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Factors in rural community buprenorphine dispensing

Erin G. Major [a,*], Courtenay Gilmore Wilson [b,c], Delesha M. Carpenter [c], J. Chase Harless [d], Grace Trull Marley [c], Bayla Ostrach [e]

[a] Boston University School of Public Health, 715 Albany Street, Boston, MA 02118, USA
[b] Charles George Veterans Affairs Medical Center, 110 Tunnel Road, Asheville, NC 28805, USA
[c] UNC Eshelman School of Pharmacy, 1 University Heights, Asheville, NC 28804, USA
[d] Eastern Tennessee State University, 1276 Gilbreath Drive, Johnson City, TN 37614, USA
[e] Boston University School of Medicine, 72 E Concord Street, Boston, MA, USA 02118

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ABSTRACT

Background: There are pharmacy-related barriers to the dispensing of buprenorphine for the treatment of opioid use disorders. These include pharmacists' moral objections and mistrust of treatment regimens; the perception of a limit on the amount of buprenorphine able to be ordered and dispensed; stigma and concerns about diversion; and knowledge and communication gaps.
Objectives: To document pharmacy stakeholders' awareness and interpretation of regulatory policies that may impact rural community pharmacists' willingness and ability to dispense buprenorphine. To identify factors that affect rural community pharmacists' willingness and ability to dispense buprenorphine in Appalachian North Carolina.
Methods: Qualitative analysis and thematic coding of phone interviews with eight pharmacists from several rural North Carolina counties where local health departments recently began prescribing MOUD and four pharmacy industry stakeholders representing knowledge of wholesale distributors and pharmacy education.
Results: Three major themes were identified: stigma and misinformation, provider-prescriber communication, and perceived and actual regulatory constraints. A number of respondents indicated a desire to better understand MOUD treatment plans and displayed a misunderstanding of evidence-based treatment guidelines. Stakeholders indicated the importance of pharmacists establishing a relationship with prescribers and described pharmacist preference for dispensing buprenorphine to established patients over new or out-of-area patients. Pharmacist stakeholders and industry/education stakeholders expressed concern over a perceived DEA 'cap' for buprenorphine ordering.
Conclusions: This study provides insight on possible approaches to address rural pharmacy-related barriers patients may face when filling buprenorphine prescriptions. There is a demonstrated need for further pharmacist training on evidence-based practices for treating opioid use disorders and ordering limits, as well as a need for increased communication between prescribers and pharmacists.

List of abbreviations

DEA	Drug Enforcement Administration
MOUD	Medications for Opioid Use Disorder
NC	North Carolina
OUD	Opioid Use Disorder
US	United States

1. Background

Negative impacts of opioid use increased in recent years. Rural opioid use disorder (OUD) diagnoses and overdoses surpassed urban rates [1,2]. Despite higher rural overdose rates [3–6], treatment access is limited. Buprenorphine is an evidence-based approach for treating opioid use disorder (OUD) and reducing overdoses [7,8]. Yet "more than half of small and remote rural counties" lack a provider with the DEA-X waiver required to

* Corresponding author.
E-mail addresses: emajor@bu.edu (E.G. Major), Courtenay.wilson@va.gov (C.G. Wilson), dmcarpenter@unc.edu (D.M. Carpenter), harlessj@mail.etsu.edu (J.C. Harless).

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prescribe buprenorphine [9]. Prescribing capacity in rural areas appears to be increasing nationally [9] with some Southern states providing funding and infrastructure to train eligible providers to obtain an X-waiver [10]. More X-waivered prescribers could increase buprenorphine prescriptions at rural pharmacies. However, in a recent Texas study just 34% of pharmacies reported availability of a one-week supply of buprenorphine (combo) product [4]. In a recent survey of North Carolina pharmacists[1] 62% reported having refused to dispense buprenorphine products while 55% had refused at least three times [11]. Pharmacy dispensing refusals can exacerbate transportation barriers and force OUD patients to travel to receive their prescribed buprenorphine [12].

1.1. Pharmacy-related barriers to buprenorphine dispensing

Though the American Pharmacists Association supports buprenorphine as evidence-based treatment [13], dispensing gaps persist, especially in Appalachia [14,15]. A number of pharmacy-related barriers to buprenorphine dispensing are documented including a perceived Drug Enforcement Agency (DEA) "cap,"[10,14]; mistrust between pharmacists and physicians [15,16]; pharmacist concerns about diversion [15–17]; and knowledge gaps [17,18]. Dispensing hesitancy is partially attributed to low trust in buprenorphine following the so-called War on Drugs [17] and knowledge gaps upon leaving pharmacy school. Though the American Association of Colleges of Pharmacy sets recommendations for minimum instruction on addiction and related disorders [19], of 75 U.S. pharmacy programs, 70% do not meet the guideline [15]. In one survey, pharmacists' average score on knowledge-based questions about medications for OUD (MOUD) was 56.2%, and pharmacists reported needing additional training to better understand use of and counseling for buprenorphine [15,20]. Yet when adequately trained, pharmacists were confident dispensing buprenorphine for OUD [19].

DEA X-waivered physicians eligible to prescribe buprenorphine have reported difficulty developing trusting relationships with community pharmacists [21]. One recent study of rural buprenorphine prescribing identified building relationships with pharmacists as a strategy physicians employ to overcome barriers [22]. Prescribers reported such relationships allowed for sharing of information about patients and prescriptions, and to address any dispensing problems "quickly and directly," [21p119].

