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## RESEARCH

## Pharmacists' perceptions regarding the impact of hydrocodone rescheduling on prescription volume, workflow management, and patient outcomes

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## ABSTRACT

**Objectives:** To determine (1) pharmacists' perceptions of how rescheduling of hydrocodone combination products (HCPs) from Drug Enforcement Agency (DEA) Schedule III to DEA Schedule II has influenced prescription volume and revenue, pharmacy workflow management, and patient outcomes; and (2) whether perceptions differed between pharmacists who support versus those who oppose HCP rescheduling.

**Design:** A cross-sectional mail survey.

**Setting:** Texas community pharmacies from October to December 2015.

**Participants:** One thousand randomly selected, registered Texas community pharmacists drawn from the Texas State Board of Pharmacy registry.

**Main outcome measures:** Pharmacists' perceptions, measured on a 5-point Likert scale of HCP rescheduling and its impact on prescription volume and revenue, workflow management, and patient outcomes. Measures were developed specifically for this study.

**Results:** The response rate was 17% ( $n = 164$ ). The majority of pharmacists (70.4%) supported HCP rescheduling. More than 80% of respondents perceived that the volume of 2 alternative pain medications—tramadol (DEA Schedule IV) and acetaminophen with codeine (DEA Schedule III) prescriptions dispensed—either “increased” or “significantly increased” (82.0% and 85.8%, respectively) following rescheduling. Overall, pharmacists who opposed rescheduling were significantly more likely to report negative perceptions regarding revenue ( $P = 0.0142$ ), inventory management ( $P = 0.0024$ ), and drug shortages ( $P = 0.0005$ ) than those who supported rescheduling. However, pharmacists who supported rescheduling had more positive perceptions about electronic prescribing ( $P < 0.0115$ ), patient safety ( $P < 0.001$ ), drug abuse ( $P < 0.0001$ ), and legitimate use ( $P < 0.0001$ ).

**Conclusion:** Results showed that legislative efforts, such as rescheduling HCPs, influenced pharmacists' perceptions of practice and patient outcomes. Currently, little is known regarding the impact of HCP rescheduling on pharmacy practice. As new laws are passed to address the opioid epidemic in America, more research will be needed to determine whether legislation is an effective means for managing appropriate access to HCPs and other narcotic analgesics.

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An estimated 26%–34% of American adults experience chronic pain.<sup>1,2</sup> Accordingly, more than 119 million prescriptions for hydrocodone combination products (HCPs) were

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issued in 2014 in the United States.<sup>3,4</sup> The United Nations reported that the total global consumption of hydrocodone was 42.4 tons in 2010, with the United States accounting for more than 99% of this total.<sup>5</sup> In 2000, 27 hydrocodone prescriptions were filled per 100 Americans and by 2010, this increased to 40 per 100.<sup>6</sup> Illicit use of HCPs has also increased concomitantly with emergency department visits relating to nonmedical opioid use, which increased 183% between 2004 and 2011.<sup>7</sup> In light of rapidly increasing prescribing rates, incidence of opioid-treated chronic pain, and illegitimate use, the Drug Enforcement Administration (DEA) reclassified HCPs from DEA Schedule III to DEA Schedule II in October 2014 to better

**Key points****Background:**

- Due to concerns of misuse, the Drug Enforcement Agency (DEA) reclassified hydrocodone combination products (HCPs) as Schedule II medications in October 2014. After rescheduling, use of HCPs decreased by 22% in 2015.
- Rescheduling HCPs has unknown implications for both patients and pharmacists. Patients may be switched from HCPs to analgesics with lower potential for misuse, but higher potential for adverse effects. Community pharmacists may have increased workload due to these medication switches and due to increased documentation and inventory requirements associated with Schedule II medications.
- Understanding more about pharmacists' perceptions regarding HCP rescheduling may lead to the development of strategies to provide optimal patient care and to better workflow management.

**Findings:**

- Approximately 70% of pharmacists supported HCP rescheduling; however, their perceptions differed according to their level of support. Pharmacists who supported rescheduling had positive perceptions regarding the impact on patient health and safety. Those who opposed rescheduling perceived more challenges regarding revenue changes, inventory management, and drug shortages.
- Pharmacists perceived increased prescription volume with tramadol and acetaminophen with codeine products. Both of these medications have different adverse event and safety risk profiles not typically associated with HCPs. Over 50% of pharmacists reported that they assumed more workload due to inventory tasks related to HCP rescheduling.
- Although HCP rescheduling has impacted pharmacist workflow and management, it presents opportunities for pharmacists to engage patients regarding appropriate and effective pain management.

monitor and control misuse and illicit use of HCPs.<sup>8</sup> DEA rescheduling to lower numbers indicates higher levels of misuse. The aforementioned DEA ruling exerts tighter controls on HCP prescribing, and it prohibits HCP prescription refills.<sup>4</sup>

Since rescheduling, the number of hydrocodone prescriptions dispensed has decreased by 22%, with fewer than 94 million prescriptions dispensed in 2015.<sup>4</sup> Although data are unavailable for 2014 and 2015, 2010 and 2012 National Health Interview Survey data reflect that the prevalence of chronic pain has remained steady.<sup>9,10</sup> Thus, it is unlikely that the epidemiology of chronic pain changed accordingly within the DEA rescheduling time frame (i.e., 2014–2015). Furthermore, the Centers for Disease Control and Prevention (CDC) recently released new guidelines recommending increased caution when prescribing opioids in chronic pain.<sup>11</sup> A recent study of

