an effective addition to current overdose prevention efforts." [43] Unfortunately, current policy restricts the ability of healthcare providers, outreach organizations, community members, social service providers, public health agencies, and local governments to legally distribute this lifesaving tool. Despite current policy, Prevention Point Pittsburgh, an SSP in Allegheny County, has safely distributed fentanyl test strips to their program participants for over a decade, who rely on their services to stay alive in the face of an increasingly potent and unpredictable drug supply.

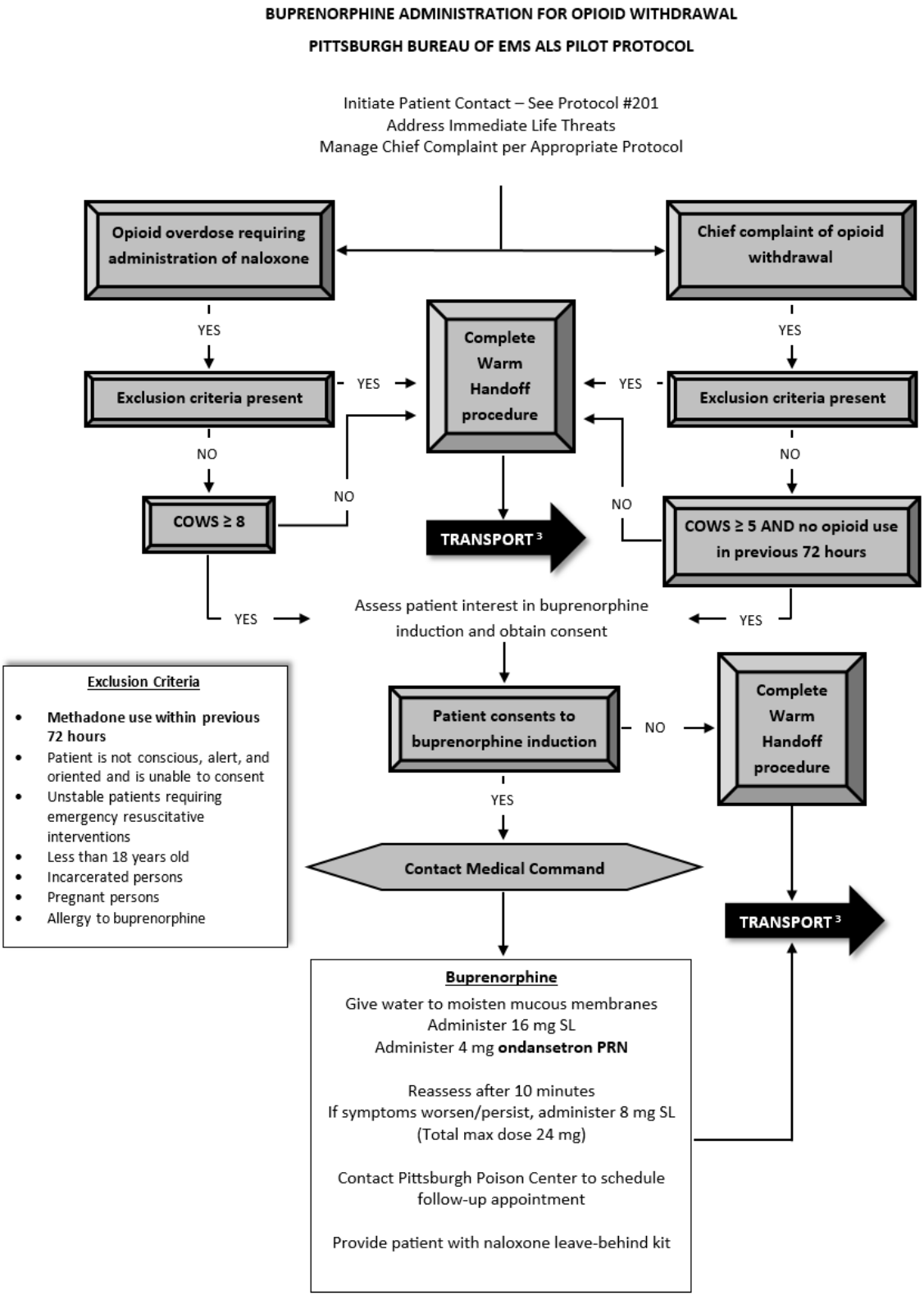
Like SSPs, the cities of Pittsburgh and Philadelphia have decriminalized fentanyl test strips. Pittsburgh EMS paramedics are distributing fentanyl test strips to patients in naloxone-leave behind kits and the Office of Community Health and Safety is coordinating community distribution of these supplies. SB 845 introduced by Senator Kearney and HB 1393 introduced by Representative Struzzi would decriminalize fentanyl test strips and help to reduce the impact of fentanyl on rising opioid overdose deaths.