1.2. Perceptions of a DEA "cap"

In some areas, pharmacy staff perceive limits on how much buprenorphine they can order and dispense [10,15]. In one study, pharmacists reported refusing to dispense new buprenorphine prescriptions; perceiving that filling 'too many' would raise regulatory concerns [15]. This study thus builds on earlier research about perceptions of a DEA 'cap' [10] that found pharmacists in Kentucky often interpret wholesale distributor-imposed ordering limits as originating from DEA rules (that in fact do not directly apply at the individual pharmacy level) [10,15]. In the absence of clear guidance from the DEA on buprenorphine distribution and sales [10] wholesale distributors are instead tasked with detecting and reporting 'suspicious' orders defined as such by the DEA only post-hoc. To minimize risk of enforcement action, wholesale distributors therefore create internal compliance programs to monitor orders, which in turn limits distribution to pharmacies [10]. Such wholesale distributor attempts to interpret opaque DEA regulations and avoid enforcement actions likely influence pharmacists to order small, frequent batches of buprenorphine [16] or think they cannot order more than a certain amount [10]. Despite the documented lack of actual DEA limits on individual pharmacies [10,15] pharmacist *perceptions* of a cap influence willingness or capacity to dispense [10,15].

1.3. Dispensing hesitancy due to stigma and bias

In addition to perceptions of a cap, stigma and bias that are already greater in rural areas also limit buprenorphine dispensing [3,12,21,22]. Burdensome medication wholesaler policies and regulations can even reinforce the stigma surrounding buprenorphine [23]. Identified barriers to dispensing include pharmacist reluctance to dispense due to negative perceptions of OUD patients and MOUD prescribers and stigma [24]. Some physicians that prescribe buprenorphine reported encountering pharmacists with stigmatizing attitudes toward OUD treatment [21]. In a West Virginia survey 73.5% of community pharmacists indicated they would be "not at all likely" to fill a prescription written by an out-of-state practitioner [25], indicating possible mistrust in the patient and/or provider. A recent phone audit of pharmacies in several small, rural, Southern Appalachian counties, published in this journal [26], found more than half of pharmacists contacted indicated willingness to dispense buprenorphine without reservation, while just over a third indicated willingness to dispense only under certain circumstances. Nearly half of audit respondents expressed hesitation or specified conditions for dispensing to out-of-area patients. Nearly half of audited encounters included indicators of possible pharmacist stigma/bias. Existing literature suggests rural physicians are concerned that poor treatment by pharmacists and unwillingness to stock MOUD can reinforce stigma for their patients [22].

In the area where this study was conducted extant literature also demonstrates values of mutual care [27,28] that Appalachian scholars [29] identify as *conditional Southern hospitality*. This is a qualified, situational acceptance that informs who is considered deserving of welcome; who is trusted in a given small community. In a rural pharmacy setting, such a desire to care for locals may intersect with wariness about outsiders, producing a tension when resources appear limited.

2. Objectives

The specific objective of this study was to collect qualitative data from a range of pharmacy stakeholders (community pharmacists, pharmacy industry/education sector) to 1) identify barriers and factors impacting community pharmacist willingness or ability to dispense buprenorphine; and 2) identify community pharmacist perceptions of a DEA "cap" and its impact on buprenorphine dispensing. This study specifically focused data collection in an area of South-Central Appalachian North Carolina where most of the population is designated rural [30,31]. This article contributes to the emerging literature on the impact of perceived DEA and wholesaler policies, and pharmacist attitudes, on buprenorphine dispensing, and ultimately aims to contribute to the work being done to reduce barriers to accessing buprenorphine.

3. Methods

3.1. Research design & setting

The interview findings presented here represent a subset of a larger multi-aim research study designed to investigate barriers to buprenorphine dispensing in Appalachian North Carolina [10,26,26,32]. Based on elements of modified Grounded Theory [33,34] and community-based participatory research [35] the specific pharmacy stakeholder subset study described here was prompted by questions and concerns from community stakeholders and clinicians directly involved in efforts to expand access to evidence-based treatment for opioid use disorder and to reduce overdose deaths, in a mostly rural region of South-Central Appalachia. They shared these concerns with the senior author within the context of regular meetings of clinicians and patient navigators serving local and regional patients diagnosed with substance use disorders; meetings that the author attends as a community-based researcher.

As the study objectives originated from questions raised by community members directly involved in efforts to expand access to MOUD and otherwise help people at risk for overdose navigate care, the study design

[1] Conducted as part of the larger study of which this study is a subset.

combined elements of modified Grounded Theory to allow for a semi-structured approach open to emerging data and themes, as well as elements of community-based participatory research with stakeholder input on data collection tools and preliminary analysis.

Recruitment and data collection were conducted with participants in a South-Central Appalachian region of Western North Carolina encompassing two rural counties, and a more rural part of another county. These areas had experienced higher overdose death rates than the state overall in the prior years [36] and public health departments in two of the counties had recently begun prescribing buprenorphine products. All are located where state and grant-funded efforts sought to increase providers eligible to apply for a DEA X-waiver to prescribe buprenorphine [6,37].