Texas Poison Control Centers' analgesic-related calls after HCP rescheduling seems to support this theory.<sup>12</sup> While calls relating to hydrocodone exposure have decreased by 28% since rescheduling, calls related to other analgesic exposures increased significantly. In 2015 alone, calls related to codeine misuse increased by 443%, codeine adverse drug reactions increased by 176%, and calls related to tramadol increased by 6%. These changes may be due to either therapeutic substitution or increased illicit use of tramadol and acetaminophen with codeine.<sup>12</sup>

After HCP rescheduling, preliminary evidence seems to indicate that the prevalence of chronic pain has likely remained unchanged and that HCPs may be substituted with other scheduled analgesics.<sup>4,12,13</sup> Patients with chronic pain can be switched from their HCP to alternative medications with lower potential for misuse. These changes may result in additional workload for pharmacists because of rescheduling. Rescheduling a drug as widely prescribed as hydrocodone to DEA Schedule II is likely to have major implications for community pharmacy practice; however, this area has not been well researched. During the DEA comment period held before rescheduling, several pharmacists voiced concerns regarding inventory requirements and workload increases associated with rescheduling.<sup>8</sup> The DEA responded by stating that “the process and procedures associated with dispensing a controlled substance are not relevant factors to the determination of whether or not a substance should be controlled...”<sup>8</sup> In a small pilot study (n = 56) utilizing a 6-item survey instrument, Covey et al.<sup>14</sup> reported that pharmacists perceived that they spent more time dispensing HCPs.<sup>14</sup> While this information is valuable, a more detailed analysis is needed to examine further how HCP rescheduling has affected pharmacy practice so that pharmacists can develop practical strategies to manage their pharmacies effectively while still providing optimal patient care related to pain management. Therefore, the study objectives were (1) to assess Texas pharmacists' perceptions of the impact of HCP rescheduling on prescription volume and revenue, workflow management, and patient outcomes, and (2) to determine whether there are significant differences in perceptions between pharmacists who support versus those who oppose HCP rescheduling.

Of note, because this was a study of Texas pharmacists, some of the items included in the instrument were unique to Texas pharmacy practice. For instance, in 1981, the Texas State Board of Pharmacy required that all DEA Schedule II prescriptions be written on a 3-part, triplicate form.<sup>15</sup> This has since been replaced by a single, official prescription form; however, they are still referred to as *triplicates*. In addition, the Texas State Board of Pharmacy did not allow for the electronic prescribing of DEA Schedule II substances until October of 2013, which coincided with HCP rescheduling.<sup>16</sup>

**Methods***Study design and sample*

A cross-sectional survey design was used to address the study objectives. Pharmacists (n = 1000) who were practicing in Texas as of October 2015 were selected randomly to participate in the study from a publicly available list

**Table 1**  
Demographic and practice characteristics

Variable	Frequency (%)	Mean (SD)
Age (y)		47.2 (13.8)
Year in practice		20.1 (14.3)
Sex (n = 164)		
Female	85 (51.8)	
Male	79 (48.2)	
Race or ethnicity (n = 159)		
White/Non-Hispanic	108 (67.9)	
Asian/Pacific Islander	19 (11.9)	
African American	16 (10.1)	
Mexican American/Hispanic	14 (8.8)	
American Indian/Alaska native	2 (1.3)	
Degree attained (n = 163)		
BSPharm	89 (54.6)	
PharmD	70 (42.9)	
MSPharm/Residency	4 (2.5)	
Average daily prescription volume (n = 162)		
<200	32 (19.8)	
200–299	41 (25.3)	
300–399	41 (25.3)	
≥400	48 (29.6)	
Pharmacy practice setting (n = 164)		
Community independent	45 (27.4)	
Community chain	53 (32.3)	
Grocery store	31 (18.9)	
Mass merchandiser	24 (14.6)	
Outpatient clinic	11 (6.7)	
Job title (n = 164)		
Staff	79 (48.2)	
Manager	75 (45.7)	
Relief/PRN	10 (6.1)	
Employment status (n = 163)		
Full time	138 (84.7)	
Part time	25 (15.3)	
Hours worked per week		37.9 (9.7)
Practice location (n = 162)		
Suburban	63 (38.9)	
Urban	58 (35.6)	
Rural	41 (25.3)	
Proportion of total Medicaid prescription volume (n = 159)		
<25%	79 (49.7)	
25%–50%	58 (36.5)	
51%–75%	22 (13.8)	
Number of CE hours in identifying prescription drug abuse or addiction (n = 161)		
0	26 (16.1)	
1–3	54 (33.5)	
4–6	35 (21.7)	
7–9	15 (9.3)	
≥10	31 (19.3)	
Number of CE hours in identifying prescription drug diversion (n = 161)		
0	25 (15.5)	
1–3	54 (33.5)	
4–6	36 (22.4)	
7–9	14 (8.7)	
≥10	32 (19.9)	

CE, continuing education; PRN, as needed.

maintained by the Texas State Board of Pharmacy. Pharmacists were included in the sampling frame only if they indicated their primary place of employment as a Class A pharmacy,

which in Texas includes independent, community chain, mass merchandisers, grocery store chain, or ambulatory clinic pharmacies. Pharmacists were excluded if they were not actively practicing, their license was inactive or expired, or they no longer resided in Texas. The study was approved by the University of Texas Institutional Review Board.