[42] Accidental Overdose Deaths in Allegheny County, January 2016 – June 2020. Allegheny County Health Department, Apr. 2021, www.alleghenycountyanalytics.us/wpcontent/uploads/2021/05/21-ACDHS-05-AccidentalOverdoses-04-09-2021_final-1.pdf.

[43] Peiper, Nicholas C et al. "Fentanyl test strips as an opioid overdose prevention strategy: Findings from a syringe services program in the Southeastern United States." *The International journal on drug policy* vol. 63 (2019): 122-128. doi:10.1016/j.drugpo.2018.08.007

Appendix

Appendix A: Buprenorphine Administration for Opioid Withdrawal Protocol



Clinical Opioid Withdrawal Scale (COWS)

< 5 – No active withdrawal	**13-24 – Moderate withdrawal**	**>36 – Severe withdrawal**
5-12 – mild withdrawal	**25-36 – Moderately severe withdrawal**	

Resting Pulse Rate: _____ beats/minute
Measured after patient is sitting or lying for one minute

0 Pulse rate 80 or below
1 Pulse rate 81-100
2 Pulse rate 101-120
4 Pulse rate greater than 120

GI Upset: *Over last ½ hour*

0 No GI symptoms
1 Stomach cramps
2 Nausea or loose stool
3 Vomiting or diarrhea
5 Multiple episodes or diarrhea of vomiting

Sweating: *Over past ½ hour not accounted for by room temperature or patient activity*

0 No report of chills or flushing
1 Subjective report of chills or flushing
2 Flushed or observable moistness on face
3 Beads of sweat on brow or face
4 Sweat streaming off face

Bone or Joint Aches: *IF patient was having pain previously, only the additional component attributed to opioid withdrawal is scored*

0 Not present
1 Mild diffuse discomfort
2 Patient reports severe diffuse aching of joints/muscles
4 Patient is rubbing joints of muscles and is unable to sit still because of discomfort

Restlessness: *Observation during assessment*

0 Able to sit still
1 Report difficulty sitting still, but is able to do so
3 Frequent shifting or extraneous movements of legs/arms
5 Unable to sit still for more than a few seconds

Yawning: *Observation during assessment*

0 No yawning
1 Yawning once or twice during assessment
2 Yawning three or more times during assessment
4 Yawning several times/minute

Pupil Size

0 Pupils pinned or normal size for room light
1 Pupils possibly larger than normal for room light
2 Pupils moderately dilated
5 Pupils so dilated that only the rim of the iris is visible

Anxiety or Irritability

0 None
1 Patient reports increasing irritability or anxiousness
2 Patient obviously irritable or anxious
4 Patient is so irritable that participation in the assessment is difficult

Tremor: *Observation of outstretched hands*

0 No tremor
1 Tremor can be felt, but no observed
2 Slight tremor observable
4 Gross tremor or muscle twitching

Gooseflesh skin

0 skin is smooth
3 Piloerection of skin can be felt or hairs standing up on arms
5 Prominent piloerection