3.2. Recruitment & participants

To best explore aspects of policy interpretation and other factors affecting buprenorphine product dispensing at community pharmacies, study team members sought to recruit participants from two categories: (1) community pharmacists working in the region described above; and (2) pharmacy industry and pharmacy education stakeholders familiar with buprenorphine stocking, ordering, and/or dispensing policies and implementation or the training pharmacists receive related to these topics. Participants needed to be over 18, English-speaking, and be either (1) a community pharmacist working in one of the rural county areas described above, or (2) a pharmacy industry or pharmacy education stakeholder with awareness of buprenorphine ordering, stocking, and dispensing policies and procedures in rural NC pharmacies and/or related training for rural community pharmacists. Using purposive sampling strategies, pharmacist recruitment consisted of cold calls to all pharmacies in both counties. To ensure a sampling strategy that would encompass recruitment of pharmacists from community pharmacies throughout the region in which community stakeholders (*i.e.* buprenorphine prescribers, health department employees, *etc.*) had reported dispensing refusals, study team members contacted all pharmacies in both counties where local health departments had recently begun prescribing buprenorphine and made a recruitment call to an additional pharmacy just outside the two fully rural counties where health departments prescribed buprenorphine. This additional location was added in order to recruit from a pharmacy where a prescriber stakeholder reported a patient was refused their complete buprenorphine prescription and instead charged repeated co-pays to fill small portions. The additional pharmacy represented a portion of a neighboring county where less than 50% of the population is designated rural by the U.S. Census Bureau, yet that represents a Health Professional Shortage Area and is scored as 'Other' (0.37) on the Index of Relative Rurality, indicating proximity to rural designations. The two counties from which all pharmacies were contacted are both designated rural by the U.S. Census Bureau [31], are both Health Professional Shortage Areas, both have rural populations greater than 50%, and have rural scores between 0.52 and 0.47 on the Index of Relative Rurality [30].

Purposive and key informant sampling and recruitment of pharmacy industry and education stakeholders consisted of contacting key informants from local and regional community pharmacies, North Carolina pharmacy education and professional organizations, and regional pharmacy managers, to ask for suggestions of and introductions to wholesale distributor representatives; current and former DEA representatives; and of directly recruiting representatives from NC pharmacy education and professional organizations, to participate.

3.3. Data collection & analysis

Data collection occurred *via* phone or video interviews. To conduct the interviews, a set of similar interview guides for each type of stakeholder were developed (Appendix). Members of the research team who conducted all interviews used existing literature, information from earlier key informant input, findings from an earlier aim of the larger study of which this was a subset [10], and regional contextual information to develop semi-structured interview guides. The interview guides contained primarily open-ended questions, with some specific closed-ended questions about participants' particular role or practice. Overall topics of the interview guides included experience with and/or awareness of pharmacy buprenorphine product ordering, stocking, and dispensing practice; demand for buprenorphine products; any rules or restrictions related to dispensing; and reasons for not dispensing, among others.

Interviews lasted 20 min to an hour and participants received a $30.00 (US) gift card incentive. Interviews with each respective group of stakeholders (community pharmacist; and pharmacy industry/pharmacy education) continued until concept saturation was met, with no new ideas emerging in interviews. Interviews with 11 of 12 stakeholders were audio-recorded and transcribed verbatim. The twelfth interview was with a pharmacy industry key informant that, in virtual meetings, shared expert policy interpretation based on past work with the DEA, culminating in a detailed written report this key informant prepared and provided to the lead investigators in lieu of a recorded interview.

Guided by principles of modified Grounded Theory, data analysis combined deductive and inductive elements, with three of the authors developing an *a priori* codebook based on a review of existing literature and the interview guide and then revising it by coding the first three transcripts to add emerging concepts, using a combination of inductive and deductive coding. At this time the codebook was iteratively updated with emerging codes, ensuring codebook completeness and accuracy. After meeting regularly to compare coding and negotiating to achieve 100% intercoder agreement on an initial set of transcripts, one coder each coded the remaining transcripts. The study team members involved in analysis continued coding using a combination of modified Grounded Theory approaches and thematic analysis techniques as described by Creswell [38], to ensure concept saturation while coding. Findings generated from close thematic analysis of the 11 verbatim transcripts were triangulated using the written report provided following an interview with the twelfth key informant. Themes were interpreted collectively by three of the authors, with other authors further refining the preliminary analysis to reach a final interpretation of relationships between and among themes.

4. Results

4.1. Participants

The study team contacted pharmacists at all independent and chain pharmacies in both counties where local health departments were then prescribing MOUD, as well as a pharmacy in a more rural part of a neighboring county at the suggestion of a community stakeholder involved in the study design. Pharmacy stakeholders at three of five pharmacies in one county, at four of five pharmacies in another county, and from the specific pharmacy in the neighboring county, all agreed to be interviewed. The study team attempted to contact a total of eight specific pharmacy industry/education stakeholders to whom they were referred by key informants; of these, four agreed to be interviewed.

The interview sample ultimately included eight community pharmacist stakeholders and four representatives from the pharmacy/wholesaler industry and/or pharmacy education. Several of the latter had previously worked or currently work in pharmacy settings. Pharmacist stakeholder participants ranged in age from 29 to 66 years old; four self-identified as male and five self-identified as female; they had 142 years of community pharmacy experience combined, ranging from two to 36 years (median 17 years, mean 17.75 years). Overall, pharmacist stakeholder participants represented four chain pharmacies and four independents. Of pharmacy industry/education stakeholder participants, two self-identified as female and one self-identified as male; all were over 40; they had worked in the pharmacy industry and/or pharmacy education for a range of 1–36 years (median 15.5 years, mean 16 years) (Table 1). These pharmacy industry/education stakeholder participants represented professional backgrounds involving familiarity with the DEA; in pharmacy education; and with

Table 1
Participant characteristics.