### Survey instrument

A 53-item, anonymous survey instrument was created specifically for the study, as no instrument was available to address the study objectives. The questionnaire items were developed for a better understanding of which elements of patient care and practice were affected by pharmacists' overall perception of HCP rescheduling. Note that the survey items did not focus on specific HCPs, but on HCPs in general. Survey questions and subscales were developed after a thorough literature review and with expert input. Face validity was then assessed via feedback from independent survey methods and community pharmacist reviewers.

Pharmacists' overall perception of hydrocodone rescheduling was assessed with a single item using a 5-point Likert scale (1 = strongly oppose to 5 = strongly support): "What is your level of support/opposition regarding the recent DEA rescheduling of hydrocodone combination products from Schedule III to Schedule II?" All other variables were assessed with 5-point Likert scales using 2 types of anchors as appropriate (1 = significantly decreased to 5 = significantly increased or 1 = strongly disagree to 5 = strongly agree). The impact of HCP rescheduling on prescription volume and revenue was measured by the following total tramadol and codeine prescription volume and revenue. The impact of HCP rescheduling on workflow management was measured by the following: inventory management, drug shortages, and electronic prescribing. The impact of HCP rescheduling on patient outcomes was measured by the following: patient safety, adverse events, drug abuse, and legitimate use of HCPs.

In addition, the following demographic and practice information was obtained: sex, age, racial or ethnic background, level of pharmacy education, years in practice, primary practice setting (mass merchandiser, independent, grocery chain, community chain, outpatient clinic), average prescription volume, current position (manager, staff, relief), hours worked per week, practice location (rural, urban, suburban), and proportion of prescriptions billed to Texas Medicaid. Pharmacists were also asked how many hours of continuing education they had received in identifying patients with drug abuse and addiction and preventing drug abuse and diversion. The survey instrument is provided as a [Supplement](#).

### Data collection and analysis

A modified Dillman mail survey method was used.<sup>17</sup>

Early notice postcards were mailed 3 days before mailing the initial survey to the randomly selected participants. The postcards informed participants that they should expect to receive a questionnaire regarding their opinions of HCP rescheduling. The first author's email address was provided on the postcard if participants wished to opt out of future

**Table 2**  
Mean and frequencies of support or opposition of hydrocodone combination product rescheduling

Support or opposition of hydrocodone combination product rescheduling		Frequency distribution of response choices				
Item	Mean (SD)	Strongly oppose (1)	Oppose (2)	Not Sure (3)	Support (4)	Strongly support (5)
What is your level of support or opposition regarding the recent Drug Enforcement Agency rescheduling of hydrocodone combination products from Schedule III to Schedule II?	3.7 (1.3)	21 (13.0)	13 (8.0)	14 (8.6)	64 (39.5)	50 (30.9)

mailings. The postcard also indicated that there was no incentive for participation in the survey. The initial questionnaire was then mailed to participants with a 2-week completion date. After 3 weeks, a follow-up questionnaire (with the same contents as the initial survey mailing) was sent with an amended cover letter thanking those who had completed the survey and encouraging those who had not to participate in the study.

All survey responses were coded in Microsoft Excel in the order received. Descriptive statistics (frequencies, means, SDs) were performed for all variables. Reliability of multiple-item scales was assessed with Cronbach alpha, with a threshold of  $\geq 0.60$  because the survey items were newly created by the researchers.<sup>18</sup> Reliability of 2-item scales (adverse events, legitimate use) was assessed with Spearman rho correlation, where  $\rho \geq 0.5$  was used. Student *t* test was used to assess the relationship between HCP rescheduling support or opposition and all independent variables. For *t* test analyses, responses on pharmacists' perceptions on HCP rescheduling were dichotomized to support (4 = agree and 5 = strongly agree) or oppose (1 = strongly disagree to 3 = neutral). The *a priori* level of significance was set at  $P < 0.05$  for all *t* tests. Data was analyzed using SAS 9.4 for Windows.

## Results

### Response rate and demographics

Of 1000 surveys mailed, 32 were returned to sender; thus, 968 were assumed deliverable. Of the 166 surveys returned completed, 164 surveys were considered usable in the final sample. Two surveys were omitted: 1 complete survey was misprinted, and 1 survey was completed by a retired pharmacist. The final usable response rate was 17%. Table 1 provides a description of respondent demographic and practice characteristics. The average age of respondents was  $47.2 \pm 13.8$  (mean  $\pm$  SD) years, and the majority were female (51.8%), white (67.9%), and had a bachelor's of pharmacy degree (54.6%). Respondents primarily worked in community chain pharmacies (32.3%) as staff pharmacists (48.2%) or managers (45.7%) and reported an average daily prescription volume of 200–299 prescriptions (25.3%) or 300–399 prescriptions (25.3%). Most pharmacists reported that they were employed full time (84.7%), worked on average  $37.9 \pm 9.7$  hours per week, and had spent an average of  $20.1 \pm 14.3$  years in practice. Almost half (49.7%) reported that their total Medicaid prescription volume was less than 25%. More than half of the respondents had received 1–6 hours of continuing education regarding drug abuse or addiction (55.2%) and drug diversion (55.9%) over the course of their career.

