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Research Paper

Identifying and responding to policy-related barriers, facilitators, and misunderstandings in the HEALing communities study: A community-driven approach

Anita Silwal [a,b,*], Robert Bohler [c,d], Timothy Hunt [e], Ramona G. Olvera [f], Michelle R. Lofwall [g,h], Christopher D. Cook [b,i], Katherine R. Marks [j], Carly Bridden [k], Patricia R. Freeman [g,l], Monica Nouvong [k], Laura C. Fanucchi [g,m], Nabila El-Bassel [e], Lisa A. Frazier [n], Sharon L. Walsh [g,h], Jeffery C. Talbert [m,o]

[a] School of Community Health Sciences, Counseling, and Counseling Psychology, Oklahoma State University, 441 Willard Hall, Stillwater, OK 74078, United States
[b] Substance Use Priority Research Area (SUPRA), University of Kentucky, Lexington, KY, United States
[c] Jiann-Ping Hsu College of Public Health, Georgia Southern University, Statesboro, GA, United States
[d] Heller School for Social Policy and Management, Brandeis University, Waltham, MA, United States
[e] Social Intervention Group, School of Social Work, Columbia University, NY, NY, United States
[f] Center for the Advancement of Team Science, Analytics, and Systems Thinking in Health Services and Implementation Science Research (CATALYST), College of Medicine, The Ohio State University, Columbus, OH, United States
[g] Departments of Behavioral Science and Psychiatry, University of Kentucky, Lexington, KY, United States
[h] Center on Drug and Alcohol Research, University of Kentucky, Lexington, KY, United States
[i] Department of Pediatric Psychology, University of Kentucky, Lexington, KY, United States
[j] Department for Behavioral Health, Developmental and Intellectual Disabilities, Cabinet for Health and Family Services, Commonwealth of Kentucky, KY, United States
[k] Section of General Internal Medicine, Clinical Addiction Research and Education (CARE) Unit, Boston Medical Center, Boston, MA, United States
[l] Department of Pharmacy Practice and Science, College of Pharmacy, University of Kentucky, Lexington, KY, United States
[m] Department of Internal Medicine, University of Kentucky, Lexington, KY, United States
[n] Battelle Center for Science, Engineering and Public Policy, John Glenn College of Public Affairs, The Ohio State University, Columbus, OH, United States
[o] Institute for Biomedical Informatics, University of Kentucky, Lexington, KY, United States

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ABSTRACT

Introduction: The HEALing (Helping to End Addiction Long-Term®) Communities Study (HCS) aimed to reduce opioid-involved overdose deaths across four states (Kentucky, Massachusetts, New York, and Ohio) via community-engaged implementation of three evidence-based practices (EBPs): (1) opioid overdose education and naloxone distribution, (2) medication for opioid use disorder expansion/linkage/retention, and (3) safer opioid prescribing and dispensing practices. A policy workgroup (PWG) was convened and developed a procedure to identify and address policies potentially impacting EBP implementation.

Methods: A five-step method was developed to identify, track, and respond to relevant policies at three of the research sites (Kentucky, Massachusetts, and New York) in collaboration with community partners and stakeholders. Policies possibly impacting EBPs were reported, reviewed, and documented, including any actions taken to address the policy issue. Policies were discussed with local, state, and federal level stakeholders in attempts to resolve barriers, clarify misunderstandings, and disseminate facilitators.

Results: A total of 87 (Kentucky = 37; Massachusetts = 19; New York = 31) policies were identified and addressed; 42 were identified as barriers, 24 as facilitators, and 21 as misunderstandings. PWG efforts resolved over 73 % ($n = 31$) of policy barriers, clarified 90 % ($n = 19$) of policy misunderstandings, and disseminated 100 % ($n = 24$) of policy facilitators.

Conclusions: A community-driven approach in policy surveillance identified, addressed, and disseminated several different types of policy issues that could impact implementation of EBPs for opioid-involved overdose

* Corresponding author at: School of Community Health Sciences, Counseling, and Counseling Psychology, Oklahoma State University, 441 Willard Hall, Stillwater, OK 74078, United States
E-mail address: anita.silwal@okstate.edu (A. Silwal).

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prevention. Many policy barriers persisted during the HCS study, which may have adversely affected study outcomes.

Introduction

Globally, there are an estimated 40.5 million people living with opioid use disorder (OUD), with the highest rates in the United States (Degenhardt et al., 2019). The U.S. opioid crisis has devastated communities and taken the lives of 600,000 Americans since 1999 (Centers for Disease Control and, Prevention [CDC], 2024). To address this public health emergency, the National Institutes of Health launched the HEAL (Helping to End Addiction Long-term®) Initiative, which included funding for the largest ever implementation study in the substance use field, the HEALing Communities Study (HCS). The HCS was a four-year study in 67 communities disproportionately impacted by opioid overdose deaths across four states: Kentucky, Massachusetts, New York, and Ohio. The multi-site, parallel arm, cluster randomized, wait-list controlled trial examined the impact of the Communities That HEAL intervention on reducing opioid-related mortality (HEALing Communities Study Consortium, 2020). In the Communities that Heal intervention, researchers worked closely with HCS communities to select and implement appropriate strategies to facilitate the uptake of three evidence-based practices (EBPs) that reduce opioid overdose mortality: (1) increasing overdose education and naloxone distribution; (2) increasing access, linkage, and retention to medications for opioid use disorder; and (3) improving safer opioid prescribing and dispensing practices (Chandler et al., 2023; Winhusen et al., 2020).

Examining the role of policy as a potential barrier or facilitator during the intervention study is critical yet often overlooked (Bullock et al., 2021). The HCS study, guided by the Practical, Robust Implementation and Sustainability Model and Reach, Effectiveness, Adoption, Implementation, and Maintenance model and (PRISM/Re-AIM) framework, calls for examination of external factors known to influence EBP implementation and sustainment (HEALing Communities Study Consortium, 2020; Knudsen et al., 2020; Rabin et al., 2022). These external context factors included policies at the local, state, and federal levels that may facilitate or hinder efforts to implement EBPs successfully. For example, Medicaid expansion through federal or state policy changes is associated with increased utilization of medication for opioid use disorder (MOUD; Knudsen et al., 2022) and naloxone distribution (Sohn et al., 2020), removal of Medicaid prior authorization requirements through state policy changes is associated with increased buprenorphine prescriptions (Keshwani et al., 2022), and Medicaid managed care policies through organizational policy changes can be barriers or facilitators to treatment access (Abraham et al., 2022; Auty et al., 2022).

In recognition of the importance of the policy landscape in the HCS, each research site was required to enlist a key government official and to form a state community advisory board, which also included state leadership, policymakers, and people with lived and living experience of opioid use and overdose. In addition, each HCS research site had several key state stakeholder agencies, such as Departments of Public Health, Behavioral/Mental Health, and Medicaid, engaged as partners within each state's community advisory board. The HCS cross-site policy workgroup (PWG) was formed by the research team to identify, document, monitor, and address relevant policy-related issues that could impact the study. The goals of the PWG were to develop a community-driven approach to identify, document, and discuss potential policy-related issues that may facilitate or impede the implementation of EBPs, support responses to those issues, provide feedback to the community and stakeholders, and note the potential impact of identified policies.

The purpose of this paper is three-fold: 1) to describe a community-driven approach to policy surveillance, which included identifying and addressing federal, state, local, and organizational-level policies that may have impacted implementation of EBPs aimed at reducing opioid-involved overdoses; 2) to summarize identified policy barriers, facilitators and misunderstandings potentially impacting implementation of EBPs; and 3) to describe how the PWG supported responses to identified policies and highlight case examples of policy-related issues identified and worked through using this surveillance approach in Kentucky, Massachusetts and New York.

Methods

Definition of HCS policy categories

Policy is conceptualized as a strategy to affect implementation outcomes of the evidence-based intervention (Purtle et al., 2023). The PWG formulated and enacted a community reporting process to identify federal, state, and local (such as municipal and organizational level) policies that may have impacted EBP implementation and outcomes in the HCS states. The PWG broadly defined policy as statutes, regulations, and other relevant policies made by federal, state, or local governance bodies as well as relevant institutional and organizational policies that may facilitate or impede addressing the opioid crisis in the HCS communities. Policies were categorized as potential barriers to, facilitators of, or misunderstandings of the three EBPs (i.e., overdose education and naloxone distribution, MOUD, and safer opioid prescribing and dispensing practices) selected and implemented in the communities. Policy barriers were defined as policy-related issues that may impede implementation of the EBPs. Policy facilitators were defined as those supporting the active implementation of the EBPs. Policy misunderstandings were defined as misinterpretation or misapplication of policies related to implementation of EBPs.

Community data collection procedures

The PWG developed a standard data collection procedure to identify, track, and address relevant policies in the HCS states (see Fig. 1). This process included a community-engaged process by which communities could report federal, state, and local policies that may impact HCS states. The data collection procedure involved five steps: (1) collect community-identified potentially relevant policies, (2) review and classify policies possibly impacting one of the EBPs, (3) record policy details in REDCap (Harris et al., 2019), including any action taken by PWG to address the policy, (4) perform data quality control processes, and (5) disseminate results which may include providing more information about the policy, policy changes, and/or implications.

The HCS used community engagement as an implementation strategy and each state-defined community was selected based on burden of opioid-involved overdose fatalities, rural/urban designation and existing public health infrastructure. Each participating community had developed a community coalition to work on the HCS with the research teams. Membership in coalitions paid special attention to representing behavioral health, criminal legal and health-focused sectors engaged in EBP implementation known to impact overdose (Martinez et al., 2020; Winhusen et al., 2020). For example, Kentucky and Massachusetts adopted a hybrid approach, utilizing both existing and new formed coalitions focused on substance use prevention and treatment. New York formed HCS-designated coalition by forming new groups or by strategically restructuring existing ones. Details on methodology used to develop the community-engagement protocol can be found in a previous publication (Martinez et al., 2020). The PWG leveraged the HCS community engagement structure to conduct community-driven policy surveillance. Site-specific PWG members were notified by community

members about a potentially relevant policy-related issue or HCS study investigators and staff could report a policy to the PWG. The PWG then reviewed the issue, followed up with the community members as needed, referred to existing federal, state, and local policies as applicable, and categorized the policy as a barrier, facilitator, or misunderstanding to one or more EBPs. Policies not impacting an EBP were excluded. The site-specific PWG teams were comprised of experts in health policy, a key government official, behavioral scientists, healthcare providers, and representatives from the Substance Abuse and Mental Health Services Administration and the National Institute on Drug Abuse. After policy categorization, site-specific PWGs developed plans of action to provide training and/or technical assistance to address and/or disseminate information about policy barriers, misunderstandings, and facilitators. The purpose of this paper is to describe the community-driven approach and report policy-issues identified and addressed those were reported between March 2020 and June 2023. Ohio did not participate in policy training and/or technical assistance; thus, results are reported from Kentucky, Massachusetts, and New York.

The data collection form was developed, pilot tested, and refined based on PWG feedback. The policy details were captured in a cross-site shared REDCap (Harris et al., 2019) form, which included data fields to capture policy characteristics and training and/or technical assistance activities. Each PWG member received data entry and quality control training to ensure data accuracy. Each policy was characterized with a title, brief description and links to full details, date it was reported to the study team, jurisdiction it covered (e.g., state, federal), if a result of the COVID-19 pandemic (yes/no), and categorized as a barrier, facilitator, or misunderstanding to implementation of a study EBP. The potential EBP(s) and any specific MOUD affected (e.g., methadone, transmucosal or injectable buprenorphine, injectable naltrexone) was also recorded. The training and/or technical assistance section documented the details of action taken to address these policies, the stakeholders engaged, and the outcomes. Upon identifying the policy-related issue, site-specific PWGs discussed necessary steps to be taken and reached out to community partners, stakeholders, or the national PWG, as appropriate. Action plan success for barriers and misunderstandings was categorized as 'yes,' categorized as 'no' if responses were unsuccessful, categorized as "other - partially resolved" when training and/or technical assistance was provided but issues were partially resolved, and categorized as "facilitator disseminated" when the training and/or technical assistance involved dissemination (see Table 3 for policy summary). Policy facilitators did not require resolution, so educational and dissemination efforts were carried out through community advisory board meetings, webinars, learning collaborative sessions, websites, flyers, and publications in newsletters. Although this shared methodology was used by all three sites, there were minor differences in data collection procedures across sites (see Table 1).

Table 1
Site-specific variation in data collection procedures.

State	Policy reporting procedures	Quality assurance/ control process	Dissemination
Kentucky	○ HCS faculty, staff, community advisory board, and community members could report policy concerns through an online form housed under the policy tab in a community dashboard.	○ The quality control process was conducted quarterly.	○ For dissemination, Kentucky specific online portal was developed, and policy updates were posted.
Massachusetts	○ PWG conducted informal interviews with the person who reported the policy.		○ The person reporting policy can request training and technical assistance via a form.
New York	○ Reporting was integrated into technical assistance request forms and flagged as a policy barrier or facilitator. ○ A training and/or technical assistance triage team with community coaches in coordination with the PWG reviewed the report and developed an action plan for the issue.	○ The PWG reviewed the reported policies quarterly, while the training and/ or technical assistance triage team reviewed the response weekly.	

Note: While a standard framework was developed for data collection, there was a slight variation by state, depending on the resources.

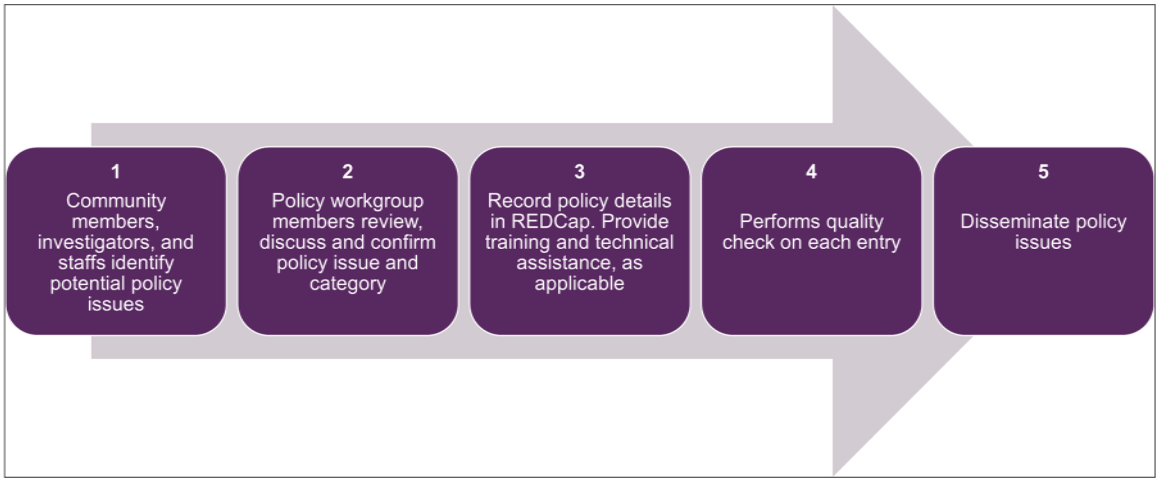

Fig. 1. Community reporting data collection procedure.