Sample = 8 community pharmacists				
4 pharmacy industry/education				
Participant	Role	Years experience	Gender*	Age
Community pharmacists				
PS1	Community pharmacist	10	Male	39
PS3	Community pharmacist	2	Female	28
PS4	Community pharmacist	7	Female	29
PS6	Community pharmacist and pharmacy school preceptor	30	Female	53
PS7	Community pharmacist	22	Male	"Past 50"
PS8	Community pharmacist	36	Male	66
PS9	Community pharmacist	12	Female	37
PS10	Community pharmacist	23	Female	47
Pharmacy industry/education				
PS2	Pharmacy industry/education	1	Female	55
PS5	Pharmacy industry/education	18	Female	67
PS11	Pharmacy industry/education	15	Male	38
PS12	Pharmacy industry/education	16	Male	48

* Gender was self-reported. The authors recognize that "male" and "female" are not genders; however, this is how these participants answered the question, "how would you like your gender listed?"

state and national professional associations related to pharmacy practice. The investigators were unable to interview a stakeholder representing pharmacy wholesale distributors, despite numerous attempts.

Among the twelve stakeholders' responses, three major themes were identified: *stigma and misinformation; provider-prescriber communication*; and *perceived and actual regulatory constraints*. These themes are exemplified in the below quotes. The authors present exemplary quotes to emphasize the ways in which the themes overlap: particularly the themes of stigma and misinformation, which highlight the desire and need for increased provider communication, as well as overlap with perceptions of regulatory constraints.

4.2. Stigma and misinformation

Almost all (83.3%, 10 of 12) stakeholder participants mentioned stigma toward people prescribed buprenorphine. Nearly two-thirds (62.5%, 5 of 8) of pharmacist stakeholders spoke of instances when a patient was unable to receive buprenorphine simply because of what medication it was. Several participants indicated this was due to pharmacists' personal preference (their own or others'). Table 2 provides exemplary quotes from participants that highlight some examples of stigmatizing behaviors or beliefs held by pharmacist participants and/or their colleagues.

In addition to the above quotes, stigmatizing comments intersected with concerns about a lack of prescriber communication; lack of awareness of evidence-based guidelines; mistrust of out-of-area patients; or diversion suspicions. As one pharmacy stakeholder articulated:

> *Patients are fearful to seek treatment because of the stigma around opioid use disorder… 'addict, druggie, junkie,' etc. are tossed around and… have a very negative impact on patient care… A patient doesn't wanna be labeled. You have to remove the stigma in your town, in your city, in your county, in your state, in your country…" (PS11).*

Some participants were explicit about reducing stigma:

> *Maybe those patients feel a little uncomfortable or stigmatized… [The pharmacy] I'm at now… we make people feel very comfortable and non-judged (PS9).*

Stigma and misinformation overlap and underlie the other two identified themes of provider-prescriber communication and regulatory constraints. The beliefs held by pharmacists and their colleagues can impact the desire for increased communication with prescribers, misinformation about treatment goals, and fears of ordering thresholds.

Table 2
Exemplary Quotes: Stigma.

Participant	Exemplary Quotes: Stigma
PS3	Interviewer: You mentioned another pharmacy in town that will not fill Buprenorphine […] why? Participant -*Our technician who used to work there just said… the [pharmacist] just doesn't want to. She's trying to prevent certain… people coming through… she doesn't sell needles or any kind of bup[renorphine]… I think it's more, I guess maybe ethical/moral. She just chooses not to.*
PS6	*It is tough to find… a providing pharmacy for [buprenorphine dispensing]. There seems to be some [pharmacists] who don't [dispense]. When we first started seeing more Suboxone [prescriptions], there was another independent [pharmacy] in town… let's just say I perceive them as being fairly vocal about not filling for* those *clients [sic].*
PS8	*Same people would come in, and they were, like, wantin' needles. I'd tell 'em no, no.*
PS11	*Is your patient strictly in one pharmacy, or are they pharmacy hopping and… not really being responsible [sic] for their treatment? I mean, those patients might be in a treatment program, and they've only got one option… if that pharmacy has to turn them away, one bad experience … could take someone that was havin' a great day and decided'* I wanna change my life. I realize I have a disease, and I wanna beat it.' *They go to their pharmacy, or they go to a pharmacy that they have never been to before, but they hope they can help there. One bad experience can take that person that was ready for help and send them right back to where they were because it's easier to go back to the street, go back to the bad habits [sic]. If [the pharmacist doesn't] understand how [buprenorphine works], or they have a negative stigma of buprenorphine-based products or a negative stigma of the patient base, it can cripple a community…*

4.3. Provider-prescriber communication

All pharmacist participants indicated that establishing a relationship with prescribers is important and may affect willingness to dispense: most (88%, 7 of 8) pharmacist stakeholders specifically mentioned wanting to know the prescriber and reported reluctance to dispense buprenorphine without an established relationship with the prescriber.