### Pharmacist support and opposition of rescheduling

Overall, HCP rescheduling was supported by pharmacists, with 70.4% of respondents either supportive or strongly supportive of HCP rescheduling (Table 2). Tables 3–5 include descriptive statistics for each survey construct (ie, prescription volume and revenue, workflow management, patient outcomes), followed by *t* test comparisons of the HCP support or opposition and the relationship to pharmacists' regarding the aforementioned constructs.

### Pharmacist perceptions of changes in prescription volume and revenue following rescheduling

Table 3 shows results for prescription volume and revenue. While 56.5% of respondents reported that the total number of prescriptions filled had not changed since rescheduling, 82.0% and 85.8% reported that the number of tramadol and acetaminophen with codeine prescriptions filled, respectively, had either somewhat increased or significantly increased since rescheduling. A *t* test revealed there was no significant difference in mean changes in perceived prescription volume and support of HCP rescheduling. Cronbach alpha for this scale was 0.64.

Regarding changes in revenue, 53.4% of respondents neither agreed nor disagreed that their overall prescription revenue changed since rescheduling. Similarly, 53.4% of respondents neither agreed nor disagreed that their total prescription revenue had decreased significantly. Pharmacists who opposed HCP rescheduling were significantly more likely to agree regarding more changes in revenue since rescheduling than those who supported rescheduling ( $3.2 \pm 0.7$  vs.  $2.9 \pm 0.6$ ;  $P = 0.0142$ ). Cronbach alpha for this scale was 0.65.

### Pharmacist perceptions of changes in workflow management following rescheduling

Table 4 shows results for inventory management, drug shortages, and electronic prescribing. Regarding inventory management, 50.9% of respondents either somewhat disagreed or strongly disagreed that they found it difficult to manage their HCP inventory. However, 69.4% either agreed or strongly agreed that they have had to modify their HCP inventory storage procedures, and 56.4% either agreed or strongly agreed that they have had to assume inventory tasks previously delegated to pharmacy technicians. A *t* test analysis showed that pharmacists who opposed rescheduling were significantly more likely to agree with these statements than those opposed to rescheduling ( $3.7 \pm 0.8$  vs.  $3.2 \pm 0.9$ ;  $P = 0.0024$ ). Cronbach alpha for this scale was 0.67.

**Table 3**Means, frequencies, Cronbach alpha, and *t* test of support or opposition of HCP rescheduling and impact on prescription volume and revenue

Prescription volume		Frequency distribution of response choices, n (%)				
Items	Mean (SD)	Significantly decreased (1)	Somewhat decreased (2)	Not changed (3)	Somewhat increased (4)	Significantly increased (5)
The total number of prescriptions I fill in my pharmacy has _____.	3.1 (0.8)	3 (1.9)	25 (15.5)	91 (56.5)	36 (22.4)	6 (3.7)
The total number of prescriptions I fill for tramadol has _____.	4.1 (0.8)	2 (1.2)	4 (2.5)	23 (14.3)	82 (50.9)	50 (31.1)
The total number of prescriptions I fill for acetaminophen with codeine has _____.	4.3 (0.9)	4 (2.5)	4 (1.9)	16 (9.9)	50 (31.1)	88 (54.7)
	Mean (SD)	Cronbach alpha	Support HCP reschedule		<i>t</i> value	<i>P</i> value
			Yes	No		
Overall scale	3.9 (0.6)	0.64	3.8 (0.9)	3.8 (0.5)	0.0	0.99
Revenue		Frequency distribution of response choices, n (%)				
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
My total prescription revenue has changed as a direct result of the DEA rule change.	3.0 (0.9)	7 (4.4)	35 (21.7)	86 (53.4)	25 (15.5)	8 (5.0)
My total prescription revenue has significantly decreased as a direct result of the DEA rule change.	2.8 (0.8)	5 (3.1)	45 (28.0)	86 (53.4)	20 (12.4)	5 (3.1)
I am more afraid of theft in my pharmacy as a result of the DEA rule change.	3.0 (1.2)	14 (8.7)	55 (34.2)	33 (20.5)	40 (24.8)	19 (11.8)
As a result of the DEA rule change, a smaller proportion of my prescription revenue is generated by hydrocodone-combination products.	3.1 (1.0)	9 (5.6)	32 (20)	58 (36.3)	55 (34.4)	6 (3.8)
	Mean (SD)	Cronbach alpha	Support HCP reschedule		<i>t</i> value	<i>P</i> value
			Yes	No		
Overall scale	3.0 (0.7)	0.65	2.9 (0.6)	3.2 (0.7)	2.5	0.0142 <sup>a</sup>

Abbreviations used: HCP, hydrocodone combination product; DEA, Drug Enforcement Agency.

<sup>a</sup> Indicates significance at *P* < 0.05.