Results

A total of 87 policies (Kentucky = 37, Massachusetts = 19, and New York = 31) were identified and addressed by the PWG via HCS investigators/staff and community reporting between March 2020 and June 2023. Among them, 48.3 % ($n = 42$) were barriers, 24.1 % ($n = 21$) were misunderstandings, and 27.6 % ($n = 24$) were facilitators. Table 2 summarizes the policy barriers, facilitators, and misunderstandings and their respective EBPs impacted. Only 9.2 % (Kentucky = 1, Massachusetts = 3, and New York = 4) of policy-related issues resulted from the COVID-19 pandemic. Among the 87 policies identified, 23 % ($n = 20$) were in the federal jurisdiction (Kentucky = 6; Massachusetts = 5; New York = 9), 64 % ($n = 56$) were in the state jurisdiction (Kentucky = 28; Massachusetts = 10; New York = 18), and 21.9 % ($n = 19$) were in the local jurisdiction (Kentucky = 8; Massachusetts = 7; New York = 4). Some policies in Kentucky and Massachusetts were in multiple jurisdictions. The PWG efforts successfully or partially resolved over 73 % ($n = 31$) of policy barriers (Kentucky = 13; Massachusetts = 8; New York= 10), clarified 90 % ($n = 19$) of policy misunderstandings (Kentucky = 7; Massachusetts = 6; New York = 6), and disseminated 100 % ($n = 24$) of policy facilitators (Kentucky = 7; Massachusetts = 4; New York = 13). However, 15 % ($n = 13$) of policy-related issues (Kentucky=10; Massachusetts = 1; New York = 2) remained unresolved (11 barriers and 2 misunderstandings).

Multiple stakeholders were involved in addressing barriers and misunderstandings and disseminating policy facilitators. Examples of stakeholders included the American Society of Addiction Medicine, the U. S. Drug Enforcement Administration, state medical, nursing, and pharmacy boards, hospital administrations and healthcare providers, Substance Abuse and Mental Health Services Administration, and state Medicaid departments. In Kentucky, along with HCS team members (investigators, community members, and pharmacists), HCS state partners (Department for Behavioral Health, Developmental and Intellectual Disabilities, Department for Community Based Services, Department for Public Health, Kentucky Chapter of the American Society of Addiction Medicine, Kentucky Board of Medical Licensure, and Office of Drug Control Policy were involved in addressing policy issues. In Massachusetts, HCS state partners (Department of Public Health, Bureau of Substance Addiction Services), HCS team members (physicians, pharmacists, community coordinators, community engagement facilitators), the key government official, the Board of Pharmacy, hospital administrators, providers, and local 911 dispatchers, were involved in addressing policy-related issues. Similarly, in New York, state offices of mental health and addiction services, Substance Abuse and Mental Health Services Administration, Drug Enforcement Administration, county government, community engagement facilitators, coaches, and a technical assistance team were involved in addressing identified policy-related issues. Policy details, rationale for categories, whether policies were defined as a barrier, facilitator, or misunderstanding, and details of training and/or technical assistance provided are detailed in Table 3.

Table 2
Barriers, misunderstandings, and facilitators affecting evidence-based practices.

	Barriers			Misunderstandings			Facilitators		
Evidence-based Practices (EBPs)	KY	MA	NY	KY	MA	NY	KY	MA	NY
	(n = 21)	(n = 9)	(n = 12)	(n = 9)	(n = 6)	(n = 6)	(n = 7)	(n = 4)	(n = 13)
Menu 1: Opioid Education and Naloxone Distribution									
1a. Active OEND	6	1	6	2	0	3	3	2	10
1b Passive OEND	5	1	5	2	1	1	1	0	9
1c. Naloxone Distribution	1	0	4	2	1	0	0	1	2
Menu 2: Medication for Opioid Use Disorder									
2a. Expansion	14	5	8	5	3	2	4	2	7
2b Linkage	9	5	9	4	4	3	1	1	8
2c. Retention	13	5	9	4	2	3	2	2	8
Menu 3: Safer Opioid Prescribing and Disposal									
3a. Safer opioid prescribing practices	0	0	4	0	0	0	0	0	3
3b Safer opioid disposal practices	0	1	5	0	0	0	0	0	1

KY=Kentucky; MA=Massachusetts; NY = New York.

Examples of policies identified and addressed

Kentucky

Policy misunderstanding: A partnering community health department notified the Kentucky HCS team about negative interactions that occurred between local law enforcement officers and individuals leaving the local syringe service program located at the health department. Upon seeing naloxone in the syringe service program participant's car, the officers searched their vehicle, confiscated the naloxone, and arrested one individual. PWG categorized the issue as a policy misunderstanding affecting overdose education and naloxone distribution because carrying naloxone was being treated as possession of 'drug paraphernalia,' leading to probable cause to search individual property. However, under Kentucky statute KRS 218A:500 (Kentucky Revised Statutes, 2023), naloxone and syringes are not considered drug paraphernalia. As a course of action, the Director of the Kentucky Office of Drug Control Policy was briefed about the incident and partnered with the Kentucky County Attorney Association to release a statement clarifying that carrying naloxone is not probable cause for vehicle searches. Kentucky HCS offered overdose education and naloxone distribution training to the community police and sheriff offices. Further, a PWG member coordinated with the state Department for Public Health to create statewide training for syringe service programs on reporting negative interactions with law enforcement if there were subsequent similar problems. PWG members and stakeholders also worked with the Kentucky Department of Criminal Justice Training to create training video materials for law enforcement to watch in their cars as part of continuing education. Finally, the PWG worked with these stakeholders to develop state-wide training materials for law enforcement, including materials on OUD, overdose education and naloxone distribution, and the benefits of syringe service programs (Silwal et al., 2024). Thus, HCS efforts in stakeholder engagement and training and/or technical assistance helped clarify this policy misunderstanding.

Policy barrier: In April 2021, the U.S. Department of Health and Human Services released federal guidelines removing the training requirements for providers prescribing buprenorphine for up to 30 patients and attestation for counseling referrals (Department of Health and Human, 2021). However, Kentucky did not update its buprenorphine regulations to reflect this change (Silwal et al., 2023). The PWG categorized this issue as a barrier affecting the expansion of MOUD treatment availability. As a course of action, the PWG members sent a letter to the Kentucky regulatory board explaining the Health and Human Services new guidelines and engaged with a key stakeholder – the

Table 3
Summary of policy categories, evidence-based practices (EBPs), and training and technical assistance (TTA) provided.

	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
KY	Kentucky Board of Medical Licensure (KBML) emergency guidance for prescribing schedule II-V medications (controlled substances) during COVID-19 pandemic[b, *]	Mar-20	The emergency guidance only allowed telemedicine use for refills of Schedule II-V medications for pain management, not for new prescriptions or Schedule III medication for opioid use disorder (MOUD) treatment.	MOUD	Barrier[2]	The emergency guidance appeared to exclude guidance on buprenorphine use of telemedicine for new prescriptions, which could decrease access to buprenorphine treatment for opioid use disorder (OUD) during the pandemic.	HEALing Communities Study (HCS) investigators discussed the issue with the university and KBML lawyers. After discussion, the KBML revised its advisory on prescribing during a declaration of emergency to include buprenorphine for OUD treatment via telemedicine and clarified that this was also for new initiates.	Yes - barrier removed
KY	Suspension of Medicaid coverage while incarcerated[b]	Apr-20	Medicaid coverage suspended upon incarceration with no immediate restoration/ reactivation, resulting in a non-coverage period.	OEND, MOUD	Barrier[1, 2, 3]	Lack of insurance coverage prevents individuals from seeking immediate medical treatment upon release due to inability to pay.	Policy WorkGroup (PWG) member worked directly with the state to reactivate Medicaid up to 60 days before release and allow for reimbursement. An informative flyer was developed to raise awareness of the process of Medicaid reinstatement.	No
KY	Pharmacy claim denial for out-of-state Medicaid patients[b]	Jun-20	Out-of-state patients receiving hospital care in KY receive buprenorphine prescriptions and other state's Medicaid deny the claim even when the KY providers are also enrolled with the other state's Medicaid.	MOUD	Barrier[2]	Prevents access to MOUD provision by denial of claims that would cover buprenorphine products.	PWG reached out to surrounding state's Department of Behavioral Health and Medicaid for discussion about policy change or potential workarounds. No response was provided.	No
KY	MOUD billing difficulties for individuals in skilled nursing facilities[b]	Jun-20	Barriers and misunderstandings about providers and billing for buprenorphine and methadone-related services within nursing homes, including considerations related to facility stays.	MOUD	Misunderstanding[1, 2]	Complexities of multiple billing and organizational policies created a barrier to offering patients in skilled nursing facilities MOUD treatment.	PWG members consulted with staff working in nursing home settings to verify regulatory concerns, identify the next steps in education, and/or identify actual barriers versus perceived barriers/ misunderstandings. The HCS team is still seeking to clarify the misunderstanding, but it has not yet been clarified.	No
KY	Pharmacy regulation barrier in dispensing naloxone from inpatient pharmacies[a]	Jul-20	Interpretation of Joint Commission/ Pharmacy regulations hinders naloxone dispensing from an inpatient hospital pharmacy, causing barriers for hospital partners without an	OEND	Barrier	The inability to dispense from the only pharmacy at the hospital created a barrier to active and passive naloxone distribution from these sites.	PWG member consulted with the Joint Commission and determined that the inpatient pharmacy can dispense nalxone, but the medication must be labeled to the patient. HCS was able to provide naloxone	Yes - barrier removed

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Table 3 (*continued*)

	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			outpatient/retail pharmacy.				and the inpatient facility can label it.	
KY	Lack of medicare billing support for peer support services[a]	Jul-20	One healthcare system identified that the peer support service codes were not being paid for Medicare patients receiving treatment for opioid use disorder at a clinic within a study county.	MOUD	Barrier	Lack of funding to pay for peer support limits implementation and sustainability for facilities wishing to use peers, thus creating potential linkage and retention barriers.	PWG members reached out to the National Institute on Drug Abuse (NIDA) to discuss the potential for Medicare to reinstate coverage of peer support services. PWG also shared this information with the HCS Data Capture Workgroup.	No
KY	First responder concerns regarding liability of administering naloxone in the field[b]	Jul-20	First responders repeatedly voiced concerns or unwillingness to administer naloxone due to fear of repercussions/ liability.	OEND	Misunderstanding	State policy offers civil and criminal liability immunity for possession and administration of naloxone used in good faith and explicitly mentions Emergency Medical Service (EMS) employees as individuals authorized to use naloxone. The misunderstanding appears that individuals are concerned with wording about "personal injury" rather than understanding "gross negligence or willful and wanton misconduct" is required to be held liable.	HCS PWG discussed the issue with state officials. The officials then reached out to the Department of Criminal Justice Training and requested a clarifying statement be issued about carrying and administration of naloxone. KY Law Enforcement magazine published an article discussing regulations that protect Good Samaritans using naloxone and highlighted instances of police departments promoting its use among first responders. The HCS team hosted a learning collaborative addressing naloxone administration liability and continued to work with the Office of Drug Control Policy to change the regulatory language to explicitly authorize persons/agencies to provide naloxone and grant them immunity.	Yes - misunderstanding clarified
KY	Community concerns about not being able to get life insurance if one got a prescription for naloxone[b]	Jul-20	Members in recovery communities were being told that if they get naloxone they won't be able to get life insurance, which was preventing some from choosing to get naloxone for themselves or loved ones.	OEND	Misunderstanding	No local, state, or federally-based policy exists preventing/denying life insurance due to having a history of naloxone on your prescription claims. However, reports that you will be denied life insurance may prevent people from filling naloxone prescriptions.	PWG contacted the Kentucky Board of Insurance for clarification of policies around naloxone. The board responded that there are no policies in place and received a written statement from the board that states one "cannot be denied" for naloxone. PWG then created a flyer to inform community members about this policy and	Yes - misunderstanding clarified

(*continued on next page*)

Table 3 (*continued*)

	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
							continued to educate community members.	
KY	KY Regulations Regarding Alcohol and Other Drug Entities (AODEs)[b]	Sep-20	State regulations regarding qualifications for non-hospital-based AODEs state that the only required service to provide is individual or group counseling. The regulations list medication for OUD and overdose education as optional "recovery support services."	OEND, MOUD	Barrier[1, 2, 3]	Listing opioid education and naloxone distribution (OEND) and MOUD as "optional" services that AODEs are not required to educate clients about, refer to, or provide may serve as a barrier to effective, evidence-based OUD care.	HCS communicated with KY Medicaid staff members to get clinical expert input into the statutes regarding EBI incorporation into AODE state regulations. PWG working to bring this issue to the Medicaid Advisory Committee or Technical Advisory Committee as a form of expert opinion and ask if can get an external consultant for addiction if that is not in the committee.	No
KY	KBML lack of amending restrictive buprenorphine prescribing and dispensing regulations despite changing regulations to allow Physician Assistants to prescribe buprenorphine[b]	Oct-20	KBML updated regulations for buprenorphine administration and distribution. The updates provide the inclusion of physician assistants to administer buprenorphine, but inconsistencies with American Society of Addiction Medicine (ASAM) best practice guidance and SAMSHA publications remain.	MOUD	Barrier[2]	KBML regulations were updated to add Physician Assistants to those who can prescribe, however, maintain discrepancies with national ASAM practice standards and SAMHSA published guidance. This creates barriers to buprenorphine treatment expansion and retention.	PWG emailed the state legislation board regarding concerns and in support of changes to current statute language to align with federal guidelines. PWG also reached out to state partner, KY Society of Addiction Medicine (KY-SAM), requesting a letter of support and attendance at the local KBML regulation meeting regarding desired language changes. PWG and KY-SAM representatives attended the KBML meeting, reviewed the changes and sent a letter recommending changes to the buprenorphine regulations. HCS Investigators provided written feedback about concerns to KBML, but no changes to regulations have been made. PWG received notification that KBML would not be uptaking recommended language changes.	No
KY	Government-Issued ID Requirements at Pharmacies and MOUD Agencies[a, b, c]	Jan-21	Federal or state policies exist requiring government-issued IDs to receive MOUD or dispense buprenorphine at a pharmacy. The KY board stance	MOUD	Misunderstanding[1, 2, 3]	There is no standard for identification guidelines when accessing MOUD treatment at different facilities. The vagueness of the language in guidance leaves identification	PWG contacted 62 community clinics and developed a provisional ID where some clinics (only 8 accepting government ID) agreed to begin MOUD treatment.	Other - partially resolved