Nearly two-thirds (62.5%, 5 of 8) of pharmacist stakeholders explicitly mentioned preferring to verify or discuss prescriptions directly with prescribers. As in Table 3, this appeared stronger in relation to patients newly prescribed buprenorphine, out-of-area patients, and patients prescribed by unfamiliar providers. Meanwhile, pharmacy industry/education

Table 3
Exemplary quotes: provider-prescriber communication.

Participant	Exemplary Quotes: Provider-Prescriber Communication
PS6	*…we do have to look at the people that we're serving. Are we serving just people inside of our county or are we getting people from outside? And we do have a couple of folks who, and I don't even remember how we ended up with them but their doctor is in a different county and, you know, generally [we] don't do that, just… they can't find anywhere else to get their medication… it's not any question as to whether they're legitimate prescriptions or not, you know, but they come here from… the next county over, and… it could be very problematic…* *I need[ed] to determine if [a certain patient was] sellin' [buprenorphine] in my parkin' lot. I've gotta resolve that before he's due for his next fill… I wish a provider… responded to me on that. In general, I don't refuse [to dispense] unless I can't determine [a] legitimate patient/doctor relationship… who the doc is, and who the patient is.* *If I'm trying to supply not just my local people but others as well… why are we getting these scripts from up here? I would talk to [the prescriber]. At first, I'm like, you know,* 'we usually just try to take care of people who are really close…' *[but] as long as it's a local provider that we know…*
PS7	*We've had customers that would literally call us and say hey, my regular pharmacy can't fill this no more. I've explained to these customers that, you know, as long as … we know that you're a regular customer, that you go to a regular doctor, you know, we have a rapport with you and the doctor, and we usually check almost 99% every patient that we have here that we speak with the office to make sure everything is legit…*

stakeholders cautioned that pharmacists are wary of unknown prescribers; half (50%, 2 of 4) specified the importance of pharmacist-prescriber communication.

In contrast, some participants, both pharmacist stakeholders and pharmacy industry/education stakeholders, indicated established patients or patients of known prescribers were less likely to encounter difficulty in rural areas as compared to new patients. This was seen as especially likely for local patients. Out-of-area patients or those with prescriptions from unknown providers may prompt pharmacists to review "red flags" they are encouraged to pay attention to when dispensing targeted controlled substances, which, in NC, includes buprenorphine [39]. Such 'red flags' include either the patient or prescriber being from out of the area (a phenomenon increasing as more clinicians obtain X-waivers and more patients encounter pharmacies with limited buprenorphine stock); a patient paying cash or asking for a specific formulation (both more common for uninsured patients who may be able to obtain a manufacturer discount coupon for a specific formulation); or attempting to fill a script 'too soon' (which may occur if a patient is turned away at another pharmacy and transfers a script). Community pharmacist concern over 'red flags' are exemplified in a passage from participant 'PS6' in Table 3.

A pharmacy industry/education stakeholder talked about reasons for a pharmacist to communicate with providers, including to "*make sure physicians have that waiver, that the physician's licensed in the state in which they're seeing the patient*" (PS11).

Just over a third (37.5%, 3 of 8) of pharmacist stakeholders expressed concerns about prescription duration; a quarter (25%, 2 of 8) mentioned wanting to understand prescriber intentions. Half (50%, 4 of 8) of pharmacy industry/education stakeholders mentioned pharmacist perceptions of diversion. One described policies intended to reduce diversion, "*We restrict 'em with controls not because we think they're abusing it* [sic]*, but we don't wanna take the chance,"* (PS1). Concerns about diversion often overlapped with knowledge gaps about evidence-based treatment, displayed by half of the rural community pharmacists interviewed. As in the first quote in Table 4, 'tapering' represented a particular concern.

A pharmacy industry/education stakeholder discussed the need to educate pharmacists about treatment duration:

> *There is no amount of time that a patient needs to be on bup[renorphine]; they need to be on medication as long as they're getting benefit from it. We need to make sure that message is… covered in our educational training so pharmacists understand that it could be a lifelong thing* (PS2).

Stakeholders described pharmacists' perceptions of supply limitations and ordering thresholds as intersecting with and being compounded by interprofessional communication gaps and stigma. A pharmacy industry/education stakeholder twice used the word "*accountable*" when describing pharmacists' approach to evaluating prescriber and patient legitimacy, and said,

> *… you have a stigma wrapped around [buprenorphine], now you have a misunderstanding of how [pharmacists] may or may not have… been in trouble over distribution of the product. Now you have pharmacies, pharmacists, etc. saying* "I don't even want to put my toes in that water; it's not worth it for me" (PS1).

4.4. Perceived and actual regulatory constraints

62.5% of rural pharmacy stakeholders ($n = 5$ of 8) perceived a 'cap' on the amount of buprenorphine that can be ordered or stocked. As a result, pharmacists expressed concerns about ensuring buprenorphine access. Concern over having enough in stock for existing patients affected willingness to accept new patients. 100% ($n = 4$ of 4) of pharmacy industry/education stakeholders spoke at length about pharmacist perceptions of an ordering limit.

Most stakeholders described the perceived 'cap' as ambiguous and were unable to indicate a specific amount that could be stocked or dispensed at a time, making it difficult to avoid exceeding a limit. There was no consensus among stakeholders whether the DEA or wholesalers implement the limit. When asked if the distributor indicates when a pharmacy approaches a limit, one pharmacist stakeholder responded "*You don't know until you get up against it… [it's] hard to hit a moving target,*" (PS6). Other quotes illustrating these patterns are in Table 5.