**Table 4**Means, frequencies, Cronbach alpha, and *t* test of support or opposition of HCP rescheduling and impact on workflow management

Inventory management		Frequency distribution of response choices, n (%)				
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
I find it difficult to manage my HCP inventory.	2.7 (1.1)	21 (12.9)	62 (38.0)	45 (27.6)	22 (13.5)	13 (8.0)
I have had to modify the way in which I store my controlled drugs in order to accommodate HCPs.	3.8 (1.1)	6 (3.7)	19 (11.7)	25 (15.3)	57 (35.0)	56 (34.4)
I have had to assume inventory tasks previously delegated to pharmacy technicians.	3.6 (1.1)	6 (3.7)	26 (16.0)	39 (23.9)	53 (32.5)	39 (23.9)
	Mean (SD)	Cronbach alpha	Support HCP reschedule		<i>t</i> value	<i>P</i> value
			Yes	No		
Overall scale	3.4 (0.9)	0.67	3.2 (0.9)	3.7 (0.8)	3.1	0.0024 <sup>a</sup>
Drug shortages		Frequency distribution of response choices, n (%)				
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
It is more difficult for my pharmacy to obtain HCPs.	3.1 (1.1)	12 (7.4)	36 (22.1)	53 (32.5)	45 (27.6)	17 (10.4)
I have noticed more prescription drug shortages of pain management drugs than ever (e.g., tramadol, hydromorphone, acetaminophen with codeine, morphine)	3.2 (1.1)	11 (6.8)	31 (19)	46 (28.2)	60 (37)	15 (9.2)
Prescription drug shortages have made my interactions with prescribers more challenging.	3.2 (1.0)	10 (6.2)	30 (18.5)	58 (35.8)	51 (31.5)	13 (8.0)
My patients become frustrated when prescription pain management medication shortages occur.	4.1 (0.8)	1 (0.6)	4 (2.5)	22 (13.7)	90 (55.9)	44 (27.3)
	Mean (SD)	Cronbach alpha	Support HCP reschedule		<i>t</i> value	<i>P</i> value
			Yes	No		
Overall scale	3.4 (0.7)	0.69	3.3 (0.7)	3.7 (0.7)	3.6	0.0005 <sup>a</sup>



Electronic prescribing	Frequency distribution of response choices, n (%)					
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
My pharmacy is prepared to receive electronic prescriptions for controlled drugs.	4.4 (0.9)	5 (3.1)	6 (3.7)	3 (1.9)	55 (34.0)	93 (57.4)
I have received several electronic prescriptions for HCPs.	4.0 (1.2)	10 (6.2)	13 (8.0)	11 (6.8)	59 (36.4)	69 (42.6)
Electronic prescriptions for controlled drugs make it easier to fill and dispense HCPs.	3.7 (1.2)	13 (8.0)	10 (6.2)	38 (23.5)	57 (35.2)	44 (27.2)
Prescribers are generally aware of how to prescribe HCPs electronically.	2.9 (1.2)	21 (13.0)	50 (30.9)	32 (19.8)	48 (29.6)	11 (6.8)
My pharmacy has a protocol in place for when we cannot dispense an HCP that was called in electronically.	3.3 (1.2)	18 (11.1)	27 (16.7)	31 (19.1)	60 (37.0)	26 (16.1)
	Mean (SD)	Cronbach alpha	Support HCP reschedule		t value	P value
			Yes	No		
Overall scale	3.6 (0.7)	0.7	3.7 (0.7)	3.4 (0.7)	-2.6	0.0115 <sup>a</sup>

Abbreviations used: HCP, hydrocodone combination product.  
<sup>a</sup> Indicates significance at  $P < 0.05$ .

Regarding drug shortages, 38% of pharmacists either agreed or strongly agreed that they now find it more difficult to obtain HCPs; 46.2% either agreed or strongly agreed that they have noticed more shortages of other pain management medications (i.e., tramadol, hydromorphone, acetaminophen with codeine, morphine). The majority of pharmacists (83.2%) either agreed or strongly agreed that their patients became frustrated with these medication shortages. A  $t$  test revealed that pharmacists who opposed rescheduling were significantly more likely to agree with these statements than were those who supported rescheduling ( $3.7 \pm 0.7$  vs.  $3.3 \pm 0.7$ ;  $P = 0.0005$ ). Cronbach alpha for this scale was 0.69.

Regarding electronic prescribing, 91.4% of respondents either agreed or strongly agreed that they are prepared to receive electronic prescriptions for controlled substances, and 79.0% either agreed or strongly agreed that they had received prescriptions for HCPs electronically. More than 60% (62.4%) either agreed or strongly agreed that electronic prescribing makes it easier to fill and dispense HCPs; however, 43.9% either disagreed or strongly disagreed that prescribers are well aware of how to prescribe HCPs electronically. Approximately half (53.1%) of the respondents either agreed or strongly agreed that they had a protocol in place for occasions when an electronic HCP prescription could not be dispensed. Those who supported HCP rescheduling were significantly more likely to agree with the earlier statements than were those who opposed rescheduling ( $3.7 \pm 0.7$  vs.  $3.4 \pm 0.7$ ;  $P = 0.0115$ ). Cronbach alpha for this scale was 0.70.

#### Pharmacist perceptions of patient health and safety outcomes following rescheduling

Table 5 shows results for patient safety, adverse events, drug abuse, and legitimate use. Overall, 65.3% of pharmacists either agreed or strongly agreed that rescheduling was in the best interest of their patients' safety. More than 60 percent (61.5%) of respondents either agreed or strongly agreed that it was in the best interest of their patients' health, and 42.9% either agreed or strongly agreed that rescheduling was beneficial to their patients' pain management therapy. Pharmacists who supported rescheduling were significantly more likely to agree with these statements than were those opposed to rescheduling ( $3.8 \pm 0.9$  vs.  $2.4 \pm 1.0$ ). Cronbach alpha for this scale was 0.91.