Runny Nose or tearing: *Not accounted for by cold symptoms or allergies*

0 Not present
1 Nasal stuffiness or unusually moist eyes
2 Nose running or tearing
4 Nose constantly running or tears streaming down

Total Score _____
The total score is the sum of all 11 items

BUPRENORPHINE ADMINISTRATION FOR OPIOID WITHDRAWAL
PITTSBURGH BUREAU OF EMS ALS PROTOCOL

Criteria:

1. Patient experiencing opioid withdrawal secondary to
    a. Naloxone administration following an opioid overdose
    b. Period of abstinence from opioid use

Exclusion Criteria:

1. Methadone use within previous 72 hours
2. Patient is not conscious, alert, and oriented, and is unable to consent
3. Unstable patients requiring emergency resuscitative interventions
4. Less than 18 years old
5. Incarcerated persons
6. Pregnant persons
7. Allergy to buprenorphine

Possible Medical Command Orders:

1. Transport to the hospital
2. Additional dose(s) of buprenorphine

Notes:

1. **Precipitated withdrawal is a potential adverse event of buprenorphine induction.**
    a. To avoid precipitated withdrawal, the patient needs to be in at least mild to moderate opioid withdrawal at the time of buprenorphine induction. A thorough assessment of the patient's Clinical Opioid Withdrawal Score (COWS) and detailed report to medical command is the best way to prevent precipitated withdrawal.
    b. Symptoms of precipitated withdrawal include nausea, vomiting, diarrhea, runny nose, goosebumps, chills, and headache. Precipitated withdrawal causes extreme discomfort, but is usually non-life threatening. Precipitated withdrawal can be dangerous for patients with underlying health issues and may cause chest pain, difficulty breathing, or loss of consciousness.
    c. The high dose of buprenorphine prescribed by this protocol should avoid precipitated withdrawal, however, EMS providers should still monitor patients for symptoms.
    d. If the patient's withdrawal symptoms worsen after the initial dose of buprenorphine, administration of the follow-up 8 mg SL dose will help improve the patient's symptoms. The maximum dose of buprenorphine under this protocol is 24 mg.
2. **Contacting Pittsburgh Poison Center following buprenorphine induction will allow the patient to receive follow-up care and will help prevent future use of emergency medical services.**

a. Administration of buprenorphine in the prehospital environment will provide the greatest benefit to patients when they continue the care they received on-scene with a recovery medicine specialist.
b. Pittsburgh Poison Center is able to register the patient in the UPMC system and schedule an appointment with the UPMC Medical Toxicology Bridge Clinic ("Bridge Clinic") where the patient can receive a buprenorphine prescription and be connected to other resources.
c. Bridge Clinic appointment slots have been reserved for Pittsburgh EMS patients. The Bridge Clinic will be able to see most patients within 24 hours.

3. **Transport to the hospital should be encouraged but is not required.**
   a. Transport to the emergency department is not required for patients who have received buprenorphine.
   b. Emergency departments can connect patients with resources and services that are beneficial for people struggling with opioid use disorder. Patients that decline transport to the hospital do not have the opportunity to access these resources and it is especially important that the EMS providers work with these patients to schedule a follow-up appointment through the Pittsburgh Poison Center.