Table 4
Exemplary Quotes: Concerns about length of prescription, diversion, misuse.

Participant	*Exemplary Quotes: Stigma & misinformation overlapping with desire for Provider-Prescriber Communication*
PS1	*I would like to have a conversation with [the prescriber] about their plans. Like, if they're just gonna keep [the [patient] on [buprenorphine] or if they plan on tapering them off slowly, or what's goin' on 'cause on our side of it, when we get prescriptions, all we see is the prescription, you know. We don't obviously see the patient notes or… know anything about what the doctor's thinking*
PS1	*They seem to start taking buprenorphine to get off of opioids which is good, but they never seem to get off of the buprenorphine so they're kind of trading one addiction for another (sic)*
PS4	*There was one [patient] I had a discussion with the other pharmacist about. [They had been getting] the Subutex product that does not include Naloxone… the other pharmacist… reached out to the provider wondering why [the patient] wasn't on the combination… product… to have the Naloxone in the product, hopefully making [it] less abusable [sic]… then we actually hadn't heard back, and it was time for the next fill of just the plain Buprenorphine product… I did fill it… I don't want the patient to go without their medication… technically there really wasn't something wrong with their prescription; it was just more of a clinical question and just, you know, checkin' all the boxes just to make sure everything was right with the patient*
PS7	*I [have a] patient. He's legit. I mean, I actually checked the website, and he goes to another competitor chain store, and he fills his normal prescriptions, and then he comes here, and I asked him one time – I said, you know, you're traveling roughly an hour away. He goes, I've gone to treatment plans where I live in the area, but none of the pharmacies even fill it. I said, did you ask 'em why, and he says I went to one or two pharmacies, and even the one that he literally uses to get his maintenance medicine, and they said just the pharmacist is not comfortable filling his prescription for that medicine even though he's goin' to a legitimate doctor; he's using his (insurance); he's, you know, not getting into anything.*
PS7	*We try not to discourage the use or misuse of [buprenorphine], making sure that everyone is properly treated…, it depends on the treatment plan, how they have it with their physicians. We try to open our eyes in making sure that we don't label people how I'm thinking other pharmacies might be labeling people…*
PS8	*[I worry about] the length of time somebody needs to be on the buprenorphine, but I guess it's a medical question. We're glad to dispense, but again, the purpose is to get them off of drugs, seems like they could be off that one too eventually. I'm just concerned about the people bein' on it for, you know, 10 years… you have to weigh the cost to society. It's better them to do that than be on black tar heroin I guess [sic]… I worry about how long - it seems like they could taper off on this – I don't know, [after] three years. Seems like a lot of people don't ever get off of the buprenorphine. They're on it for years.*

Pharmacist stakeholders that heard of a threshold indicated there was no related training. When asked how they became aware, one responded:

> *Rumor mill, pharmacists questioning* have you heard of [this]? Have you seen if it's real? *They are ordering a certain amount which isn't even astronomical … all of a sudden, they place the order one night, and the next day, they get no product* (PS11).

As seen in Table 5, participants described the challenge of balancing perceived buprenorphine ordering limits with the need to dispense as seemingly heightened when demand increased: for example, when a pharmacy begins receiving more prescriptions written by newly waivered providers. Pharmacist stakeholders indicated they prioritized stock for established and/or local patients and expressed hesitation to dispense to new, out-of-area patients:

> *We started getting prescriptions from [county suppressed], '…* wait a minute, you're new to us. This doctor is new to us.' *Hang on… why are you here and not closer to where you live or see your provider?'* (PS6).

Pharmacist stakeholder desires to conserve what they perceived as a limited supply of buprenorphine for local, known, and trusted patients; or patients of local, known, and trusted prescribers, at times intersected with

Table 5
Exemplary Quotes: Regulatory Constraints.