Regarding adverse events, 46.3% of pharmacists neither agreed nor disagreed that they have noticed more patients suffering from opioid withdrawal following rescheduling, whereas 47.9% either disagreed or strongly disagreed that they have noticed more patients with adverse effects of pain management drugs following rescheduling. The  $t$  test did not reveal a significant difference between those who supported and those who opposed HCP rescheduling. Spearman's rho for this scale was 0.59 and significant ( $P < 0.0001$ ).

When respondents were asked their perceptions about drug abuse, 62.3% of respondents either agreed or strongly agreed that rescheduling would help to limit abuse of HCPs. Approximately 39% of respondents (38.7%) either disagreed or strongly disagreed that triplicate prescribing is the best way to limit prescription drug abuse, whereas 44.8% either agreed or strongly agreed that it is the best way to decrease trafficking of HCPs. A  $t$  test revealed that pharmacists who supported HCP

**Table 5**Means, frequencies, Cronbach alpha, and *t* test of support or opposition of HCP rescheduling and impact on patient outcomes

Patient safety		Frequency distribution of response choices, n (%)				
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
The DEA rule change is in the best interest of my patients' safety.	3.6 (1.2)	15 (9.3)	17 (10.6)	24 (14.9)	74 (46.0)	31 (19.3)
The DEA rule change is in the best interest of my patients' health.	3.5 (1.2)	14 (8.7)	27 (16.8)	21 (13.0)	70 (43.5)	29 (18.0)
The DEA rule change is beneficial to my patients' pain management therapy.	3.1 (1.2)	21 (13.0)	35 (21.7)	36 (22.4)	50 (31.1)	19 (11.8)
		Mean (SD)	Cronbach alpha	Support HCP reschedule		<i>t</i> value
				Yes	No	<i>P</i> value
Overall scale	3.4 (1.2)	0.91		3.8 (0.9)	2.4 (1.0)	−8.8 <0.001 <sup>a</sup>
Adverse events		Frequency distribution of response choices, n (%)				
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
I have noticed more patients struggling with opiate withdrawal following the DEA rule change.	2.5 (0.9)	18 (11.1)	56 (34.6)	75 (46.3)	9 (5.6)	4 (2.5)
I have encountered more patients with side effects of pain management drugs following the DEA rule change (e.g., constipation, nausea and vomiting, rash).	2.5 (0.9)	20 (12.3)	58 (35.6)	70 (43.0)	12 (7.4)	3 (1.8)
		Mean (SD)	Spearman rho	Support HCP reschedule		<i>t</i> value
				Yes	No	<i>P</i> value
Overall scale	2.5 (0.7)	0.59		2.5 (0.7)	2.6 (0.8)	1.29 0.2000
Drug abuse		Frequency distribution of response choices, n (%)				
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
The DEA rule change will help limit abuse of HCPs.	3.4 (1.4)	25 (15.4)	18 (11.1)	18 (11.1)	64 (39.5)	37 (22.8)
Triplicate prescribing <sup>b</sup> is the best way to decrease prescription drug abuse.	2.9 (1.2)	20 (12.3)	43 (26.4)	41 (25.2)	44 (27.0)	15 (9.2)
Triplicate prescribing is the best way to decrease trafficking of HCPs.	3.1 (1.2)	20 (12.3)	41 (25.2)	29 (17.8)	57 (35.0)	16 (9.8)
		Mean (SD)	Cronbach alpha	Support HCP reschedule		<i>t</i> value
				Yes	No	<i>P</i> value
Overall scale	3.1 (1.1)	0.83		3.4 (1.0)	2.5 (1.0)	−5.6 <0.0001 <sup>a</sup>



Frequency distribution of response choices, n (%)						
Items	Mean (SD)	Strongly disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
The DEA rule change will help decrease illegitimate use of HCPs.	3.2 (1.3)	26 (16.1)	22 (13.6)	24 (14.8)	67 (41.4)	23 (14.2)
If a patient is not abusing HCPs, then the DEA rule changes makes obtaining a prescription for legitimate use easier.	2.4 (1.0)	33 (20.3)	67 (41.1)	41 (25.2)	15 (9.2)	7 (4.3)
	Mean (SD)	Spearman's rho		Support HCP reschedule		P value
				Yes	No	
Overall scale	2.8 (1.0)	0.60	3.1 (0.9)	2.1 (0.9)	−6.4	<0.0001 <sup>a</sup>

Abbreviations used: DEA, Drug Enforcement Agency; HCP, hydrocodone combination product.

<sup>a</sup> Indicates significance at  $P < 0.05$ .

<sup>b</sup> Triplicate prescribing is used to prevent drug abuse. Three copies of the prescription are maintained by the physician, pharmacist, and state agency (e.g., state board of pharmacy).

rescheduling were significantly more likely to agree with the above statements than those who opposed ( $3.4 \pm 1.0$  vs.  $2.5 \pm 1.0$ ;  $P < 0.0001$ ). Cronbach alpha for this scale was 0.83.