Appendix B: State Telehealth Laws and Reimbursement Policies

Center for Connected Health Policy | THE NATIONAL TELEHEALTH POLICY RESOURCE CENTER

State Telehealth Laws and Reimbursement Policies

AT A GLANCE I Fall 2021

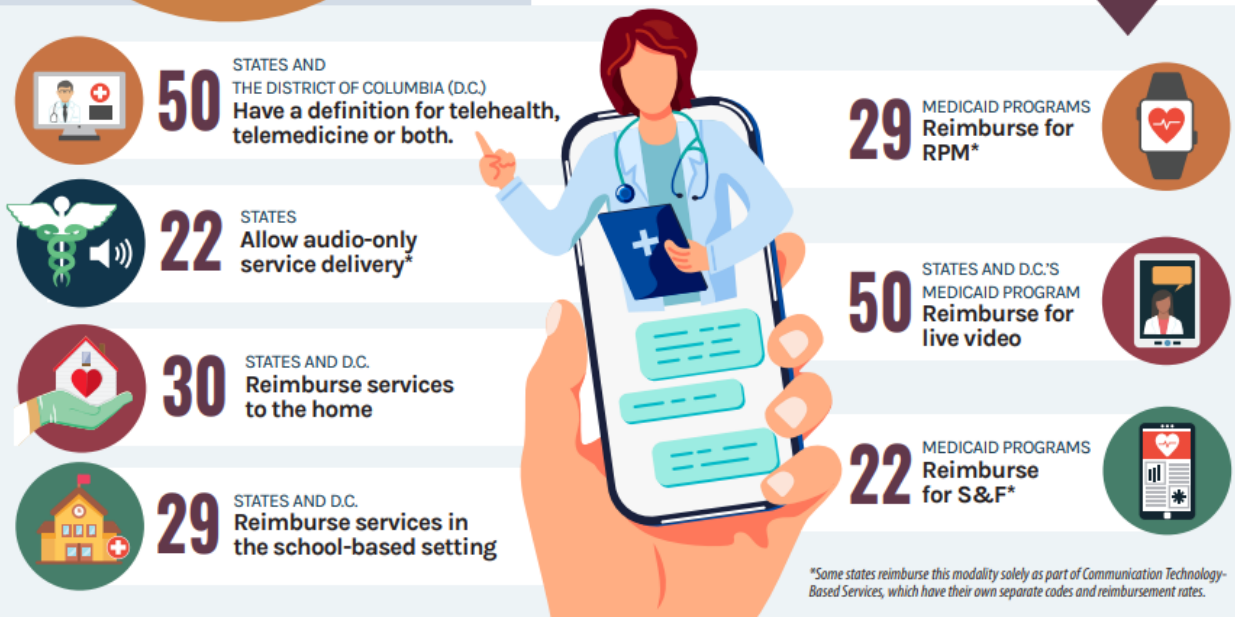
** Please note that many states continue to keep their temporary telehealth COVID-19 emergency policies siloed from their permanent telehealth policies. In instances where the state has made policies permanent or extended for multiple years, CCHP has incorporated those policies into this report, however policies tied to the COVID-19 emergency specifically are not included. For information on state temporary COVID-19 telehealth policies, visit CCHP's COVID-19 Telehealth Policy tracking webpage.**

Telehealth policy trends continue to vary from state-to-state, with no two states alike in how telehealth is defined, reimbursed or regulated. A general definition of telehealth used by CCHP is the **use of electronic technology to provide health care and services to a patient when the provider is in a different location.**

Medicaid Policy Trends

All 50 states and D.C. now reimburse for some type of live video telehealth services in Medicaid. Twenty-two state Medicaid programs reimburse for store-and-forward and twenty-nine states reimburse for remote patient monitoring (RPM), a slight increase from Spring 2021. Additional states have laws requiring Medicaid reimbursement for store-and-forward or RPM, however no official written Medicaid policies indicating that they have been implemented have been made available yet. Some states are also adopting the Centers for Medicare and Medicaid Services' (CMS) communication technology-based services (CTBS) codes, including the virtual check-in and remote evaluation of pre-recorded information, audio-only service codes and remote physiologic monitoring. However, states' approaches to CTBS vary, with some separating it from their telehealth policies, while others include it under the umbrella of telehealth. Audio-only reimbursement, saw the biggest jump, with 22 Medicaid programs reimbursing the modality (up from 15 in Spring 2021). This is likely a result of policies during the pandemic either being made permanent or being extended multiple years into the future, although often on a more limited basis than what was allowed during the COVID-19 public health emergency (PHE).