Participant	*Exemplary Quote*
Perceived regulatory constraints	
PS5	*DEA does not issue a cap on what [wholesalers] can order. They do not issue a cap on what a wholesaler can distribute to the pharmacies… to call it a cap is kind of like a shorthand… it's really complex legal issues that we're talking about. [Pharmacists] don't really have that capacity to get into the complex laws and requirements… but there is no such thing as a DEA cap. What is happening, though, is because a number of wholesalers have been – they've been the subject of very strong DEA action to suspend their registrations, the wholesalers are intentionally being… gun-shy about how much they distribute, and so they will not distribute large amounts to pharmacies out of fear that DEA will say* 'oh, you're distributing too much.'
PS7	*I've heard… competitors say that they've reached a limit… of how many patients they can fill, and I'm not sure. I haven't seen a limit cap on filling medicine. I'm not sure if that's a federal mandated law where they can only fill for a certain amount of patients or somethin' like that…*
Impact of constraints on willingness to take new patients	
PS6	*you've got these folks who are already your patients… you want to be able to provide for them… you get to the end of the month, and you're like oh, crap, I can't get this, and this isn't something that… can wait three days until we get to the first of the month and I can order again and they've got to go out and find this somewhere else, and that puts that threshold [pressure on] another pharmacy who is, like,* hey, man, I've gotta take care of my customers, so I can't pull somebody else in [take a new patient]…
PS4	"*We were not able to keep the opioids in stock that our normal patients were getting if we filled [buprenorphine] for these patients that would just come for, you know, one month they would come, and then for four months they would go to a different pharmacy*"
Stigma & misinformation overlapping with regulatory constraints	
PS5	*Be a little bit careful about how specific you give the guidance to your audience because you don't wanna tip your hand so that any criminals [sic] reading this report says oh, (name) says do this and this and this to avoid DEA's oversight or to get prepared for a DEA review because you may give… them a guideline that tells them how to avoid DEA oversight… something that says look at factor a, b and c, and the criminal will say let's us go with d, e and f 'cause that's not something they're gonna be looking at… I would urge you to be really careful how you write up your report so that you don't give any criminals a roadmap to how they can game the system [sic].*
Stigma & misinformation overlapping with perceived regulatory constraints and desire for provider-prescriber communication	
PS11	*Stigma is probably one of the biggest barriers. The only thing that ever gets put in the news are pharmacies that get raided or physician's offices that get raided. That's an extreme outlier. What that group, practice, pharmacy, etc. was probably doing was well outside of what's allowed … but that's all you see. That [stigma] barrier needs to be squashed, and that has to come from the top. It has to start with your federal regulatory bodies providing an understanding and education of how they view [dispensing] and what they look for all the way down to the state level. What does your board of pharmacy know about medication-assisted treatment and opioid use disorder treated in the outpatient basis with buprenorphine-based products? It's a multi-level educational approach to your pharmacies…*

apparent stigma toward OUD patients and prescribers. In addition to ordering constraints, pharmacist stakeholders mentioned additional regulatory and bureaucratic obstacles including lack of insurance coverage and costs. Some were especially concerned that such constraints disproportionately affect uninsured patients or limit benefits of insurance:

> *If you're filling with insurance, [it] probably has a restriction… on the pharmacy side making sure you have enough [buprenorphine] in stock… refills are on hold… Some pharmacies keep a list of what to do even if it's a few days ahead, they're able to check and make sure they have enough in stock… it helps to follow [insurance] rules so prescriptions don't get filled earlier than they should.[We offer reduced] pricing for cash-paying customers…* (PS6).

5. Discussion

This study identified three intersecting and overlapping major themes from stakeholder interviews with rural community pharmacists in South-Central Appalachia and with pharmacy industry and pharmacy education representatives familiar with rural community pharmacy settings in the region: *stigma and misinformation*; a *need for improved provider-prescriber communication*; and *community pharmacist perceptions of regulatory constraints*. Confusion surrounding dispensing regulations, combined with stigma, impacted communication between providers and prescribers; while such lack of communication appeared to reinforce stigma and misinformation. Existing regulations and resulting confusion, and pharmacist concerns about dispensing, also appeared to be interconnected themes; though for the purposes of this article they are presented distinctly.

This study aimed to fill gaps in the MOUD access literature specific to South-Central Appalachia, and to document pharmacy stakeholder perspectives on barriers to buprenorphine dispensing in a rural area where overdose deaths remain high. As noted in this journal, there are limited qualitative studies "focused on the pharmacists roles in MOUD," [40]. It is necessary to better understand the role pharmacists' play and the attitudes held that may impact patients' ability to access their medications.

Pharmacist-prescriber communication was a consistent theme. Bidirectional lack of communication contributed to pervasive misinformation and mistrust. Within the largely rural geography and culture of the area studied, misinformation about evidence-based OUD treatment and distrust of out-of-area patients and providers coupled with pervasive stigma, disrupted buprenorphine dispensing. Simultaneously, among rural community pharmacist stakeholder participants, a strong sense of community and local trust; paired with mistrust of non-locals, seemed to be reinforced by awareness and interpretations of narcotic-dispensing "red flags" highlighted for the dispensing of targeted controlled substances. Local pharmacist preference for dispensing to local patients was evident in this study and in other emerging literature [15]. Yet the authors argue this also signals what may be a positive motivation: a desire to ensure continuity of care for local, established patients.

Pharmacists' desire to improve communication with prescribers was often expressed in the context of questioning or doubting prescribers' approaches to treating OUD (*e.g.*, critiquing the duration of buprenorphine scripts; stating a desire to ask prescribers about treatment plans). Pharmacist stakeholders described wanting to better understand patients' treatment plans, though often framed this as questioning or not trusting the prescribers' judgment. Some pharmacist stakeholders' emphasis on buprenorphine tapering (which is contradictory to evidence-based treatment) also seemed to indicate a lack of knowledge and/or comfort with evidence-based treatment plans, as well as a lack of trust in prescribers' competence to determine how long the patient may benefit from treatment.

Many stakeholders expressed ideas about buprenorphine that were explicit examples of misinformation, especially regarding recommended treatment duration and the actual risks of diversion or misuse (see Table 4). In addition to these issues, pharmacists endorsed common myths, such as the perception of MOUD as "trading one addiction for another," which is contrary to evidence-based practice.

This misinformation and concerns about treatment plans could be mitigated through improved communication with providers and expanded pharmacist education that includes best practice guidelines supporting the use of buprenorphine for as long as the patient finds it beneficial [8]. This information, along with coverage of reduced clinical concerns about diversion [41], could be reinforced through better pharmacist-provider communication and pharmacist training. Without open channels of communication, trust between pharmacists, prescribers, and patients cannot be built, allowing continued misinformation to permeate patient care.

