Iowa Department of Public Health
Promoting and Protecting the Health of Iowans

Gerd W. Clabaugh, MPA
Director

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

February 12, 2016

Christopher A. Hart
Chairman
NTSB
Washington, DC 20594

Sent via email to: correspondence@NTSB.gov

Dear Chairman Hart:

Governor Branstad has asked me, as Director of the Iowa Department of Public Health, to respond to your letter to him, dated November 12, 2015, requesting information regarding the State of Iowa's response to NTSB Safety Recommendations I-14-1 and I-14-2, relating to the prescribing of controlled substances by Iowa licensed healthcare providers, and recommendations from NTSB regarding healthcare provider communication to patients who also operate vehicles while on these medications. The recommendations emanate from a study *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*.

Attached to this cover memorandum you will find more detailed information from the Directors of the following licensing boards in Iowa: Medicine, Nursing, Dental, Pharmacy, Physicians Assistants, and Podiatry. Each provides an overview of their individual activities relating to the adoption of guidelines and efforts to communicate with licensed practitioners regarding the topics outlined in the *Drug Use Trends* study.

Thank you for the opportunity to supply information to you regarding our work on this important topic. Please feel free to contact me with any questions.

Sincerely,

Gerd W. Clabaugh
Director
Iowa Department of Public Health

Cc: The Honorable Terry E. Branstad, Governor of Iowa
Doug Hoelscher, Director, Iowa Office of Federal and State Relations
Mark Bowden, Executive Director, Iowa Board of Medicine
Kathleen Weinberg, Executive Director, Iowa Board of Nursing
Jill Stuecker, Executive Director, Iowa Board of Dentistry
Andrew Funk, Executive Director, Iowa Board of Pharmacy
Sarah Reisetter, Administrator, Bureau of Professional Licensure, Iowa Department of Public Health
Tim McClung, Iowa Department of Transportation
Patrick Hoye, Iowa Department of Public Safety

Fields of Opportunities

STATE OF IOWA

TERRY BRANSTAD, GOVERNOR
KIM REYNOLDS, LT. GOVERNOR

IOWA BOARD OF MEDICINE
MARK BOWDEN, EXECUTIVE DIRECTOR

December 16, 2015

TO: Gerd Clabaugh, Iowa Department of Public Health
FR: Mark Bowden, Iowa Board of Medicine
RE: Board of Medicine's response to NTSB safety recommendation, 1-14-1 and 2

The following is a summary of the Board of Medicine's response to the National Transportation Safety Board's safety recommendation, 1-14-1 and 2, dated September 23, 2014, and received September 27, 2014:

September 27, 2014 – Board received notification from NTSB regarding recommendations from the safety study, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment."*

October 3, 2014 – Board initiated rulemaking to require physicians to discuss with patients the effects their medical conditions and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

October 28, 2014 – Proposed rule, **ARC1708C**, was published in the Iowa Administrative Bulletin. **(attached)**

November 18, 2014,noon – Proposed rule, **ARC1708C,** reviewed by the legislative Administrative Rules Review Committee.

November 18, 2014, 1 p.m. – Board of Medicine's public hearing on proposed rule, **ARC1708C**. The proposed rule received several comments from physicians and healthcare organizations who said a mandated requirement was not necessary as it is standard practice for physicians and pharmacists to have conversations with patients about the effects of any prescribed medications, including pain medications. **(attached)**

December 5, 2014 – Board of Medicine determined to discontinue the rulemaking process for **ARC1708C,** but directed Board staff to issue a press release to draw attention to the NTSB study that identified potential risks that prescription medications and a patient's medical condition can create when a patient operates a motor vehicle in any mode of transportation.

December 16, 2014 – Board of Medicine issued a press release drawing attention to the NTSB study that identified potential risks that prescription medications and a patient's medical condition can create when a patient operates a motor vehicle in any mode of transportation. This press release is indexed on the Board's website and is included with mailings to new licensees. **(attached)**

ARC 1708C

MEDICINE BOARD[653]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 147.76 and 272C.2, the Board of Medicine hereby proposes to amend Chapter 13, "Standards of Practice and Principles of Medical Ethics," Iowa Administrative Code.

The purpose of Chapter 13 is to establish standards of medical practice for medical physicians and osteopathic physicians. The proposed amendments address a National Transportation Safety Board recommendation that states adopt guidance for physicians to discuss with patients the effects that patients' medical conditions and the medication they use may have on their ability to safely operate a vehicle in any mode of transportation.

The Board approved this Notice of Intended Action during a regularly scheduled meeting on October 3, 2014.

Any interested person may present written comments on the proposed amendments not later than 4:30 p.m. on November 18, 2014. Such written materials should be sent to Mark Bowden, Executive Director, Board of Medicine, 400 S.W. Eighth Street, Suite C, Des Moines, Iowa 50309-4686; or sent by e-mail to mark.bowden@iowa.gov.

There will be a public hearing on November 18, 2014, at 1 p.m. at the Board of Medicine, 400 S.W. Eighth Street, Suite C, Des Moines, Iowa, at which time persons may present their views either orally or in writing.

After analysis and review of this rule making, no adverse impact on jobs has been found.

These amendments are intended to implement Iowa Code chapters 147, 148 and 272C.

The following amendments are proposed.

ITEM 1. Renumber subrule **13.2(8)** as **13.2(9)**.