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Table 3 (*continued*)

	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			mentions that individual pharmacies can decide to require government ID, though there is no state policy requiring the use of government IDs. Most pharmacies and clinics choose to enforce government ID requirements.			requirements up to interpretation/ misunderstanding.	PWG reviewed regulations and worked with partners to develop workarounds and provide funding to obtain new government IDs.	
KY	Medicaid Requiring Prior Authorizations or Denying Claims for Naloxone In 2021[b]	Feb-21	Patients with Medicaid were being required to receive prior authorization, being denied, and/or required to pay a co-pay to receive naloxone due to a change in the preferred drug list at the beginning of 2021 (naloxone not on list).	OEND	Barrier	Individuals are unable to access naloxone due to policy change in Medicaid formulary.	PWG reached out to state partners and the Cabinet of Health and Family Services Department of Medicaid Services. All KY Medicaid MCOs removed the prior authorization by the end of February 2021.	Yes - barrier removed
KY	Pharmacy Misunderstanding on Legality of Multi-Day Buprenorphine Home Induction Prescriptions[b]	Mar-21	The KY Board of Pharmacy had an outdated frequently asked question section regarding the regulations for buprenorphine home induction and dosing that was influencing pharmacists' decisions not to fill prescriptions for multi-day induction. Board inspectors were also saying some actions are "legal but 'frowned upon."'	MOUD	Misunderstanding[2]	This misunderstanding prevents access to people prescribed buprenorphine.	PWG member contacted the board about the inaccuracies on the KY Board of Pharmacy website and planned educational resources so UK pharmacists are aware of buprenorphine home induction rules and dosing.	Yes - misunderstanding clarified
KY	Kentucky Board of Medical Licensure (KBML) Restrictions When Dispensing and Prescribing Buprenorphine in Emergency department and Inpatient hospital settings[b]	Mar-21	State medical board regulations regarding buprenorphine prescribing state providers must "obtain written informed consent from the patient in a manner that meets professional standards". Staff from two different hospitals partnering with HCS reported their organization interprets this to indicate that patients with OUD must provide a separate written consent (in addition to general consent to treat) in order to prescribe or dispense buprenorphine. Additionally, the	MOUD	Misunderstanding[2]	The legal team at two hospitals misinterpreted Kentucky Administrative Regulations (KAR) regulations, which affect care.	PWG conducted meetings between hospital and HCS staff to discuss the regulations and provided clarification that KAR 201.09.270 Section 4.2 has an allowance that providers can document any practices that do not comply with KY standards that, in professional opinion, are appropriate and are in accordance with national guidelines (e.g., SAMHSA). PWG also expressed concerns about the cooling effect and limitations to prescribing buprenorphine to KBML, but the	No

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			guidelines prohibit use of 4 mg for buprenorphine initiation.				regulations have not been changed.	
KY	Pharmacist Compensation for OUD Prevention and Treatment Services[b]	Mar-21	A new act created amends Kentucky Revised Status (KRS) 304.14–135 to establish reimbursement of certain pharmacist services or procedures, including providing OEND and administering naltrexone.	OEND, MOUD	Facilitator[3]	Allowing pharmacists to conduct and be reimbursed for OEND and naltrexone administration should increase access to naloxone and naltrexone use.	HCS notified other pharmacists of the policy change as part of HCS ongoing community education efforts. With the signing of House Bill HB 48, the pharmacist compensation plan allows pharmacists to be compensated for services rendered under their scope of practice that other practitioners can do.	Facilitator disseminated
KY	Medical provider within detention center discontinuation/ refusal of MOUD treatment to incarcerated individuals[c]	Apr-21	A detention center medical provider denied continuation of MOUD or transport for clients wanting MOUD to a community provider. Barriers cited included lack of staffing, concerns about narcotics on-site/diversion, costs of buprenorphine, and belief that detox is proper medical treatment/that suffering is acceptable in jail, all constituting an American Disability Act (ADA) violation.	MOUD	Misunderstanding[2]	The medical provider's organizational policy of discontinuing MOUD treatment for those already receiving it and not offering treatment beyond opioid withdrawal appears to be due to misunderstandings of how MOUD works and also did not appear to understand how ADA applies to those with opioid use.	PWG team consulted with the Mayor's substance use disorder (SUD) Council and county coalition member involved in criminal legal system to discuss concerns and the possibility of an ADA violation. PWG reached out to national PWG since the medical provider is a national organization and see if this provider is within any of the jails in other HCS communities and see if there is potential to work at a larger scale. The team followed up with a medical provider who has also been involved in follow-up calls with the coalition. This detention center ultimately was involved in a settlement for an ADA violation and now working to offer MOUD treatment.	Yes - misunderstanding clarified
KY	KY state regulations removed training requirement to get certified to initiate dispensing of naloxone[b]	May-21	New state regulation removed the 1.5–2 hr training requirement for pharmacists to get certified to initiate dispensing of naloxone and the barrier of educating on 7 specific pieces of information before being able to distribute naloxone, though pharmacists must counsel and document education specific to the dosage	OEND	Facilitator	This policy change further facilitates naloxone access by reducing barriers and length of time to education and distribute naloxone.	Pharmacists on the team were instrumental in sharing information about this need with state policymakers, and pharmacists provided education about this policy change in training as part of individual academic detailing sessions when appropriate.	Facilitator disseminated

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			form of naloxone dispensed.					
KY	Kentucky Board of Medical Licensure (KBML) Lack of Uptake of New HHS Federal Buprenorphine Guidelines Waiver Exemption and Mainstreaming Addiction Treatment (MAT) Act Waiver Removal[b]	Apr-21	The Department of Health and Human Services released a new federal buprenorphine prescribing Guideline in April 2021 removing the training requirements for prescribing to up to 30 patients and attestation for counseling referrals. However, KY state requirements remained more restrictive (maintaining training requirements), thus limiting access to buprenorphine treatment in KY.	MOUD	Barrier[2]	The state regulations are a barrier, because they may limit the prescribing of buprenorphine if providers must first complete waiver training and certify the ability to refer to ancillary counseling when they are required by the state but not federally.	PWG emailed the state legislation board regarding concerns and in support of changes to current statute language to align with federal guidelines. PWG also reached out to the state society of addiction medicine and received a letter of support for changes. PWG representatives attended a KBML meeting to discuss potential changes to the buprenorphine regulations. PWG received notification from KBML indicating KBML would not comply with the federal HHS guideline and continue to maintain training requirements. In December 2022, the MAT Act removed the federal waiver certification to prescribe buprenorphine. In Jan 2023, The PWG spoke with KBML about amending the regulations again to remove waiver and certification requirements. In Jan 2023, the KBML issued guidance regarding removal of the data waiver, noting "All KBML licensees with a valid DEA registration may prescribe or dispense buprenorphine."	No
KY	KY Medicaid pharmacy dispensing reimbursement change[b]	Jun-21	Kentucky is setting a new prescription reimbursement policy by moving to a single pharmacy benefit manager (PBM) to manage pharmacy services for all the managed care organizations (MCOs) and fees for service Medicaid. The new PBM will reimburse pharmacies one dispensing fee of $10.64 per month for	MOUD	Barrier[2]	This is a significant barrier to buprenorphine dispensing. This reimbursement policy change may reduce access to buprenorphine at pharmacies as pharmacies may be reluctant to dispense multiple prescriptions for only a single dispensing fee. If pharmacies have additional barriers to	PWG members discussed the issue at the PTAC meeting. The KY Pharmacy Association (KPA) sent a letter to Medicaid with a concern that the policy should exclude buprenorphine prescriptions and allow multiple dispensing fees per month. The issue was raised with the Department for Behavioral Health,	Yes - barrier removed

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			dispensing oral buprenorphine medications to patients multiple times.			buprenorphine reimbursement and dispensing, they may be less likely to fill prescriptions and make it more difficult for patients to start or be retained in buprenorphine treatment.	Developmental and Intellectual Disabilities (DBHDID) and Medicaid by key government officials. The team ultimately was able to discuss this issue with the PTAC and MAC (medical advisory committee) meetings, where IQVIA data was shared about national supply and prescriptions in KY being much lower than in other states for all payor sources due to this issue. As a result, an emergency regulation was put in place to allow a 1064 dispensing fee once every 7 days instead of 28 days for buprenorphine dispensing to go into effect June 1, 2022.	
KY	Statewide training efforts following negative interactions with law enforcement/ confiscation of naloxone[b, c]	Jul-21	Two individuals were stopped by local law enforcement, resulting in negative interactions related to the Syringe Access Exchange Program (SAEP) and having naloxone in the car. Officers searched their car upon seeing Narcan and used it as "probable cause" and naloxone was confiscated by the officers and one individual was arrested from this encounter. Other reports included descriptions of police officers driving very slowly by the building while individuals were outside and sitting directly across the street from the SAEP such that people were not getting out of the cars/not entering the SAEP.	OEND	Misunderstanding	Local law enforcement officers believed naloxone is "drug paraphernalia", therefore giving them "probable cause" to search a person's property. It could also be a barrier as awareness of this may hinder participants' willingness to enter the Syringe Service Program (SSP) to receive a variety of OEND, harm reduction services, and information about OUD treatment.	PWG faculty member shared details captured about the negative experiences with the Office of Drug Control Policy (ODCP) executive director. As a result, ODCP partnered with the KY County Attorney Association issuing a statement about naloxone not being probable cause for a search as well as creating a state-wide training for law enforcement. Additionally, Department of Public Health (DPH) staff created a state-wide training for SSPs on how to report negative interactions if they have any, and the CLS team offered OEND to local police and sheriff's offices. Key government official (KGO) worked with Shatterproof to create training material for police cars for police to watch in downtime.	Yes - misunderstanding clarified
KY	New Drug Enforcement Agency (DEA) Mobile Methadone Van Rule - new federal	Jul-21	The new DEA Mobile Methadone Van rule waives the requirement of a separate registration	MOUD	Facilitator[1]	This is a policy facilitator, because it makes it easier for an OTP to establish a mobile van without	PWG confirmed that current KY regulations were silent on the issue and provided feedback to	Facilitator disseminated

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	Policy categories						Training and Technical Assistance (TTA)	
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	changes for mobile opioid treatment programs[a]		at each principal place of business or professional practice where controlled substances are dispensed for those OTPs with mobile components that fully comply with the requirements of this rule. OTPs can now start a mobile unit without any additional licensing.			acquiring an additional license.	DBHDID on the language added to KY's regs to facilitate the implementation of mobile methadone. PWG also confirmed that a new Medicaid code will not be needed for mobile methadone and that it can be billed as part of the weekly bundled rate using a modifier for a remote location.	
KY	KY Supreme Court rule placed restrictions on the KY Good Samaritan law's protections against being charged with illicit drug possession in case of an overdose[b]	Aug-21	Supreme Court ruling on Wilson vs. Commonwealth restricts Good Samaritan Law's protections against being charged with illicit drug protection in cases of overdose. The ruling now states that the "Good Samaritan" must know that it is an opioid overdose and state they witnessed the overdose/are certain it is an opioid overdose in order for the person experiencing the overdose to not be charged.	OEND	Barrier	This is a barrier because it may be a deterrent/cause a chilling effect for people to call and report an overdose for fear of prosecution.	PWG members communicated with state legal and national research center, notifying them of a priority concern. The discussion indicated that the research center would likely recommend a legislative correction to a policymaker and said that they have dealt with similar scenarios in other states. HCS team recommends in the meantime to share with coalitions and educate others if they call to state, "I think this is an opioid overdose," and should be covered.	Other - partially resolved
KY	Removing state requirements of logging of syringes and other dispensed Items by KY pharmacies[b]	Jun-21	Pharmacy statutes 217.177 and 218A.500 related to syringe sale laws were updated, including noting that logging sale of syringes and obtaining the name, address, and planned use of syringes is no longer required.	OEND	Facilitator	The removal of logs regarding syringes is a facilitator for individuals receiving syringes and may facilitate OEND because pharmacists are also required to offer naloxone to those who seek syringes under this law.	The HCS prevention team created flyer to educate community pharmacists about changes to this law. HCS prevention team pharmacists have also discussed the change to the law from June 2021-September 2021 with a mixed reception.	Facilitator disseminated
KY	Car ownership as a barrier to obtaining Medicaid transport[b]	Mar-22	HCS partner's clients are unable to access Medicab services due to having a vehicle registered under their name despite it being inoperable or another car-related barrier.	MOUD	Barrier[1, 2, 3]	This is a barrier because not being able to access reliable transportation could inhibit one's ability to access healthcare and other services, including MOUD.	PWG discussed the issue and it was determined no recourse for changing the regulations regarding Medical eligibility for these circumstances. Thus, no further plans of action were discussed.	No
KY	Community reports of court sentencing preventing clients from receiving MOUD or requiring a particular medication,	May-22	Judges of certain courts have required that individuals with OUD who are on MOUD to stop their MOUD treatment or force them to be on a particular	MOUD	Barrier[1, 2, 3]	Local rulings of judges are preventing individuals from being on MOUD or requiring only an antagonist prevents individuals who are interested in MOUD	PWG collected stories of clients who were required to stop/not begin MOUD based on judge rulings from peer support specialists. These stories were	Other - partially resolved

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	Policy categories						Training and Technical Assistance (TTA)	
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	appearing to be an ADA violation[c]		medication. These actions appear to be in violation of the ADA.			from beginning MOUD treatment and/or preventing people from being retained in MOUD treatment, thus creating a barrier to accessing and retaining on treatment.	presented to state justice partners to try to bring attention and education to judges on the potential negative consequences of these rulings. PWG also developed a state-wide on-demand learning collaborative with continuing education for lawyers and judges (CLE) about the science of addiction and evidence base about MOUD and OEND. PWG also provided education to partners attending KY-OPEN about ADA and how they could report potential ADA violations. However, this problem is not fully addressed with judges in part possibly because drug court is voluntary and because it is likely long-held stigma-oriented views that are not fast to change.	
KY	Corporate pharmacy policy metrics for number of fills doesn't include controlled substances[c]	Jul-20	Corporate pharmacies do not have policies that include medications for OUD in their fill metrics. It can take longer to fill MOUD prescriptions and potentially create a barrier for patients trying to access/fill their prescriptions.	OEND, MOUD	Barrier [2]	This policy limits/ prevents access to receiving naloxone or buprenorphine formulations in a timely manner and thus may impact starting or being retained in MOUD or having access to naloxone when needed.	PWG notified national pharmacy association regarding this issue. As a result, the American Pharmacy Association is conducting a national survey related to this to see how it is impacting pharmacies nationally, and HCS pharmacy team is writing manuscript about this issue.	Other - partially resolved
KY	Hospital Policy Updates Requiring Providers to become X Waivered[c]	Mar-22	Partnering community hospital reported that the hospital put in place a new policy that requires all current and new hospitalist and emergency department providers to obtain their waiver to prescribe buprenorphine	MOUD	Facilitator[2]	By requiring all providers in the emergency department and hospital to be waivered, this hospital will be able to more effectively implement buprenorphine induction protocols and likely increase access to bridging MOUD medications/ access to MOUD in the community.	PWG team members worked with local champions of MOUD in both inpatient and emergency department settings to support efforts to make a mandatory policy. After the removal of the x-waiver, this was no longer applicable.	Facilitator disseminated
KY	Misunderstandings regarding Mainstreaming Addiction Treatment	Oct-20	KBN regulations for advanced practice registered nurses (APRNs) prescribing	MOUD	Barrier[2]	Non-psychiatric APRNS must refer patients for an additional referral for	HCS faculty and state government leaders met with the Board of Nursing Executive	No