Finally, when asked about legitimate use, 55.6% of pharmacists either agreed or strongly agreed that rescheduling will help to decrease illegitimate use of HCPs, and 61.4% either disagreed or strongly disagreed that rescheduling makes obtaining a prescription for legitimate use easier. A  $t$  test revealed that pharmacists who supported rescheduling were significantly more likely to agree with these statements than were those who opposed rescheduling ( $3.1 \pm 0.9$  vs.  $2.1 \pm 0.9$ ;  $P < 0.0001$ ). Spearman rho for this scale was 0.60 and was significant ( $P < 0.0001$ ).

A chi-square test was used to assess nonresponse bias by comparing the first 30 and last 30 responders. This strategy was chosen because the survey was anonymous. There was a significant difference in support and opposition for HCP rescheduling ( $P = 0.0004$ ). A higher proportion of the first 30 respondents was in support of the legislation compared with the last 30 respondents (89.7% vs. 46.7%, respectively). Further analysis revealed that a significantly ( $P < 0.05$ ) higher proportion of the first 30 respondents were used by mass merchandiser, grocery store chain, or community chain pharmacies compared with those used by independent pharmacies. In addition, a significantly higher proportion of the first 30 respondents filled between 300 and 400 prescriptions per day, whereas the last 30 respondents were more likely to fill fewer than 200 prescriptions per day.

## Discussion

This work sought to identify community pharmacists' perceptions of HCP rescheduling and how it has affected their practice. The majority of pharmacists (70.4%) either supported or strongly supported hydrocodone rescheduling. Pharmacists who opposed rescheduling were more likely to report negative perceptions regarding revenue, inventory management, and drug shortages than were those who supported rescheduling. However, pharmacists who supported rescheduling had perceptions about electronic prescribing that were more positive, and they were likely to have more positive perceptions regarding patient safety, drug abuse, and legitimate use. Despite their opinions of rescheduling HCPs, respondents agreed that acetaminophen with codeine and tramadol prescription volumes have increased since rescheduling. This finding is consistent with extant literature.<sup>12,19</sup>

Although there is no literature to compare HCP rescheduling, policy concerning pseudoephedrine dispensing provides a close parallel.<sup>20,21</sup> Historically, pharmacists have supported legislation that restricts access to substances with high misuse potential, with 56.2% of Kentucky pharmacists supporting a proposed 2012 legislation to classify pseudoephedrine as a legend drug.<sup>21</sup> Similar to the findings presented in the current study, pharmacists in the Kentucky study who opposed the proposed legislation perceived that classifying pseudoephedrine as a legend drug would increase their workload.<sup>21</sup> One study that examined the effects of pharmacist workload on patient safety demonstrated that overworked pharmacists were more likely to dispense medications that have potentially dangerous drug interactions.<sup>22</sup>

In the current study, more than half of all respondents (56.4%) reported that since rescheduling, they have assumed inventory tasks previously delegated to pharmacy technicians. More than 80% (89%) of American pharmacists cite a lack of additional staffing as a barrier to provision of medication therapy management services.<sup>23</sup> Further tasking their time and human resources with additional inventory tasks related to HCP rescheduling may limit pharmacists' ability to provide direct patient care services. The current study did not assess how rescheduling has affected individual pharmacy services; however, future work should focus on quantifying how similar increases in workload affect the ability of pharmacists to provide patient-centered care.

To date, no known evidence exists to quantify the effect of HCP rescheduling on patient health and safety. This study focused on pharmacists' perceptions, and it showed that pharmacists in support of and those in opposition to the rule change have differing opinions regarding whether HCP rescheduling is in the best interest of patient health and safety. This issue warrants further research. Although the survey items were general (i.e., only included the terms *health* and *safety*), 1 aspect of this could be related to therapeutic conversion from HCPs to tramadol and codeine combination products.<sup>10,24,25</sup> A majority of survey respondents either agreed or strongly agreed that the volume of tramadol and acetaminophen with codeine increased since rescheduling. However, pharmacists primarily disagreed that they encountered problems with withdrawal and adverse effects among patients.

Nevertheless, increased therapeutic substitution and transition to opioid-sparing pain management regimens introduces agents with different adverse event profiles and safety risks that are not typically associated with opioid analgesic therapy.<sup>12,24,25</sup> The Texas Poison Control Study, described earlier, provides a direct example of how therapeutic substitution with tramadol and acetaminophen with codeine can lead to an increase iatrogenic toxicity.<sup>12</sup> This example provides pharmacists the opportunity to counsel patients and other providers about the selection and provision of safe and effective opioid-sparing therapy.

A majority of respondents (61.4%) either agreed or strongly agreed that rescheduling makes it more difficult for legitimate users of HCPs to obtain a prescription. However, respondents who supported rescheduling were more likely to perceive that HCP rescheduling facilitated legitimate use than were those who opposed rescheduling. Several professional organizations, including the American Pharmacists Association, are concerned that rescheduling will hinder legitimate use of HCPs.<sup>26</sup> Although estimates differ regarding opioid use disorders, 1 study showed that among outpatients who were prescribed at least 4 opioid prescriptions annually, 25.8% had current opioid dependence and 35.5% had lifetime opioid dependence.<sup>27</sup> Although it appears that the majority of patients are legitimate users, one-fourth to one-third may be at risk for opioid misuse.