Many of the reimbursement policies that do exist continue to have restrictions and limitations, creating a barrier to utilizing telehealth to deliver services. In the past, restrictions on eligible services, where the patient is located (originating site), and the type of provider eligible to deliver services have been the most common. While many states have kept these restrictions in place, over the past year we have seen many Medicaid programs expand the eligible providers (often to FQHCs, RHCs and therapy providers), originating sites (often to the home and schools) and services eligible for reimbursement. Since Spring 2021, one of the last remaining states to have a broad geographic restriction on the originating site (South Dakota), eliminated it. Thirty states and D.C. explicitly and permanently allow the home to be an eligible originating site under certain circumstances. Additionally, twenty-nine states and DC explicitly note that their Medicaid program will reimburse telehealth delivered services in a school-based setting.



OTHER COMMON TELEHEALTH RESTRICTIONS

THE SPECIALTY that telehealth services can be provided for

THE TYPES OF SERVICES or CPT codes that can be reimbursed *(inpatient office, consult, etc.)*

THE TYPES OF PROVIDERS that can be reimbursed *(e.g. physician, nurse, etc.)*

TELEPHONE/AUDIO-ONLY SERVICE DELIVERY

The addition of telephone was one of the most common COVID-19 temporary telehealth policy expansions, and twenty-two states are now reimbursing the modality permanently, although some only through specific audio-only or CTBS codes that include audio-only service delivery.

PRIVATE PAYER REIMBURSEMENT

43 STATES AND D.C.

43 states and the District of Columbia have laws that govern private payer reimbursement of telehealth. Laws requiring the reimbursement rate be the same as the rate covered in-person are becoming more prevalent, however the majority still only require parity in covered services, but not reimbursement amount.

CONSENT

44 STATES AND D.C.

44 States and D.C. have a consent requirement in either Medicaid policy, law or regulation. This number has increased by two since Spring 2021.

ONLINE PRESCRIBING

States approach online prescribing in different ways. Some states explicitly allow the establishment of a patient-provider relationship (needed for the prescribing of medication) via telehealth under certain circumstances. Others are silent on the issue. Most states consider an online questionnaire only as insufficient to establish the patient-provider relationship and prescribe medication. A few states have stricter requirements to meet for prescribing controlled substances vs. regular scheduled drugs, although there is sometimes an exception specifically made for the prescribing of controlled substances used in medication assisted therapy (MAT) as a result of the opioid epidemic.

States are increasingly passing legislation directing healthcare professional boards to adopt practice standards for its providers who utilize telehealth. These standards often address criteria to form a patient-provider relationship, prescribe, obtain consent and comply with privacy and practice standards. Regulatory telehealth standards are most common for Medical and Osteopathic Boards, however other professional boards (such as mental health, dentistry and therapist boards) are increasingly adopting them as well.

Rx

Often, internet/online questionnaires are not adequate; states may require a physical exam prior to a prescription for controlled substances.

LICENSURE

Twelve states issue special licenses or certificates, or have a telehealth specific exception for out-of-state licensed providers, including both Arizona and Florida which now only require out-of-state telehealth providers to register with their applicable professional board.
Licensure Compacts have also become increasingly common. For example:

- **33** States, D.C. & Guam: **Interstate Medical Licensure Compact**
- **33** States: **Physical Therapy Compact**
- **15** States: **Audiology and Speech-Language Pathology Interstate Compact (ASLP-IC)**
- **37** States: **Nurse Licensure Compact**
- **26** States and DC: **Psychology Interjurisdictional Compact (PSYPACT)**
- **21** States: **Emergency Medical Services Personnel Licensure Interstate Compact (REPLICA)**
- **9** States: **Occupational Therapy Compact**
- **2** States: **The Counseling Compact**

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