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
	(MAT) act related to Kentucky regulations[b]		buprenorphine require any non-psychiatric APRN to refer patients for an assessment by a mental health provider who agrees buprenorphine is needed before they can initiate buprenorphine treatment. Regulations also require APRNs to consult with obstetrical care prior to prescribing buprenorphine to pregnant persons and consult with an addiction specialists/ psychiatric nurse practitioners to treat patients who are also being prescribed any benzodiazepines, sedative-hypnotics, stimulants, or other opioids.			a mental health evaluation from a specialized provider before initiating buprenorphine. There are also additional requirements made for pregnant persons. Neither of these are required by federal guidelines. These barriers make it more challenging for APRNs to effectively treat OUD patients with buprenorphine.	Director and KY Board of Nursing General Counsel to discuss the barrier. KY Board of Nursing (KBN) shared that they have received feedback from other stakeholders as well and will revise to retain this need about consultation but would be within 90 days of initiation presently; this regulation was updated in December 2021 and ultimately included restrictions only for those on the medications listed above. The team also talked with the board about the potential to write an emergency regulation to suspend additional needs during COVID and reach out to KY-SAM to potentially write an official letter of support for changes. Despite these additional supports in place, no emergency regulations for suspension of the MH requirement or requirement for pregnant patients have been put in place.	
KY	Medicaid requiring prior authorization for extended-release buprenorphine[b]	Mar-20	Some Medicaid MCOs require prior authorization for extended-release buprenorphine, sometimes resulting in delays in treatment with injectable buprenorphine and the patient's treatment plan.	MOUD	Barrier[2]	Medicaid MCO prior authorization requirements for extended-release buprenorphine sometimes resulted in delays in treatment with injectable buprenorphine. PWG faculty reported in 2018–2019 that 40 % of all KY extended-release buprenorphine prior authorizations were denied by Medicaid.	PWG and KY HCS state partners worked with the BHDID/ Medicaid office and the MCO's to review the current pharmacy prior authorization policy for extended-release buprenorphine in the treatment of OUD. In April 2020, state Medicaid waived the need for prior authorization for extended-release buprenorphine from all MCOs.	Yes - barrier removed
KY	Pharmacy Regulation Changes allowing pharmacists to be in OUD treatment with MOUD[b]	Jun-22	KPA amended an update to the regulations allowing pharmacists to take MOUD for OUD treatment and still be in practice.	MOUD	Facilitator[1,2,3]	Prior to this revision, pharmacists in Kentucky were not allowed to practice if they took MOUD. Because of this change, pharmacists may now be more likely to engage in MOUD treatment.	HCS pharmacist on team was instrumental in the development and revision of language to this policy revision. HCS team members also are looking into whether KY is the first state to explicitly state	Facilitator disseminated

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
							pharmacists can be on MOUD and maintain their positions and encourage other states to do the same.	
KY	City Ordinance Not Allowing Outdoor OEND Events[c]	Oct-22	City government official stopped a prevention specialist, who obtained permission from local business owner, to provide OEND outside local business office citing that city ordinance prevents anyone from conducting business outside of city business walls.	OEND	Barrier	The interpretation/ application of this city ordinance is preventing team members from engaging in active OEND events within this city.	HCS team members spoke with a city code enforcement officer who reported "nothing they can do" and provided specific component of the city code interpreted to be breached. HCS team member then reached out to city mayor, who was unresponsive. HCS shared the city ordinance with UK legal team to further understand interpretation/ application and review if there may be additional ordinances that would supersede the city ordinance. Since the initial occurrence, the prevention specialist (PS) has been approached by Code Enforcement in a different city within the same county twice. One said they could cite PS but would not since what PS was doing is important for the community. The other specifically asked if PS was exchanging any money. When PS said no, officers allowed to proceed.	Yes - barrier removed
KY	Organizational policies hindering alignment with state regulation regarding Logging of Syringes and other dispensed Items by KY Pharmacies[b, c]	Jun-21	Pharmacy statutes 217.177 and 218A.500 related to syringe sale laws were updated, including noting that logging sale of syringes and obtaining the name, address, and planned use of syringes is no longer required. However, as HCS prevention team began to provide education to community pharmacists about the policy change, community pharmacists reported that many of their	OEND	Barrier	The continued requirement of logging at the organizational level by corporate pharmacies despite new state regulation that would make logging no longer required is a barrier to implementing this change in state regulations.	HCS prevention team created flyer to educate community pharmacists about changes to this law. HCS prevention team pharmacists have also discussed the change to the law June 2021-September 2021 with mixed reception. Only one pharmacy made a policy change around it, but many people were positive and unaware of the change prior to the education around it. HCS team placed the syringe flyer on community website as of October 2021	Yes - barrier removed

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State	Policy categories						Training and Technical Assistance (TTA)	
	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			corporate policies of the pharmacy itself required the pharmacists to maintain logging of syringe sales.				and continue to educate to try to support corporate policy changes.	
KY	Kentucky Board of Nursing (KBN) Buprenorphine Prescribing Restrictions for Advanced Practice Nurses (APRN)s[b]	Oct-20	New KBN regulations for APRNs prescribing buprenorphine require any non-psychiatric APRN to refer patients for an assessment by a mental health provider who agrees buprenorphine is needed before they can initiate buprenorphine treatment. Regulations also require APRNs to consult with obstetrical care prior to prescribing buprenorphine to pregnant persons and consult with addiction specialist/ psychiatric nurse practitioner to treat patients who are also being prescribed any benzodiazepines, sedative hypnotics, stimulants, or other opioids.	MOUD	Barrier[2]	Additional consultations for APRNs to initiate treatment are not required by federal guidelines. These barriers make it more challenging for APRNs to effectively treat OUD patients with buprenorphine.	After multiple e-mail communications, the PWG and state government leaders met with Board of Nursing Executive Director and KY Board of Nursing General Counsel. PWG suggested that the board eliminate the requirement for a separate mental health assessment requirement because primary care APRNs provide general mental health treatment as part of their scope of practice, and requiring an additional assessment by a mental health provider may serve as a barrier to patients entering buprenorphine treatment. KBN shared that they had also received feedback from other stakeholders and suggested a revision to the regulation. This regulation was updated in December 2021 and no longer requires a separate mental health assessment. However, other more restrictive components such as consultation for pregnant persons prior to initiation still exist.	Yes - barrier removed
KY	SAMHSA Regulations Regarding Opioid Treatment Program (OTP) Based mobile medication units and Whether they Can Receive their Medication Supply from brick-and-mortar medication stations[a]	Mar-23	Federal Regulation 42 CFR Part 8 states that each entity of an OTP must operate under its own DEA number. While this regulation makes it clear that a medication station and a mobile unit can be operated under the main brick-and-mortar hub of an OTP, a SAMHSA representative reported that these regulations would not allow a mobile	MOUD	Misunderstanding[1]	The interpretation that the medication station could not be used for mobile OTP operations did not allow us to move forward with implementation in a rural HCS county, because the OTP partner willing to attempt implementation operates a medication station one hour each way, whereas the full-OTP is two and half hours each way.	Team members met with State Opioid Treatment Authorities (SOTA) and subsequently, DEA to develop and share the proposal of using the medication station as primary source of operations for the mobile unit. SAMHSA was notified of this policy issue during the meeting with SOTA and DEA. The HCS team submitted public comments to	Yes - misunderstanding clarified

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			unit to operate under an OTP's medication station.				potentially change the regulation. HCS also notified SAMHSA representatives of this issue and requested clarification or information regarding potential need to apply for an exemption. After multiple contacts with SAMHSA and NIDA throughout April and May 2023, SAMHSA was able to clarify the regulations to verify that mobile units could operate with the use of a medication station instead of only a full OTP.	
KY	State medical board buprenorphine regulations impeding MOUD implementation at detention centers[b]	Apr-23	HCS study county detention center signed a memorandum of understanding stating they would provide access to all three FDA-approved medications for OUD as an ADA violation settlement for not providing access to medication in the past. The center has attempted to comply by transporting patients to medication providers for these medications. However, the frequency required in the KBML regulation exceeds the detention's transporting ability of the patients to the treatment center.	MOUD	Barrier[1,2,3]	Additional state regulations beyond the federal requirements are making it difficult to implement MOUD treatment.	PWG contacted the KBML regarding this issue, and the KBML reported being open to receiving a request for an emergency board opinion regarding the regulations as they apply to jails. The PWG contacted the KY-SAM, who sent a letter supporting the need to change the KY regulations to be in agreement with national guidelines. The PWG also reached out to the Board of Pharmacy to see if they will write a letter in support of these changes (Board of Pharmacy declined June 2023 due to competing priorities at time). On June 15, two PWG members went in person to a meeting of the KBML to discuss this issue. On June 16, KBML issued the statement that while established visit frequency is appropriate for buprenorphine treatment and hope telemedicine appointments may allow correctional facilities to meet these frequency guidelines, that "in the absence of these accommodations, it is the Board's opinion that it is an acceptable and	Yes - barrier removed

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State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
							prevailing practice to exclude patients from the frequency of visit requirements… while they are incarcerated."	
KY	Medicaid coverage of new extended-release buprenorphine formulations[a, b]	Jun-23	FDA released a statement that they have approved Brixadi to treat OUD. Because the medication is new, the KY policy team also wanted to verify its access on Medicaid within the state by supporting its inclusion on the KY Medicaid formulary.	MOUD	Facilitator[2]	Providing additional formulations of MOUD and ensuring that these medications are available on Medicaid help increase access to MOUD.	PWG contacted the Medicaid Pharmacy services, asking whether or not Brixadi would be included on the KY Medicaid formulary. The Medicaid director responded, stating that it would be included. The KY policy team is monitoring whether Medicaid MCOs approve both Brixadi formulations as they come to market.	Facilitator disseminated
KY	Two MCO's implemented a prior authorization and reauthorization requirement for receiving methadone and services at KY's OTPs[b]	Mar-20	Methadone became a covered Medicaid benefit on 7/1/2019. Prior authorization was not mandated by Medicaid, but two MCOs elected to required prior authorization for methadone in KY.	MOUD	Barrier[1]	Requiring prior authorization and re-authorization may slow or prevent access to individuals for methadone.	Department of Medicaid Services directed the suspension of all Physician Assistants (PAs) for medical services from 2/4/2020 forward. It was clarified in April that methadone fit under this umbrella of medical services and the two MCOs removed their prior auth requirements accordingly. When enacted, the waiver of PAs is anticipated to end when the emergency order is lifted. PAs will be reinstated for many medical services, but at this time behavioral health services (which methadone falls under) will continue with a waiver of PAs (confirmed December 2021).	Yes - barrier removed
MA	Naloxone leave behind program[b]	Dec-20	Emergency medical service providers were only allowed to leave behind naloxone if the individual for whom the call was for refused transport and could only leave with the person who overdosed.	OEND	Barrier	Existing policy led to less naloxone administration, likely leading to fewer overdose reversals.	HEALing Communities Study (HCS) worked with Department of Public Health (DPH) to change the policy around naloxone administration to allow EMS to leave behind naloxone to friends/family regardless of whether the patient refuses hospital transport or not. HCS also conducted learning collaborative for HCS	Yes - barrier removed

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
							communities on policy change.	
MA	Drug Enforcement Agency (DEA) requirements for medication for opioid use disorder (MOUD) storage[a]	Dec-21	Regulation related to the storage of long-acting formulations of buprenorphine (Sublocade).	MOUD	Barrier[2]	Complicated logistics for storage and administration of the medication.	HCS worked with bridge clinics to ensure that they had the necessary resources and equipment to safely provide the medication. This helped increase access to sublocade in bridge clinics.	Other- partially resolved
MA	Third-party reimbursement for recovery coaches[b]	Sep-21	One of the HCS communities was not billing for recovery coach services due to low reimbursement and requirements related to the supervision structure for MassHealth billing.	MOUD	Barrier	Although MassHealth covers recovery coaching, one of the HCS communities is not billing for this service due to low reimbursement and a lack of infrastructure for reimbursement, thus limiting this service.	Provided coaching to the HCS implementation team and TTA to the HCS community with reimbursement memos. A learning collaborative was organized to raise awareness around recovery coaching billing. Later in the study period, MassHealth created more flexibility for recovery coach reimbursements independent of HCS researchers.	Other - partially resolved
MA	COVID-19 medication dosing in opioid treatment program (OTPs)[a, b, *]	Sep-21	The state may request blanket exceptions for all stable patients in an OTP to receive 28 days of take-home doses and request up to 14 days for those patients who are less stable but who the OTP believes can safely handle this level of take-home medication.	MOUD	Facilitator[1]	Patients are able to get more take-home methadone doses due to relaxed federal and state regulations.	HCS team members provided periodic presentations in the community advisory board meetings and state steering committee meetings highlighting policy facilitators. The policies were also discussed with Communities That Heal (CTH) implementers.	Facilitator disseminated
MA	Pharmacies requiring ID to access buprenorphine prescription[c]	Sep-21; Apr-22	Pharmacies refused to fill buprenorphine prescriptions for patients without a photo ID, despite a state policy exemption giving pharmacists discretion to fill these prescriptions.	MOUD	Barrier[2]	People were not able to access a life-saving medication unless they have a photo ID despite a policy exemption stating otherwise.	HCS pharmacists provided academic detailing to pharmacies in HCS communities. Also, one of the HCS communities created a flyer for patients to carry to show to pharmacists.	Other - partially resolved
MA	Advisory on the sale of hypodermic syringes and needles[c]	Aug-21	The law (M.G.L. c. 94C, 27) related to the sale of hypodermic syringes or hypodermic needles authorizes pharmacies to sell hypodermic syringes and needles to any person, of any age, without a prescription, and without identification. However, some	OEND	Barrier	Policy states that pharmacies can sell syringes to any person at any age without a prescription or ID, but pharmacies may refuse to carry syringes which would negatively impact harm reduction strategies in these communities.	HCS pharmacist provided academic detailing to pharmacies in HCS communities.	Other - partially resolved