Pharmacy stakeholders' perceptions of regulatory and other constraints, including the ambiguity of DEA and wholesaler rules, were consistent with limited but growing literature on perceived 'DEA caps.' While no such cap exists, as evident in these findings and in that of other researchers [15], the *perception* of a cap or ordering limit and other regulatory issues directly affected dispensing capacity in rural NC pharmacies.

Pharmacist stakeholders that are aware of wholesale distributor-imposed limits on the total amount of targeted controlled substances (opioids *and* buprenorphine) a pharmacy can order or stock may see such limits

as potentially reducing their capacity to dispense opioids needed by established patients. This study identified pharmacist concerns that balancing perceived ordering constraints with dispensing demand could compromise their ability to ensure continuity of care. Similar to stakeholder participants' concerns that dispensing buprenorphine to new patients; patients from out of the area; and patients of new or unknown prescribers could threaten the stability of the buprenorphine supply for established (*i.e.*, known and trusted) patients, their concerns about how dispensing ratios (narcotics *vs.* buprenorphine) could affect established patients suggested an overlap between prevalent stigma toward buprenorphine patients, and the impact of regulatory constraints. The authors argue this illuminates communication breakdowns at multiple points in the DEA-wholesale distributors-pharmacies equation. Without clarity around regulatory constraints, pharmacists may only order buprenorphine in small batches, or believe they cannot order more than a certain amount. Pharmacists need reliable access to buprenorphine ordering and need to ensure patients have reliable access to dispensing, to ultimately help prevent overdoses.

Given the evident prevalence of stigma and misunderstandings of evidence-based treatment among pharmacist stakeholders, the authors argue that regulatory confusion and perceived constraints surrounding buprenorphine ordering and dispensing likely reinforce negative attitudes toward people prescribed buprenorphine. This is consistent with existing literature on the role of stigma in reinforcing restrictive regulations, and *vice versa* [23]. Moreover, misguided concerns over treatment duration and diversion may well be rooted in bidirectional stigma stemming from lack of exposure to evidence-based OUD treatment information. Yet given that pharmacy stakeholders in this study described a preference for ensuring continuity of care by prioritizing limited buprenorphine supply for known patients and patients of known providers the authors also recognize that some rural community pharmacists' well-intentioned desires to ensure medication availability for their patients indicates a commitment to continuity of care, consistent with literature on the Appalachian ethos of *taking care of our own* [27,29].

Greater access to and uptake of evidence-based training by community pharmacists could address both stigma and lack of accurate knowledge about OUD treatment. Such trainings, with credit for continuing education and focused on evidence-based OUD treatment, improved communication with prescribers, how to create welcoming and nonjudgmental pharmacy environments, and resources to overcome barriers to stocking and dispensing buprenorphine, could help ensure access to lifesaving medication. Trainings covering these subjects are in development and beginning to be offered to prescribers and pharmacists [42].

A limitation of this study is the disparate and relatively small sample of respondents from different professions. Despite the small sample, the diversity of professions within the sample also allowed for a range of perspectives and experiences, across community pharmacists, the pharmacy industry, and pharmacy education. Concept saturation was achieved, while the sample represented the majority of pharmacies in the region of focus as well as representing pharmacy industry/education stakeholders from a range of relevant sectors. Though the recruitment strategy ensured that respondents had knowledge of the topic, this may have biased the sample toward people with opinions on buprenorphine dispensing. While the data are qualitative, frequencies and percentages are listed for ease of comparison.

6. Conclusions

This study illuminates and confirms earlier findings about persistent rural pharmacy-related barriers patients may face when attempting to fill buprenorphine product prescriptions and offers insight on possible approaches to improving access. Community pharmacists and pharmacy industry/education stakeholders described stigmatizing and/or misinformed beliefs about the use of buprenorphine for opioid use disorder treatment. Such stigma and misinformation influenced the need and desire for an increased level of communication with prescribers, particularly to understand the evidence for treatment duration and to address exaggerated concerns about diversion. In addition, participants reported concerns over perceived DEA regulations and ordering thresholds that shaped dispensing behaviors, while also expressing a desire to ensure continuity of care for known patients. Untangling interconnected layers of trust, mistrust, commitment to continuity of care, and stigma, displayed by rural pharmacists, may be an important area for future research.

The need for additional and consistent training for pharmacists and pharmacy staff is clear. Such training and education must include an emphasis on the evidence for OUD treatment with buprenorphine, and evidence against (unwanted) tapering, as well as information on what regulatory constraints are actually in place and how these apply to community pharmacists. In addition to continuing education, there is a need for better prescriber-pharmacist communication especially when the provider is newly prescribing; new to the community; or has a new or out-of-area patient. Such training could provide a better channel for pharmacists' understanding of patients' treatment plans, and in turn, their willingness to dispense buprenorphine. Provider training could include encouragement for OUD treatment clinicians to facilitate increased order sizes by documenting their anticipated prescribing.

Future research and implementation efforts should include developing, implementing, and assessing the impact of targeted pharmacist training on best practices for OUD treatment and stigma reduction. Other areas of focus could include educating providers and pharmacists on how to improve their communication, and encouraging OUD treatment providers to collaborate with pharmacists to increase order sizes.

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Declaration of Competing Interest

No conflicts.

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Appendix A. Supplementary data

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