Of all opioid misusers, however, data from the 2013 National Survey on Drug Use and Health revealed that 23.7% of users obtain their opioids from a physician source.<sup>28</sup> Although these findings demonstrate that a significant number of misusers obtain their opioids through physician prescribing, a majority do not. Prescribers must remember to exercise

caution when initiating opioid therapy without imposing undue barriers on legitimate users. This balance is difficult to meet; however, new guidance from the CDC suggests that limited and incremental prescribing may help to reduce opioid misuse while still allowing for efficacious opioid therapy.<sup>11</sup> Pharmacists can also help to ensure judicious use by using prescription drug monitoring programs where available and being attentive to signs of misuse, such as early refill requests and prescriptions from multiple physicians, and by identifying patients receiving more than 120 mg of total morphine equivalents daily. Pharmacists should approach opioid prescriptions with a reasonable amount of skepticism, in the absence of evidence-based signs of misuse or suspicious PDM activity, but the focus should be on actively participating in pain management care and ensuring safe and efficacious opioid therapy. Lembke et al.<sup>29</sup> suggest that if opioid misuse is detected, rather than immediately discontinuing treatment, providers should include it as part of the problem list and work toward effective treatment strategies, such as buprenorphine and naloxone for opioid misuse and overdose, respectively.<sup>29</sup> In addition to opioid misuse disorders such as addiction, dependence, tolerance, opioid-induced hyperalgesia, additional risks for long-term opioid use include cardiovascular events, constipation, depression, and hormone dysregulation. Lembke et al.<sup>29</sup> identify strategies for addressing these issues, including talking points to communicate these issues better with patients.<sup>29</sup>

Finding a balance between supporting legitimate use and preventing misuse and diversion presents a difficult challenge for health care professionals and policy-makers.<sup>30,31</sup> Given these concerns, it is necessary to determine whether rescheduling disproportionately hinders legitimate users rather than preventing opioid misuse and diversion. However, the study results show disagreement among those who support versus oppose the legislation, which represents a need to determine whether HCP rescheduling presents significant barriers to patients who need narcotic analgesics to maintain their quality of life. This need was recently addressed when the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 became law.<sup>32</sup> This law is unique in that rather than just seeking to end misuse and diversion directly, it aims to monitor and protect controlled drug supply distribution to decrease diversion and misuse. The law seeks to identify and decrease barriers to appropriate medication use. Research is needed to determine how HCP rescheduling has affected pharmacy practice, patient outcomes, and patient access to HCPs and other analgesics. Research from the present study, although primarily descriptive and subjective in nature, may be beneficial in initiating a dialogue for future studies focused on identifying strategies to deter opioid misuse while promoting positive opioid analgesic outcomes. Pharmacists can play a significant role in helping patients with legitimate need for HCPs to better understand the new rules, in helping them overcome barriers to accessing needed medications, and in helping to provide safe and effective pain management therapy. Furthermore, pain management and misuse and diversion control present opportunities for pharmacy practice expansion and the provision of patient-centered care.

## Limitations

The results of this study are limited, primarily, by a low response rate of 17%. Despite the low response rate, participant demographics in this sample were comparable to data from the 2014 National Pharmacist Workforce Survey<sup>33</sup> and to a 2008 Texas pharmacist study.<sup>34</sup> In addition, given that this was a newly developed survey instrument, scales were assessed for reliability with a lower alpha value cutoff of 0.60<sup>18</sup> compared with the preferred 0.70. However, Cronbach alphas ranged from 0.64 to 0.91. Results of the nonresponse bias may indicate that pharmacists who worked in larger stores may have been more supportive of the legislation and responded more quickly than did independent pharmacists and those who were more opposed to the legislation. Although these post hoc nonresponse bias results were significantly different, this bias may be mitigated in light of the aforementioned similarities in demographic and practice characteristics. However, the reader should still interpret these results in relation to the reported bias.

Another limitation relates to the validity of the survey responses. It is possible that pharmacists who work for large chains and those who work as staff or relief pharmacists may not have been familiar with their pharmacy's revenue data. In fact, only 27.4% of respondents reported an independent pharmacy as their place of employment, and only 45.7% reported that they were employed as pharmacy managers. Thus, the validity of revenue perceptions should be interpreted with caution. Pharmacists indicate that they did not encounter adverse events post HCP rescheduling (i.e., opioid withdrawal, side effects) to a large degree. Either the prevalence was low, or it is possible that patients may have reported opioid adverse events to the prescribing physician, a poison control center, or an emergency department rather than the pharmacist. This was a cross-sectional study and our findings are not causal; however, they provide a snapshot of pharmacist perceptions of the impact of rescheduling on pharmacy practice. Additional studies are needed to quantify long-term effects of rescheduling HCPs.

## Conclusion

Although most pharmacists supported the DEA's decision to reschedule HCPs, the rule still presents some challenges to pharmacy practice. Pharmacists who support hydrocodone rescheduling are more likely to believe that rescheduling is in the best interest of patient health and safety, whereas those in opposition are more likely to perceive that rescheduling introduces disproportionate workflow challenges. Considering new and necessary restrictions on opioid prescribing, research is needed to determine how these changes affect patient outcomes and pharmacy practice. As additional opioid guidance emerges from organizations such as the Centers for Disease Control and Prevention, researchers have an opportunity to further assess the impact that the new policy has on practice and on management of patients with chronic pain.

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## Supplementary Data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.japh.2017.01.020>.

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