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Table 3 (*continued*)

	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			organizational policies are in place that prevent the stocking of syringes at pharmacies.					
MA	Inpatient methadone administration[a]	Sep-21	Provider misunderstanding of liability when providing MOUD in inpatient hospital setting.	MOUD	Misunderstanding[1]	Nurses misunderstood how to distribute methadone in inpatient settings.	HCS staff disseminated Boston Medical College protocols and guidelines about administering inpatient methadone.	Yes - misunderstanding clarified
MA	Bridge program billing for patients in other Accountable Cate Organization (ACOs)[b]	Apr-21	The HCS bridge clinic perceived that they could not bill for patients receiving substance use disorder (SUD) treatment outside of their ACO despite a policy stating otherwise.	MOUD	Misunderstanding[2, 3]	Unawareness of policy where ACOs can bill the carve-out for addiction sub-speciality treatment.	The MassHealth provider bulletin and a frequently asked questions sheet, which was created by the Boston Medical College ACO, were distributed via email with the HCS bridge clinic.	Yes - misunderstanding clarified
MA	Collaborative models for medication for opioid use disorder treatment[b]	Dec-21	An effective pilot buprenorphine treatment model with a nurse care manager was expanded across the state and financially supported by the state to increase access to MOUD.	MOUD	Facilitator	This policy change increased provider reimbursement by subsidizing non-billable services	HCS team members provided periodic presentations in the community advisory board meetings and state steering committee meetings highlighting policy facilitators. The policies were also discussed with CTH implementers.	Facilitator disseminated
MA	Peer stipend program funded by American Rescue Plan Act of 2021[a, b, *]	May-22	A harm reduction organization operating in one HCS community received $25,000 to expand its opioid treatment and overdose prevention programs through federal American Rescue Plan Act legislation appropriated by the state.	OEND	Facilitator	The funding helps increase naloxone distribution in some HCS communities by adding more naloxboxes and supporting a peer stipend program.	HCS team members provided periodic presentations in the community advisory board meetings and state steering committee meetings highlighting policy facilitators. The policies were also discussed with CTH implementers.	Facilitator disseminated
MA	Lack of institutional policies and protocols to address OUD[c]	Jun-21	Several HCS communities did not have standardized policies and protocols in place to address a range of issues related to treating opioid use disorder (OUD) in the healthcare system, such as switching a patient from methadone to buprenorphine.	OEND, SPDP	Barrier[1, 2, 3]	Policies and protocols were not in place in hospitals in some HCS communities to appropriately address OUD.	HCS shared policies and protocols with local Boston hospitals including management of inpatient withdrawal, using naltrexone, ordering buprenorphine for hospital patients, microdosing to initiate buprenorphine, perioperative pain management for patients on MOUD, and using patches appropriately as analgesics.	Yes - barrier removed
MA	"Meds to Beds" providing naloxone to patients upon discharge at a community hospital[c]	Jun-22	An addiction consult service in one HCS community adopted a policy that provides patients	OEND	Facilitator	The policy is expected to increase naloxone distribution.	HCS team members provided periodic presentations in the community advisory board meetings and	Facilitator disseminated

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Table 3 (*continued*)

	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			naloxone at the bedside before they leave the hospital.				state steering committee meetings highlighting policy facilitators. The policies were also discussed with CTH implementers.	
MA	Oversight of mobile units[c]	Oct-20	The city council and city manager's office in one HCS community maintain unclear yet heavily policed enforcement where a mobile unit may be located on city property. They also use police to monitor private properties.	MOUD	Barriers[2, 3]	HCS was unable to implement an EBP using a mobile unit providing MOUD, which may have resulted in, fewer people potentially having access to MOUD.	HCS discussed this issue with the city officials to raise awareness. The City Council was not supportive of changing their policies despite the HCS efforts in trying to intervene.	No
MA	Prescribing MOUD off-site to people working in the fishing industry[b, c]	May-22	MOUD provider was unsure if medical licensing and insurance would allow them to prescribe outside of the main clinic setting, specifically on the pier where local fishing communities operates.	MOUD	Misunderstanding[2]	The lack of any codified guidance led to questions about malpractice insurance coverage and created misunderstandings. Prescribers were unclear whether existing policies would prevent them from prescribing MOUD at an off-site location, such as near a fishing pier.	HCS research staff provided training and technical assistance to community teams and providers to raise awareness about regulations that allow prescribing buprenorphine off-site, such as at fishing piers.	Yes - misunderstanding clarified
MA	Addiction Recovery Coach Certification[b]	May-21	The Certified Addiction Recovery Coach (CARC) Credential is a complicated and burdensome certification for recovery coaches provided by a private non-governmental entity.	MOUD	Barrier	The process for credentialing recovery coaches in Massachusetts is overly burdensome and difficult to obtain. Recovery Coaches apply and pay fees for the CARC and try to contact the Massachusetts Board of Substance Abuse Counselor Certification but are still unable to obtain their credentials.	HCS members discussed the issue with the Massachusetts Department of Public Health. The department was aware of the issue and working towards a solution.	Other - partially resolved
MA	Controlled Substances Act (CSA)[a]	May-21	The CSA creates pharmacy quota limits on buprenorphine creating a barrier to access to MOUD.	MOUD	Barrier[2]	Pharmacies restrict their stock of buprenorphine in response to perceived DEA quota limits, driven by concerns about potential scrutiny from the DEA.	HCS pharmacists provided academic detailings to pharmacies in the HCS communities.	Yes - barriers partially resolved
MA	MassHealth status of inmates upon release[b]	Sep-21	State law (Section 227 of Chapter 165 of the Acts of 2014) requires MassHealth benefits to be suspended when incarcerated and reactivated immediately after release	MOUD	Misunderstanding[1, 2, 3]	Even though the policy states that benefits are to be reactivated immediately, pragmatically, it is not an immediate process and results in barriers to patients trying to access treatment after release.	HCS members verified that MassHealth should be turned back on before folks are released. However, the HCS did not engage in any large-scale TTA to resolve the issue globally.	Other - partially resolved

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
MA	Some pharmacies asking for ID when getting naloxone[b]	Mar-23	The policy states that MA residents can obtain naloxone without showing identification. However, some pharmacists misunderstand this state policy.	OEND	Misunderstanding	Despite a state policy stating otherwise, some pharmacists still are requiring an ID for naloxone.	HCS pharmacist provided academic detailing to pharmacies in HCS communities.	Yes - misunderstanding clarified
MA	Dispatch is not giving instructions on rescue breathing for an overdose[c, *]	Mar-23	Medical dispatch in one HCS community is not advising individuals who call them about an overdose to perform rescue breathing while administering naloxone.	OEND	Misunderstanding	Given that xylazine is increasingly being found in the drug supply, it is important that naloxone administration be paired with rescue breaths.	HCS team members conducted informal discussions with 911 dispatch about the importance of giving rescue breaths when responding to an overdose.	Other - partially resolved
NY	Perception that Drug Enforcement Agency (DEA) is tracking buprenorphine going out from manufacturers to wholesalers to local pharmacies with caps.[a]	Oct-21	The local pharmacy and champion in the HEALing Communities Study (HCS) communities has had a limited supply of buprenorphine. The issue stemmed from a misunderstanding and misinterpretation of the DEA regulation of the cap on buprenorphine provided by wholesalers and pharmacies. Pharmacies were not willing to identify themselves or speak to state partners for fear of being redlined.	MOUD	Barrier[2, 3]	Included as a barrier to medication for opioid use disorder (MOUD) access due to pharmacy medication supply challenges for new Suboxone prescriptions. The interpretation of DEA goals led the chain of supply to institute restrictions and CAPs that should not exist.	HCS team members reached out to the regional DEA office, New York State Department of Health (NYS DOH), and the NYS Office of Addiction Services and Support (OASAS). A one-day conference was convened with SAMHSA in June 2022 to address the misunderstanding regarding DEA regulations, support for MOUD, and messaging for wholesalers and pharmacies. As a result, the DEA mentioned the support for MOUD access on its website. This was shared with all community implementation teams and coalitions during the first phase of the study.	Yes - barrier removed
NY	Nurse Practitioners with a large MOUD caseload refused the COVID-19 vaccine disagreeing with mandated vaccination. [b *]	Jan-21	NYS DOH issued a statement on repealing the COVID-19 healthcare worker vaccine requirement.	MOUD	Barrier[2, 3]	Noted as a barrier to a needed workforce for MOUD providers, especially in rural counties.	HCS convened a meeting with the hospital medical director, who is also the Communities That Heal (CTH) MOUD champion, to advocate with the emergency room director.	Yes - barrier removed
NY	Providers were unable to provide an expedited bridge MOUD prescription.[b]	Jun-22	Urgent Care Clinics under Article 31 regulations are unable to provide a bridge MOUD prescription to people living with opioid use disorder (OUD) without going through the extensive assessment	MOUD	Misunderstanding[2, 3]	Noted as a misunderstanding as the clinic administrators were unawared of the option to expedite assessments providers for short-term care of people with OUD.	HCS convened a meeting with Office of Mental Health (OMH) and the leadership from substance use treatment clinic to provide technical assistance. OMH provided guidance on ways to document assessment,	Yes - misunderstanding clarified

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			which can take 3 visits				induction, or maintenance for MOUD, and assured support of service of patients with OUD and co-occurring mental health issues.	
NY	Office of National Drug Control Policy (ONDCP) Non-Fatal Opioid Overdose Tracker Funding. [a]	Dec-22	The goal of the ONDCP Non-Fatal Opioid Overdose Tracker is to track non-fatal opioid overdose in the pre-hospital setting using nationally submitted Emergency Medical Services (EMS) data.	OEND, MOUD	Facilitator	Data sharing is being promoted between first responders and state agencies. It allows the county to plan for hotspots for Opioid Education and Naloxone Distribution (OEND) outreach and promotion.	Details on ways to receive data use agreement with DOH for data sharing at the local level were provided to counties. A webinar designed by NYS DOH was offered to all sites.	Facilitator disseminated
NY	Amendment of policy related to the possession of opioid antagonists.[b]	Oct-22	The policy amended the criminal procedure law, the civil practice law and rules, and the executive law to promote the use of opioid antagonists in preventing drug-related overdoses. This bill aims to decriminalize the possession of opioid antagonists.	OEND	Facilitator	The amended policy aims to reduce barriers for those accessing MOUD.	Disseminated the legislative change to implementation staff and coalitions.	Facilitator disseminated
NY	Policy to establish a program for the use of MOUD for incarcerated individuals.[b]	Oct-22	The policy establishes a program for the use of MOUD treatment for incarcerated individuals in state and local correctional facilities. It expands MOUD across state and local facilities allowing incarcerated individuals access to medications and therapies to provide them the opportunity to overcome substance use and lessen the likelihood that they may suffer drug-related overdoses upon reentry into society.	OEND, MOUD	Facilitator[1, 2, 3]	The law assures access to assessment and MOUD treatment and OEND for those with substance use disorder (SUD) incarcerated in jails and state prisons.	Provided TTA to the implementation teams to message the legislative requirements and support preparation for compliance. Provided technical tool on costing for screening, assessment, and provision of MOUD in county jails. Convened a panel on the topics with state agency partners in the state Community Advisory Board (CAB), promoting understanding and messaging of the legislation.	Facilitator disseminated
NY	Decriminalization of the possession and sale of hypodermic needles and syringes[b]	Oct-22	The policy decriminalizes the possession and sale of hypodermic needles and syringes, which contributes to public safety by permitting harm reduction approaches for those suffering from SUD and by reducing the rate at which HIV and hepatitis are transmitted.	OEND, MOUD	Facilitator	The law aims to reduce barriers to harm reduction methods for those with OUD or people who inject drugs and increase outreach for OEND and MOUD.	Disseminated the legislative change to implementation staff and coalitions.	Facilitator disseminated

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State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
NY	An online directory was established for distributors of opioid antagonists.[b]	Oct-22	Policy establishes an online directory for distributors of opioid antagonists making them more accessible to New Yorkers who may want to equip themselves with these life-saving medications.	OEND	Facilitator	The establishment of an online directory promotes access to OEND.	Disseminated the legislative change to implementation staff and coalitions	Facilitator disseminated
NY	Policy related to a judicial diversion program for certain felony offenders.[b]	Oct-22	The policy expands the number of eligible crimes committed by individuals with an SUD that may be considered for diversion to a substance use treatment program and updates the term "substance abuse" to "substance use." This ensures judges can order an individual to treatment instead of incarceration, allowing them a greater chance for successful, long-term rehabilitation.	OEND, MOUD	Facilitator[1, 2, 3]	The law aims to increase the options for diversion and increased access to drug treatment for those with OUD. The treatment by NYS law requires access to MOUD and harm reduction.	Disseminated the legislative change to implementation staff, coalitions and criminal justice workgroup.	Facilitator disseminated
NY	State Senate Bill requires funds from opioid settlements to be used for the development of new services and supports[b]	Jun-21	Requires all funds received by the state as the result of a settlement or a judgement in litigation against opioid manufacturers, distributors, dispensers, consultants or resellers shall be deposited into the opioid settlement fund, and that such funds shall not supplant or replace existing state funding.	OEND, MOUD	Facilitator[1, 2, 3]	Funds must be made available to EBPs, services, and the workforce needed to address the impacts of substance use and to reduce overdose.	Disseminated the legislative requirements to implementation staff, and HCS leadership to prepare for local settlement fund decision making.	Facilitator disseminated
NY	Policy stating the commissioner's role in opioid overdose prevention[b]	Oct-22	The policy states that the commissioner is authorized to establish standards for approval of any opioid overdose prevention program, and opioid antagonist (naloxone) prescribing, dispensing, distribution, possession, and administration.	OEND, SPDP	Facilitator	Requires naloxone be prescribed (with some exceptions) with the 1st opioid prescription when (a) a history of SUD; (b) high dose or cumulative prescriptions that result in ninety morphine milligram equivalents or higher per day; (c) concurrent use of opioids and benzodiazepine or nonbenzodiazepine sedative hypnotics.	Legislative facilitator disseminated to implementation and coalitions to be open to MOUD expansion and request for proposal opportunities	Facilitator disseminated
NY	Drug Enforcement Administration Rule 86 FR 33861[a]	Jul-21	SAMHSA must also study the impact of certain exemptions	OEND, MOUD, SPDP	Facilitator[1, 2, 3]	Included as a facilitator as the new expansive legislation	Communities were made aware of legislative potentials	Facilitator disseminated

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			from certification requirements for opioid treatment programs that were granted as part of COVID-19 response efforts. The rule also (1) allows specified types of health care providers to prescribe (subject to certain requirements) methadone that is dispensed through pharmacies for a patient's unsupervised use, and (2) allows DEA registrants who are authorized to dispense methadone for opioid use disorder to add a "mobile component" to their existing registration – eliminating the separate registration requirement for mobile medication units of Opioid Treatment Programs (OTPs).			can have an impact the care of those with OUD broadly.	to impact service delivery.	
NY	Continuing Medical Education (CME) certified training to promote safer prescribing practices [b, *]	Jul-21	Mandatory annual prescriber education must be completed, which requires at least three hours of coursework or training in pain management, palliative care, and addiction.	SPDP	Facilitator[2, 3]	Included as a facilitator which promotes and provides incentive for engagement of MOUD providers into training and implementation technical assistance.	Opioid Response Network (ORN) shared virtual training for pharmacists with technical assistance coordinators for review and implementation with CMEs and implemented in county strategies.	Facilitator disseminated
NY	PART 599 Article 31 Mental Health Clinic [b, *]	Nov-22	In the face of the opioid overdose crisis, the NYS OMH and OASAS recognize the urgent and growing need to address co-occurring mental health and substance use disorders in an integrated and person-centered manner, wherever individuals are most comfortable receiving services. This treatment often includes medication management, both for psychiatric conditions as well as MOUD. OMH and OASAS offer guidance about submitting claims for	MOUD	Facilitator[2, 3]	Included as a facilitator that increases integration of care for those with OUD and Mental Health challenges, and reduces barriers to care.	To begin the expansion of MOUD in Article 31, TTA was offered on the protocol for inductions and education on policies. ORN is offered along with OMH policies and best practices. ORN provided OMH Guidance Memo OUD Billing and Clinic OUD Capacity Building Initiative.	Facilitator disseminated

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State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			medication management services in Article 31 and/or 32 licensed clinic programs.					
NY	NYS DOH lacked a completed policy on passive naloxone distribution through naloxone housing units[b]	May-21	Partner organizations concerned about hosting naloxone boxes and their liability, and lack of awareness of pharmacy policy for dispensing naloxone.	MOUD	Facilitator	Included as a facilitator as clear direction on Good Samaritan law and NCAP program in pharmacies was provided by state agency.	NYS DOH addressed questions around organizations liablity while dispensing naloxone and pharmacies policies to dispense naloxone.	Facilitator disseminated
NY	Enhancing Peer Driven Interventions and Strategies for Opioid Overdose Prevention[a]	May-21	Peer driven intervention addresses sustainability, billing, and quality assurance for successful outcomes training.	OEND, MOUD	Facilitator[1, 2, 3]	Included as a facilitator with training on how to bill Medicaid for peer services, and to improve quality of the peer driven approach.	NYS OASAS representative presented on peer billing in OASAS settings. Additionally, a large Outpatient Substance Abuse Treatment Clinic presented on peer sustainability and unique ways to integrate peers into the community.	Facilitator disseminated
NY	Legal issues around the Medical Examiner's (ME) Office sharing de-identified data with the county health department[a]	Jun-22	The Health Insurance Portability Act (HIPAA) for the protection of certain personal health information includes protections for the deceased for 50 years. Medical examiners government offices are not covered entities and may share with public health and law enforcement (45 CFR 164.512). However, State and The Joint Commission requirements may impact disclosures.	OEND, MOUD, SPDP	Barrier[1, 2, 3]	Included as a barrier since overdose data was not being shared from ME to public health department and commissioner due to interpretation of HIPAA.	Legal Counsel, is working on the issue with the county but believes they will not change course (which is to not share identifiable data to confidential sources within the county).	No
NY	County Procurement Policy[b]	Jan-23	New York State general municipal law 103 states all purchase contracts involving an expenditure of $20,000+ and all public works contracts exceeding 35,000+ must be publicly bid.	OEND, MOUD, SPDP	Barrier[1, 2, 3]	Included as a barrier since extensive procurement processes inhibits contracting and efficient implementation of the action plans. In some cases the policy stopped a strategy if found to be beyond the $20,000 CAP in the community without RFA process.	Advocacy within county legal and procurement did not provide any flexibility, and many contracts could not be executed in a timely manner. The HCS Implemention team and coalition followed the contract process, kept partners informed as to status, and initiated programs that did not require the same detailed county approvals.	Other - partially resolved
NY	Vendor Insurance Requirements[c]	Apr-23	Insurance liability coverage required for county contracting.	MOUD	Barrier[1, 2, 3]	Included as a barrier as minority run smaller vendors did not have the capacity for the percieved	The County required levels of insurance for agencies providing transportation services that were	No

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State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
						excessive transportation insurance required for an MOUD reducing transportation barrier strategy. No replacement was found.	found to be impractical for transportation companies. No adequate solution was found when advocating with legal and procurement and seeking an alternative vendor, and the transportation strategy was discontinued.	
NY	County policy prohibits mandating training for unionized staff due to agreed upon contracts.[c]	Apr-23	For the OEND strategy involving staff training, the HCS was not able to mandate training of all county staff due to the need for negotiation with unionized government-employed staff with union contracts already negotiated.	OEND	Barrier	Included as a barrier as the strategy called for mandatory training of all county staff in OEND.	Staff training is voluntary. Encouragement by county leadership promoting OEND was applied for OEND training engagement.	Yes - barrier removed
NY	NYS Public Health Law Section 3309 (2)[c]	Sep-22	NYS Public Health Law Section 3309(2) allows registered programs to train community members (lay responders), other paraprofessionals, professionals, clients or patients, and their families on how to recognize and respond to overdose and to distribute Naloxone. This includes EMS and Leave Behind.	OEND	Misunderstanding	Local EMS leadership misunderstood laws about what was allowed with naloxone, stating they were prohibited from leaving naloxone behind at the scene of an overdose or with people who overdosed or reported an overdose. They were unsure about the ability to leave printed materials behind.	The implementation team struggled to get EMS interested in having a discussion about the policy as they understood it. HCS worked with the local health department and neighboring county to assure EMS leadership of the agreement that this service is allowable by law. The team also disseminated a copy of the regulation.	Yes - misunderstanding clarified
NY	DEA Registration Requirements for Narcotic Treatment Programs with Mobile Components [a, *]	Jun-21	This final rule waives the requirement of a separate registration at each principal place of business or professional practice where controlled substances are dispensed for those NTPs with mobile components that fully comply with the requirements of this rule. These revisions to the regulations are intended to make maintenance or detoxification treatments more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion.	OEND, MOUD	Barrier[1]	Law enforcement opposition to harm reduction services in certain locations without a known formalized policy creates a barrier. Law enforcement partners prohibit the syringe Service Program (SSP) mobile unit from operating at fixed locations within the city limits without special arrangements. The SSP mobile unit hides some services and finds locations outside of the city limits.	Provide TA on regulations for mobile SSP units. A meeting with the chief of police and the harm reduction program was facilitated, and a clearer agreement on time, place, and method of service delivery was achieved. The work is ongoing to change attitudes and address concerns about this service delivery.	Other - partially resolved
NY	The Privacy Rule located at 45 CFR Part 160 and	Sep-22	Lack of legislation and guidance giving authority/standing	OEND, MOUD, SPDP	Barrier[1, 2, 3]	Included as a barrier due to misunderstanding	Implementation teams were trained on forming Fatality	Other - partially resolved

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Table 3 (*continued*)

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State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
	Subparts A and E of Part 164.[a]		to Overdose Fatality Review teams to launch review teams. Concerned about confidentiality breaches has stalled the active implementation of this strategy.			and interpretation of 45 CFR Part 160 and Subparts A and E of Part 164 that stalled the convening of the fatality review board to inform all ORCCA strategy selection and outreach with *epi* data, even after training was provided.	Review Boards, and were connected with other HCS counties with active boards. Additional guidance was requested from state DOH still being developed.	
NY	NYS Medicaid Program -Transportation Manual Policy Guidelines (Version 2019–1)[b]	Sep-22	NYS Medicaid reimbursement program to private transport companies for travel to methadone treatment is reportedly subject to abuse which complicates retention in MOUD and more efficient access to more localized OTPs. Sometimes counseling session length is dictated by taxi companies willingness to wait.	MOUD	Barrier[1, 2, 3]	Included as a barrier as Medicaid sets regulations on health transport. Quality of services in OTP is impacted by taxi and Medicaid interpretation of billing for transport. There is no oversite of taxi companies.	The barrier was discussed in a state CAB meeting. The state agency launched a fraud investigation due to reports from numerous counties. PWG has not heard the outcome of the investigation.	Other - partially resolved
NY	US Dept of HHS, Summary of HIPAA Rule impacting referrals[a]	May-23	Privacy Rule includes who is covered, what information is protected, and how protected health information can be used and disclosed. Because it is an overview of the Privacy Rule, it does not address sufficient detail of each provision requiring additional technical assistance to facilitate cross-organizational referrals and case coordination.	MOUD	Misunderstanding[2]	Included as a misunderstanding as staff were concerned about making referrals for MOUD maintenance and had not developed a protocol for permissions.	TTA was provided on confidentiality regulations and on protocol for documentation of patient consent for care coordination.	Yes - misunderstanding clarified
NY	Requests for County Purchasing approval/Renewals/ Amendments[c]	Dec-22	County contracting, procurement process and amendment process requires lengthy approvals.	OEND, MOUD, SPDP	Barrier[1, 2, 3]	Included as a barrier county approval policies were not recognized early and not applied consistantly.	Followed contract process, kept partners informed as to status, initiated programs that did not require county approval.	Other - partially resolved
NY	Probation supervision practices[b]	Feb-23	Mission and purpose of community supervision and probation requirements describe risk reduction, knowledgable awareness of services and motivational strategies to support changing behaviors. There is no prohibition	OEND	Misunderstanding	Included as a misunderstanding as probation leadership interpreted their regulation as not allowing OEND without accompanying adherence to a requirement for SUD counseling attendance.	Engaged probation leadership in clarifying legislative requirements that does not penalize those in low threshhold MOUD services by withholding access to OEND. Additionally, the legislation for those with SUD requires access to OEND and MOUD	Yes - misunderstanding clarified

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	Policy categories						Training and Technical Assistance (TTA)	
State	Policy title	Date reported Month-Year	Policy Details	EBPs impacted	Policy Categories	Rationale for policy category	HCS action details	Was action plan successful?
			articulated addressing OEND.				and harm reduction services.	
NY	Chapter 120 Laws of 2018, the New York State Drug Take Back Act[b]	Apr-23	New York State Department of Health, in consultation with the Department of Environmental Conservation, announced the approval of two Drug Take Back programs.	SPDP	Barrier	Included as a barrier as medication transport from take back program was only allowed by law enforcement.	Implementation site chose to pivot to providing mail-back bags at other locations for expediency.	Other - partially resolved
NY	Revision of New York State Good Samaritan Law[b]	Jan-21	County government legal department delayed approval of OEND naloxone boxes due clarify liability of county with the contracted CBO.	OEND	Misunderstanding	Included as a misunderstanding of Good Samaritan Law as county attorney had concerns about liability of county for Naloxone distributed by a partner organization.	Provided connection to the NYS DOH and guidance on distribution and naloxone boxes.	Yes - misunderstanding clarified
NY	Statute for Article 28 Standards for OASAS funded Programs (2019)[b]	Jun-22	MOUD services should be offered or continued, regardless of a person's full engagement in treatment services. A person should not be discharged from care and/or be denied access to MOUD solely because of continued substance use or because they are not fully engaging in other treatment services.	MOUD	Misunderstanding[1, 2, 3]	Misunderstanding and interpretation of OASAS (state) issued guidance.	Lack of referrals to low threshold MOUD services in the county due to required MOUD be accompamied only with counseling.	Yes - misunderstanding clarified
NY	US Dept of Health and Human Services Summary of HIPAA Rule[a]	Jan-23	The Privacy Rule and all the Administrative Simplification rules apply to health plans, healthcare clearinghouses, and any healthcare provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA. This was considered in designing an alert system for persons in overdose incidents where a neighbor could respond with OEND.	OEND	Barrier	Concern that public health information would be made accessible to community members in order to provide OEND to those with a non-fatal overdose through an "Amber-like" alert system.	Pivoted to designing a website that would allow community members to easily sign up for Narcan training alerts in their zipcode, find upcoming trainings on a calendar, locate naloxboxes for use in an emergency, and locate naloxone vending machines to obtain naloxone for personal or community use.	Other - partially resolved

Evidence-based Practices: Opioid Education and Naloxone Distribution (OEND), Medication for Opioid Use Disorder (MOUD), and Safer Opioid Prescribing/ Dispensing Practices (SPDP).

1 = Affecting methadone formulation; 2 = affecting buprenorphine formulation; 3 = affecting naltrexone formulation.

a = federal jurisdiction creating or changing the policy issue; *b* = state jurisdiction creating or changing the policy issue; *c* = local/organizational creating or changing policy issue.

Kentucky Chapter of the American Society of Addiction Medicine (KYSAM). KYSAM provided a letter supporting the Department of Health and Human Services new guidelines to the Kentucky Board of Medical Licensure. PWG members who were American Society of Addiction Medicine members and KYSAM leaders also attended a public meeting of the medical licensing board to voice support for the new federal guidelines and followed up with a written summary of desired language changes in Kentucky buprenorphine regulations to align with federal changes and published American Society of Addiction Medicine best practices. However, the medical board did not update its regulations to align with the Health and Human Services' April 2021 guidelines. Thus, this remained a barrier to buprenorphine expansion, particularly linkage to buprenorphine treatment. Given this barrier in Kentucky, the PWG conducted a nationwide study surveying other states' medical and nursing boards and single state agencies, and searched state regulations in Westlaw. The PWG found that several other states also had similar barriers (Silwal et al., 2023) and concluded that the Mainstreaming Addiction Treatment (MAT) Act (SAMHSA, 2023), passed in December 2022 by Congress removing all training requirements for prescribing buprenorphine, may struggle to be implemented. The PWG shared these findings with Substance Abuse and Mental Health Services Administration, the Food and Drug Administration, and the National Institute on Drug Abuse to ensure federal stakeholders were aware that state regulations may not align with federal changes to expand clinician prescribing of buprenorphine.

Massachusetts

Policy barriers: A community coordinator in one HCS community reported a policy barrier related to a statewide protocol from the Massachusetts Department of Health directing the state leave-behind naloxone program. The original protocol stated that Emergency Management Services could only distribute naloxone to a person who experienced a nonfatal overdose, and only if that person refused medical transport. The PWG worked with the key government official, the Massachusetts Department of Health, and other policy stakeholders to amend the protocol so that Emergency Management Services could distribute naloxone to the person experiencing an overdose as well as individuals in their social network regardless of medical transport status. Following the amended protocol, the PWG conducted learning collaboratives with the HCS communities to raise awareness of the policy change. Thus, HCS stakeholder engagement and training and/or technical assistance resolved the policy barrier.

A community partner identified a policy-related barrier due to onerous regulations where, although Medicaid covers recovery coaching in Massachusetts, one organization in HCS community did not bill for these services due to a complicated billing process, a low reimbursement rate, and a requirement for supervision infrastructure to be eligible for reimbursement. The PWG raised awareness of this issue with HCS team members working in this community and provided guidance on facilitating the recovery coaching reimbursement process by creating a memo. In addition, a learning collaborative was organized to raise awareness around recovery coaching billing for all HCS communities. The PWG considered this policy issue partially resolved. Later in the HCS study period, MassHealth, which oversees Medicaid in Massachusetts, created more flexibility for recovery coach reimbursements.

Policy misunderstanding: Several policy misunderstandings at the pharmacy level were identified by community partners in Massachusetts. For example, several HCS communities reported that individuals were being asked for identification to obtain naloxone from pharmacies despite the prohibition of such a requirement in state law (Bohler et al., 2023; Massachusetts Board of Registration, 2025). Additionally, one HCS community reported that individuals were being asked for identification to obtain buprenorphine from pharmacies despite a state policy exemption allowing pharmacists to dispense all lifesaving medications without identification (Massachusetts Prescription Monitoring Program, 2023). Identification of these policy misunderstandings informed academic detailing (i.e., one-on-one education delivered to pharmacists by an HCS pharmacist) that was provided to pharmacies in HCS communities. Also, one of the HCS communities created a flyer for patients prescribed buprenorphine to share with pharmacists to help raise awareness of the policy exemption.

New York

Policy misunderstanding: Multiple HCS communities reported having difficulties filling buprenorphine prescriptions due to an insufficient medication supply at pharmacies. Pharmacists reported supply challenges as manufacturers and wholesalers instituted restrictive safeguards (order thresholds) in response to the Drug Enforcement Administration's requirements for monitoring suspicious orders of controlled substances, including buprenorphine distributed to local pharmacies. A kind of chain reaction of safeguards, along with pharmacists' fear of being discerned, resulted in patients with OUD being denied buprenorphine and other prescription medications and referred to alternative pharmacies. A PWG member reported the policy misunderstanding to the cross-site PWG and to the National Institute on Drug Abuse representatives for systemic support, then contacted the regional Drug Enforcement Administration office, the New York State Department of Health, and the New York State Office of Addiction Services and Support. A conference was convened by state partners along with the Drug Enforcement Administration and Substance Abuse and Mental Health Services Administration in July of 2022 to address the misunderstanding of regulatory guidance, to hear of the support for MOUD access, and to direct messaging for wholesalers and pharmacies (Drug Enforcement Administration, 2023). The Drug Enforcement Administration featured support for access to buprenorphine on their website home page (Drug Enforcement Administration, n.d.), and this was shared with HCS-funded community implementation teams and coalitions.

Policy facilitator: Key to the policy work in New York was capturing distinct policy facilitators supportive of HCS-identified EBPs and disseminating these to HCS communities. Landmark New York State legislation S.1795/A.533 (New York Correction Law 626, 2024), signed in October 2021 and implemented in October 2022, established a program for the use of all forms of Food and Drug Administration approved medications for OUD for incarcerated individuals in New York and includes requirements for screening, assessment, and voluntary treatment and harm reduction strategies for people with OUD in New York jails and state prisons. HCS provided coaching and training and/or technical assistance to HCS-funded community staff regarding legislative-required elements to support community partners in preparation for compliance with overdose education and naloxone distribution and MOUD-related strategies and convened a panel discussion on the legislation with state agency partners during the HCS state community advisory board meeting. A technical tool on costing for screening, assessment, and provision of MOUD in county jails was provided with ongoing training and/or technical assistance to implementation teams and county sheriffs in New York HCS communities (Ryan et al., 2023).

Discussion

This study describes a community-driven policy surveillance procedure to report identified policies that could have impacted the implementation of EBPs in 67 communities participating in the HCS and summarizes the actions taken and outcomes of the training and/or technical assistance provided. Of the policies identified and addressed, there were twice as many barriers as facilitators or misunderstandings. Overall, the vast majority of policies were fully or partially addressed.

The community-reporting surveillance procedure was developed to examine policy barriers, misunderstandings, and facilitators, and was deployed in the context of a multidisciplinary and large-scale

implementation study. Policy surveillance, a relatively new scientific methodology, examines how policies are a determinant of the cause and distribution of diseases as well as interventions to address them (Burris et al., 2016), and these methods typically employ systematic coding to track policies over time, creating a scientific dataset that can be used for research and evaluation (Burris et al., 2020). Examples of substance-related policy surveillance projects include the Alcohol Policy Information System, the State Tobacco Activities Tracking and Evaluation System, and the Prescription Drug Abuse Policy System. However, policy surveillance studies have generally cataloged laws and regulations using legal databases or government websites (Burris et al., 2016; Sanner et al., 2021) rather than collecting information from the community in the context of a community-based research study to inform the implementation of the study's interventions or analyses of the study's outcomes. The community-driven methodology for policy surveillance used in this study offers new insights into the challenges of implementing substance use interventions at the community level and how policy contexts might affect study outcomes. This approach allowed continuous feedback through a policy lens to optimize the HCS study during the study period, as emphasized in implementation science and practical approaches, rather than restrict the availability of data until the study's conclusion (Bertram et al., 2015). Future large-scale implementation studies could benefit from a community-driven policy surveillance approach as it proactively helps identify and address barriers to and facilitators of intervention success, accounts for the regional and local policy variations, and strengthens community engagement to promote a community's response to overdose prevention and deaths.

The results also highlight how federal-level policy changes are implemented, enforced, and interpreted differently at the state and local levels. For example, Department of Health and Human Services federal guidelines in April 2021 eased regulatory barriers for healthcare professionals to prescribe buprenorphine by removing waiver training and referral requirements to treat up to 30 patients (Department of Health and Human, 2021). However, several states continued to have more restrictive policies not supported by the guidelines (Silwal et al., 2023). Further, in December 2022, the Mainstreaming Addiction Treatment Act was passed, permanently removing the waiver requirements (MAT Act, 2022); however, providers in Kentucky were unsure about whether nursing and medical boards would come into alignment with this federal law and thus were not able to immediately take advantage of this policy change aimed at expanding access to MOUD. Understanding diffusion of policies across levels is critical in identifying and describing factors necessary for dissemination and implementation success (Crable et al., 2022)

The study findings also indicate that local and organizational policies, such as city-level zoning regulations and health insurance regulations, can present barriers to implementing EBPs in addressing the opioid crisis. For example, a city ordinance in Kentucky prevented peer specialists from engaging in overdose education and naloxone distribution activities outside of local business buildings, resulting in a legal interpretation of the ordinance and discussion with local authorities to clarify the misunderstanding. Further, law enforcement in one HCS community in New York prohibited syringe service program mobile units from operating at fixed locations within the city limits, resulting in the units having to hide some services and find locations outside the city limit to provide services. Moreover, health insurance-related policies in Massachusetts potentially affected MOUD initiation, linkage, and retention.

Study findings further identified the likely presence of stigma and biases embedded in policy or contributed to policy misinterpretation. In Kentucky, local rulings of some judges prevented individuals from receiving MOUD or sometimes only allowed MOUD treatment with an opioid antagonist. Despite providing training and/or technical assistance through educational sessions and learning collaboratives, the barrier was not fully resolved. Quick resolutions within the study timeframe are not expected if the barriers are based on long-held stigmatized views of MOUD, particularly among those justice-involved organizations, including recent cases of Americans with Disabilities Act violations due to withholding access to MOUD (Booty et al., 2023; South et al., 2023). The results further indicate that entrenched beliefs in the criminal legal system about the use of MOUD treatment can cause barriers to treatment expansion. For example, a city ordinance in one of the Massachusetts HCS communities prevented mobile MOUD unit placement in a high-need area and used police to monitor city and private properties where mobile MOUD units could be located. Developing partnerships with local government units and continuing efforts to educate important stakeholders in the criminal legal and municipal systems about the proven effectiveness of MOUD treatment and harm reduction services may be beneficial in addressing the stigma.

Ineffective dissemination and lack of education about policy changes also contributed to misunderstandings. In HCS communities, ineffective communication between law enforcement and communities, as well as misunderstanding of the regulations around naloxone, have created confusion in naloxone distribution and fear of calling the police during an overdose (Olvera et al., 2025). Previous studies indicate that communication strategies tailored to policymakers or the general public may be one pathway to more public health-oriented policies to support people with OUD (Bandara et al., 2020; Barry et al., 2018; McGinty et al., 2018), but some policy issues may require formal guidance, including mandates at the federal, state, and local levels to ensure successful implementation.

The PWG attempted to address identified policy issues through stakeholder engagement and training and/or technical assistance including dissemination of facilitating policies. In many instances, the PWG was successful in resolving policy issues with state partners, such as amending the leave-behind naloxone policy in Massachusetts to expand access to naloxone to individuals likely to witness an opioid overdose and clarifying a misunderstanding in Kentucky where law enforcement was using naloxone possession as drug paraphernalia. However, some issues remained unresolved. For example, despite its best efforts, the PWG was not able to align state buprenorphine prescribing regulations in Kentucky with national practice guidelines/best practice, nor was the PWG able to convince city leadership in one HCS community in Massachusetts not to heavily police an area where a mobile MOUD clinic was designated. In New York, the interpretation of policies to protect health information among overdose decedents differed by stakeholders in some communities, and the state is developing additional guidelines for fatality review boards to inform data sharing limits.

Some policies implemented during the HCS study period served as facilitators for overdose education and naloxone distribution and MOUD expansion, linkage, and retention. Several naloxone policy changes likely increased naloxone distribution, including a statewide standing order and co-prescription mandate in New York and a statewide standing order for community distribution of naloxone in Massachusetts (Bohler et al., 2023). In Kentucky, an amendment to legislation on pharmacist compensation requires commercial insurance plans to compensate pharmacists for services, including overdose education and naloxone distribution and administering naltrexone, thus potentially increasing access to naloxone and MOUD use. There was also a legislative amendment in New York that decriminalized the possession of opioid antagonists and the possession and sale of hypodermic needles and syringes, thus reducing barriers to harm-reduction strategies. Further, a new policy in New York, discussed above, increased overdose education and naloxone distribution and MOUD access for incarcerated individuals. The PWG made efforts to raise awareness and disseminate these policy facilitators in HCS communities. Policies are tools that can shape the delivery of interventions to treat OUD and opioid overdoses. Our findings indicate that even though communities reported policies that impeded HCS interventions, some policies may translate to better access to naloxone and MOUD. These facilitators differed by state, and efforts should be made to consider them when analyzing the study

outcomes.

The U.S. opioid crisis worsened during COVID-19 pandemic and people with OUD were at increased risk during this public health emergency (Davis & Samuels., 2020; Laing & Donnelly, 2024). Some policy barriers related to OUD treatment were eased during the pandemic. For example, Substance Abuse and Mental Health Services Administration issued guidance allowing states to permit all patients who were on a stable methadone treatment plan to receive 28 days of take-home medication, while those considered less stable could receive up to 14 days of take-home medication. Furthermore, the Drug Enforcement Administration lifted a requirement for in-person consultation prior to initiating buprenorphine treatment, allowing patients to begin treatment without an initial face-to-face visit. While the federal government took crucial steps to support OUD treatment access, not all states adopted this federal guidance (Pessar et al., 2021; Ward et al., 2022). For example, in Kentucky, the emergency guidance from the state medical board during COVID-19 initially did not include buprenorphine initiation via telehealth. The issue was later resolved with a revised medical board advisory that allowed buprenorphine initiation for OUD treatment via telehealth. This shows that state-level regulations could challenge the adoption and implementation of federal guidance. Although some regulations were temporarily relaxed during the COVID-19 pandemic, it is important to pursue permanent policy changes at federal as well as state levels to improve and sustain access to treatment for OUD.

While the current study provides an overview of the community-driven approach in identifying and addressing the policies hindering or facilitating the HCS study, some limitations should be noted. First, this study described only the policy issues that were community-reported and acted upon by the PWG; there may be other policy issues potentially impacting the study EBPs that were not reported by the community members with this approach. Second, this study does not measure the impact of these policies nor the PWG's actions on the study outcomes, although this is an area of future research. Third, the categorization of some policy-related issues was nuanced and disentanglement of whether the issue was a barrier or misunderstanding was difficult. Finally, this study does not represent a national perspective, and states are likely to have different policy contexts than the states participating in the HCS study. Policies from Ohio, one of the HCS research sites, were also not considered, as Ohio did not participate in training and/or technical assistance. The purpose of this study was to describe and summarize a community-driven policy surveillance procedure and actions taken that were implemented alongside the HCS Communities that Heal intervention that could inform the implementation of EBPs and the analysis of study outcomes.

Conclusion

The study highlights policies that may have impacted the implementation of the EBPs known to reduce opioid overdose deaths in HCS communities across Kentucky, Massachusetts, and New York. Policies and interpretation of policies can have an impact on large-scale implementation studies. Specifically, this study identified a myriad of policy-related issues in implementing EBPs, especially expanding access to MOUD. Using opioid agonist medications, like methadone or buprenorphine, as first-line treatment for OUD is known to substantially reduce mortality (Larochelle et al., 2018). In addition, retention on MOUD is strongly associated with reduced mortality (Wakeman et al., 2020). However, it is possible that HCS communities will not fully realize the benefits of EBPs aimed at expanding access to and retention on MOUD due to the policy landscape in which these interventions are implemented. It is noteworthy that, in the implementation science field, the importance of the policy landscape in implementing EBPs has been emphasized (Rabin et al., 2022). Future implementation studies should consider policies within the external context when implementing interventions and measuring outcomes, especially in multi-state studies where the policy context may vary. The insights from this community-driven approach also highlight the potential for a broader global and cross-context application and underscore the necessity for localized and community-specific understanding of policies.

CRediT authorship contribution statement

Anita Silwal: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Robert Bohler:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation. **Timothy Hunt:** Writing – review & editing, Writing – original draft, Formal analysis, Data curation, Conceptualization. **Ramona G. Olvera:** Writing – review & editing, Writing – original draft. **Michelle R. Lofwall:** Writing – review & editing, Formal analysis, Conceptualization. **Christopher D. Cook:** Writing – review & editing, Data curation. **Katherine R. Marks:** Writing – review & editing. **Carly Bridden:** Writing – review & editing. **Patricia R. Freeman:** Writing – review & editing. **Monica Nouvong:** Writing – review & editing. **Laura C. Fanucchi:** Writing – review & editing, Methodology, Investigation. **Nabila El-Bassel:** Writing – review & editing, Funding acquisition. **Lisa A. Frazier:** Writing – review & editing. **Sharon L. Walsh:** Writing – review & editing, Funding acquisition. **Jeffery C. Talbert:** Writing – review & editing, Supervision, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Michelle R. Lofwall reports research consulting in the last three years for Braeburn Pharmaceuticals, Journey Colab, and Berkshire Biomedical. Sharon Walsh reports scientific consulting in the last three years for Braeburn Pharmaceuticals, Titan, Cerevel Therapeutics, Astra Zeneca, Kinoxis, Lundbeck, Opiant, Pocket Naloxone, and Reacx.

All other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Ethics approval

The authors declare that they have obtained ethics approval from an appropriately constituted ethics committee/institutional review board where the research entailed animal or human participation.

This study protocol (Pro00038088) was approved by Advarra Inc., the HEALing Communities Study Single Institutional Review Board

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References

Abraham, A. J., Andrews, C. M., Harris, S. J., Westlake, M. M., & Grogan, C. M. (2022). Coverage and prior authorization policies for medications for opioid use disorder in Medicaid managed care. *JAMA Health Forum, 3*(11), Article e224001. https://doi.org/10.1001/jamahealthforum.2022.4001

Auty, S. G., & Griffith, K. N. (2022). Medicaid expansion and drug overdose mortality during the COVID-19 pandemic in the United States. *Drug and Alcohol Dependence, 232*, Article 109340. https://doi.org/10.1016/j.drugalcdep.2022.109340

Bandara, S. N., McGinty, E. E., & Barry, C. L. (2020). Message framing to reduce stigma and increase support for policies to improve the wellbeing of people with prior drug convictions. *The International Journal of Drug Policy, 76*, Article 102643. https://doi.org/10.1016/j.drugpo.2019.102643

Barry, C. L., Sherman, S. G., & McGinty, E. E. (2018). Language matters in combatting the opioid epidemic: Safe consumption sites versus overdose prevention sites. *American Journal of Public Health, 108*(9), 1157–1159. https://doi.org/10.2105/ajph.2018.304588

Bertram, R. M., Blase, K. A., & Fixsen, D. L. (2015). Improving programs and outcomes. *Research on Social Work Practice, 25*(4), 477–487. https://doi.org/10.1177/1049731514537687

Bohler, R. M., Freeman, P. R., Villani, J., Hunt, T., Linas, B. S., Walley, A. Y., Green, T. C., Lofwall, M. R., Bridden, C., Frazier, L. A., Fanucchi, L. C., Talbert, J. C., & Chandler, R. (2023). The policy landscape for naloxone distribution in four states highly impacted by fatal opioid overdoses. *Drug and Alcohol Dependence Reports, 6*, Article 100126. https://doi.org/10.1016/j.dadr.2022.100126

Booty, M. D., Harp, K., Batty, E., Knudsen, H. K., Staton, M., & Oser, C. B. (2023). Barriers and facilitators to the use of medication for opioid use disorder within the criminal justice system: Perspectives from clinicians. *Journal of Substance Use and Addiction Treatment, 149*, Article 209051. https://doi.org/10.1016/j.josat.2023.209051

Bullock, H. L., Lavis, J. N., Wilson, M. G., Mulvale, G., & Miatello, A. (2021). Understanding the implementation of evidence-informed policies and practices from a policy perspective: A critical interpretive synthesis. *Implementation Science, 16*(1). https://doi.org/10.1186/s13012-021-01082-7

Burris, S., Cloud, L. K., & Penn, M. (2020). The growing field of legal epidemiology. *Journal of Public Health Management and Practice, 26*(2), S4–S9. https://doi.org/10.1097/phh.0000000000001133

Burris, S., Hitchcock, L., Ibrahim, J., Penn, M., & Ramanathan, T. (2016). Policy surveillance: A vital public health practice comes of age. *Journal of Health Politics, Policy and Law, 41*(6), 1151–1173. https://doi.org/10.1215/03616878-3665931

Centers for Disease Control and Prevention (2024, April 5). Overdose Prevention. https://www.cdc.gov/overdose-prevention/about/understanding-the-opioid-overdose-epidemic.html?CDC_AAref_Val=https://www.cdc.gov/opioids/basics/epidemic.html.

Chandler, R., Nunes, E. V., Tan, S., Freeman, P. R., Walley, A. Y., Lofwall, M., Oga, E., Glasgow, L., Brown, J. L., Fanucchi, L., Beers, D., Hunt, T., Bowers-Sword, R., Roeber, C., Baker, T., & Winhusen, T. (2023). Community selected strategies to reduce opioid-related overdose deaths in the HEALing (Helping to End Addiction Long-term[SM]) communities study. *Drug and Alcohol Dependence, 245*, Article 109804. https://doi.org/10.1016/j.drugalcdep.2023.109804

Crable, E. L., Lengnick-Hall, R., Stadnick, N. A., Moullin, J. C., & Aarons, G. A. (2022). Where is "policy" in dissemination and implementation science? Recommendations to advance theories, models, and frameworks: EPIS as a case example. *Implementation Science, 17*(1). https://doi.org/10.1186/s13012-022-01256-x

Davis, C. S., & Samuels, E. A. (2020). Opioid policy changes during the COVID-19 pandemic and beyond. *Journal of Addiction Medicine, 14*(4). https://doi.org/10.1097/adm.0000000000000679

Degenhardt, L., Grebely, J., Stone, J., Hickman, M., Vickerman, P., Marshall, B. D. L., Bruneau, J., Altice, F. L., Henderson, G., Rahimi-Movaghar, A., & Larney, S. (2019). Global patterns of opioid use and dependence: Harms to populations, interventions, and future action. *The Lancet, 394*(10208), 1560–1579. https://doi.org/10.1016/s0140-6736(19)32229-9

Department of Health and Human, Services. (2021). Practice guidelines for the administration of buprenorphine for treating opioid use disorder. *Federal Register, 86*(80), 22439–22440. https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder.

Harris, P. A., Taylor, R., Minor, B. L., Elliott, V., Fernandez, M., O'Neal, L., McLeod, L., Delacqua, G., Delacqua, F., Kirby, J., & Duda, S. N. (2019). The REDCap consortium: Building an international community of software platform partners. *Journal of Biomedical Informatics, 95*, Article 103208. https://doi.org/10.1016/j.jbi.2019.103208

Drug Enforcement Administration. (2023). *Medication assisted treatment*. U.S. Department of Justice. https://www.deadiversion.usdoj.gov/pubs/docs/MATE_training.html.

Drug Enforcement Administration, Diversion Control Division. (n.d.). *Pharmacy: Information for pharmacies*. U.S. Department of Justice. https://www.deadiversion.usdoj.gov/pharmacy.html.

HEALing Communities Study Consortium. (2020). The HEALing (Helping to End Addiction Long-term[SM]) Communities Study: Protocol for a cluster randomized trial at the community level to reduce opioid overdose deaths through implementation of an integrated set of evidence-based practices. *Drug and Alcohol Dependence, 217*, Article 108335. https://doi.org/10.1016/j.drugalcdep.2020.108335

Kentucky Revised Statutes. (2023). *218A.500 Definitions for KRS 218A.500 and 218A.510* https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=54121.

Keshwani, S., Maguire, M., Goodin, A., Lo-Ciganic, W., Wilson, D. L., & Hincapie-Castillo, J. M. (2022). Buprenorphine use trends following removal of prior authorization policies for the treatment of opioid use disorder in 2 state Medicaid programs. *JAMA Health Forum, 3*(6), Article e221757. https://doi.org/10.1001/jamahealthforum.2022.1757

Knudsen, H. K., Drainoni, M., Gilbert, L., Huerta, T. R., Oser, C. B., Aldrich, A. M., Campbell, A. N., Crable, E. L., Garner, B. R., Glasgow, L. M., Goddard-Eckrich, D., Marks, K. R., McAlearney, A. S., Oga, E. A., Scalise, A. L., & Walker, D. M. (2020). Model and approach for assessing implementation context and fidelity in the HEALing Communities Study. *Drug and Alcohol Dependence, 217*, Article 108330. https://doi.org/10.1016/j.drugalcdep.2020.108330

Knudsen, H. K., Hartman, J., & Walsh, S. L. (2022). The effect of Medicaid expansion on state-level utilization of buprenorphine for opioid use disorder in the United States. *Drug and Alcohol Dependence, 232*, Article 109336. https://doi.org/10.1016/j.drugalcdep.2022.109336

Larochelle, M. R., Bernson, D., Land, T., Stopka, T. J., Wang, N., Xuan, Z., Bagley, S. M., Liebschutz, J. M., & Walley, A. Y. (2018). Medication for opioid use disorder after nonfatal opioid overdose and association with mortality. *Annals of Internal Medicine, 169*(3), 137. https://doi.org/10.7326/m17-3107

Laing, R., & Donnelly, C. A. (2024). Evolution of an epidemic: Understanding the opioid epidemic in the United States and the impact of the COVID-19 pandemic on opioid-related mortality. *PLoS One, 19*(7), Article e0306395. https://doi.org/10.1371/journal.pone.0306395

Martinez, L. S., Rapkin, B. D., Young, A., Freisthler, B., Glasgow, L., Hunt, T., … Battaglia, T. (2020). Community engagement to implement evidence-based practices in the HEALing communities study. *Drug and Alcohol Dependence, 217*, 108326. https://doi.org/10.1016/j.drugalcdep.2020.108326

Massachusetts Board of Registration in Pharmacy. (2025). *February 6). policy 2024-01: Naloxone dispensing*. Massachusetts Department of Public Health. https://www.mass.gov/doc/2024-01-naloxone-dispensing-pdf/download.

McGinty, E., Pescosolido, B., Kennedy-Hendricks, A., & Barry, C. L. (2018). Communication strategies to counter stigma and improve mental illness and substance use disorder policy. *Psychiatric Services, 69*(2), 136–146. https://doi.org/10.1176/appi.ps.201700076

New York Correction Law - COR 626. (2024). Medication assisted treatment in correctional facilities. https://codes.findlaw.com/ny/correction-law/cor-sect-626/.

Rabin, B. A., Cakici, J., Golden, C. A., Estabrooks, P. A., Glasgow, R. E., & Gaglio, B. (2022). A citation analysis and scoping systematic review of the operationalization of the practical, robust implementation and Sustainability model (PRISM). *Implementation Science, 17*(1). https://doi.org/10.1186/s13012-022-01234-3

Ryan, D. A., Montoya, I. D., Koutoujian, P. J., Siddiqi, K., Hayes, E., Jeng, P. J., Cadet, T., McCollister, K. E., & Murphy, S. M. (2023). Budget impact tool for the incorporation of medications for opioid use disorder into jail/prison facilities. *Journal of Substance Use and Addiction Treatment, 146*, Article 208943. https://doi.org/10.1016/j.josat.2022.208943

Olvera, R. G., Cogan, A. G., Bartkus, M., Benjamin, S. N., Davis, J., Frazier, L. A., Henry, B. F., Hunt, T., Kinnard, E. N., Mattingly, H., McAlearney, A. S., Rivera, D., Drainoni, M., & Walker, D. M. (2025). Community coalitions' navigation of policies to address the opioid epidemic: Insights from qualitative interviews in four states. *BMJ Public Health, 3*(1), Article e001924. https://doi.org/10.1136/bmjph-2024-001924

R. Pessar, S., Boustead, C., Ge, A., Smart, Y., & Pacula, R. L. (2021). Assessment of state and federal health policies for opioid use disorder treatment during COVID-19 pandemic and beyond *JAMA Health Forum, 2*(11), Article e213833. https://doi.org/10.1001/jamahealthforum.2021.3833

Purtle, J., Moucheraud, C., Yang, L. H., & Shelley, D. (2023). Four very basic ways to think about policy in implementation science. *Implementation Science Communications, 4*(1). https://doi.org/10.1186/s43058-023-00497-1

Sanner, L., Grant, S., Walter-McCabe, H., & Silverman, R. D. (2021). The challenges of conducting intrastate policy surveillance: A methods note on county and city laws in Indiana. *American Journal of Public Health, 111*(6), 1095–1098. https://doi.org/10.2105/ajph.2021.306227

Silwal, A., Talbert, J., Cook, C., Harris, D. R., Redmond, D. T., Gallivan, M., Speer, D., Freeman, P. R., Marks, K. R., Fanucchi, L., Walsh, S., & Lofwall, M. (2024). Policies relevant to the Healing Communities study Kentucky site implementation. *Drug and Alcohol Dependence, 260*, Article 110546. https://doi.org/10.1016/j.drugalcdep.2023.110546

Silwal, A., Talbert, J., Bohler, R. M., Kelsch, J., Cook, C., Blevins, D., Gallivan, M., Hunt, T., Hatcher, S. M., Thomas, C. P., Williams, S., Fanucchi, L., & Lofwall, M. R.

(2023). State alignment with federal regulations in 2022 to relax buprenorphine 30-patient waiver requirements. *Drug and Alcohol Dependence Reports, 7*, Article 100164. https://doi.org/10.1016/j.dadr.2023.100164

Sohn, M., Talbert, J. C., Delcher, C., Hankosky, E. R., Lofwall, M. R., & Freeman, P. R. (2020). Association between state Medicaid expansion status and naloxone prescription dispensing. *Health Services Research, 55*(2), 239–248. https://doi.org/10.1111/1475-6773.13266

South, A., Fanucchi, L., & Lofwall, M. (2023). Advocacy for patients with opioid use disorder: A primer for physicians and other clinicians on the Americans with Disabilities Act. *Journal of Opioid Management, 19*(7), 53–60. https://doi.org/10.5055/jom.2023.0799

Substance Abuse and Mental Health Services Administration. Waiver elimination (MAT Act). Published January 10, 2023. Accessed November 29, 2023. https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act.

Wakeman, S. E., Larochelle, M. R., Ameli, O., Chaisson, C. E., McPheeters, J. T., Crown, W. H., Azocar, F., & Sanghavi, D. M. (2020). Comparative effectiveness of different treatment pathways for opioid use disorder. *JAMA Network Open, 3*(2), Article e1920622. https://doi.org/10.1001/jamanetworkopen.2019.20622

Ward, K. M., Scheim, A., Wang, J., Cocchiaro, B., Singley, K., & Roth, A. M. (2022). Impact of reduced restrictions on buprenorphine prescribing during COVID-19 among patients in a community-based treatment program. *Drug and Alcohol Dependence Reports, 3*, Article 100055. https://doi.org/10.1016/j.dadr.2022.100055

Winhusen, T., Walley, A., Fanucchi, L. C., Hunt, T., Lyons, M., Lofwall, M., Brown, J. L., Freeman, P. R., Nunes, E., Beers, D., Saitz, R., Stambaugh, L., Oga, E. A., Herron, N., Baker, T., Cook, C. D., Roberts, M. F., Alford, D. P., Starrels, J. L., & Chandler, R. K. (2020). The Opioid-overdose Reduction Continuum of Care approach (ORCCA): Evidence-based practices in the HEALing Communities study. *Drug and Alcohol Dependence, 217*, Article 108325.