ITEM 2. Adopt the following **new** subrule 13.2(8):

13.2(8) *Ability to safely operate a vehicle.* Physicians who prescribe controlled substances for pain management shall discuss with patients the effects their medical conditions and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

Fields of Opportunities

STATE OF IOWA

TERRY BRANSTAD, GOVERNOR
KIM REYNOLDS, LT. GOVERNOR

IOWA BOARD OF MEDICINE
MARK BOWDEN, EXECUTIVE DIRECTOR

FOR IMMEDIATE RELEASE: November 14, 2014
CONTACT: Mark Bowden, (515) 242-3268 or
Mark.bowden@iowa.gov

Public hearing is 1 p.m. Tuesday, Nov. 18, on new rule about effects of pain medications

DES MOINES, IA – The Iowa Board of Medicine will hold a public hearing at 1 p.m. Tuesday, November 18, 2014, to receive comments on a proposed amendment to 653 Iowa Administrative Code Chapter 13.10 to establish a rule to require physicians to discuss with their patients the effect of pain medications.

The Board approved a notice of intended action to amend Chapter 13.10 on October 3, 2014. The proposed amendment addresses a National Transportation Safety Board recommendation that states adopt guidance for physicians to discuss with patients the effects that patients' medical conditions and the medications they use may have on their ability to safely operate a vehicle in any mode of transportation.

The hearing will be held at the Board's office, 400 SW Eighth Street, Suite C, Des Moines. The public can also submit written comments on the proposed amendment not later than 4:30 p.m. November 18. Written comments should be sent to Mark Bowden, Executive Director, Iowa Board of Medicine, 400 SW Eighth Street, Suite C, Des Moines, Iowa 50309-4683 or sent by e-mail to ibm@iowa.gov

The proposed rule was published as **ARC 1708C** in the October 28, 2014, Iowa Administrative Bulletin. The proposed rule can be read here.

Mr. Mark Bowden
Executive Director
Board of Medicine
mark.bowden@iowa.gov

November 18, 2014

Dear Mr. Bowden,

UnityPoint Health operates in the states of Iowa, Illinois and Wisconsin, with over 30,000 employees including more than 900 doctors and specialists. Our team of professionals communicates with our patients to clearly and effectively address the patients' health care in the most appropriate setting: whether that is a clinic, a hospital or at home. We are constantly looking for ways to improve the way health care is delivered. We describe our professional culture as "physician-led" always from the perspective of the best interests of the patient.

With that in mind, UnityPoint Health submits the following comments in regard to the Notice of Intended Action, ARC 1708C. UnityPoint Health believes the rules are unnecessary, too prescriptive and could expose our physicians to potential liability.

Pharmacists must comply with extensive protocols when dispensing pain medication. The pharmacist is already counseling the patient on the potential impact of the medication and how use of the medication may affect the patient's ability to safely operate a vehicle. The pharmacist who is physically handing the patient the pain medication is in the best position to counsel the patient. The proposed rule adds another layer of bureaucracy, without measurably adding to patient safety. Requiring the physician to also counsel the patient is unnecessary.

The proposed rule enters into the physician/patient relationship and is unnecessarily prescriptive from the physicians' perspective. The rule would appear to create exposure to liability on the part of a physician who may fail to document that a discussion was had in regard to safe operation of a vehicle.

UnityPoint Health urges the Board of Medicine to withdraw this rule from further consideration based upon the fact that this type of patient education is already taking place under existing rules governing pain management and existing pharmacy protocols.

Respectfully Submitted,
Julie Smith
UnityPoint Health

POLK COUNTY MEDICAL SOCIETY

1520 HIGH STREET • DES MOINES, IOWA 50309-3110 • (515) 288-0172 • FAX (515) 288-0173
website: http://www.pcms.org • email: pcms@pcms.org

KATHIE J. LYMAN
Executive Director

November 5, 2014

Mark Bowden, Executive Director
Iowa Board of Medicine
400 SW Eight Street, Suite C
Des Moines, IA 50309-4686

Director Bowden:

On Behalf of the Polk County Medical Society, we are opposed to the Board of Medicine's noticed rule, ARC 1708C, adding a new subrule, 13.2(8) – *Ability to Safely Operate a Vehicle.*

The Polk County Medical Society (PCMS) is the oldest continuously operating medical society in the state of Iowa, representing more than 1242 physicians and their patients since 1851. Members are local physicians and residents dedicated to serving Des Moines area patients in medical care. Throughout the changes that have taken place in medicine, PCMS has remained a leader at the local, state and national levels. Our Physicians represent thousands of patients, their staff and families. A primary purpose of the Polk County Medical Society is to promote the science and art of medicine and the betterment of public health.

We believe the noticed rule, ARC 1708C, is not a workable or enforceable regulation. If a regulation cannot be uniformly and consistently enforced, our view is that it is not a viable standard of care and by definition will not improve public health.

Secondly, counseling and warnings to patients about the effects of pain medications already exist at many stages of care including at the point of purchase. We believe the rule is unnecessary as written due to these practices, especially when a patient receives guidance at the point of purchase before they take their pain medication.

For these reasons, the Polk County Medical Society respectfully opposes the Board of Medicine's noticed rule, ARC 1708C. We request that the rule not proceed any further in the rulemaking process.

Sincerely,

Philip Colletier, M.D.
President
Polk County Medical Society

Craig Mahoney, M.D.
Chair, Legislative Committee
Polk County Medical Society

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IMS
IOWA MEDICAL SOCIETY

November 17, 2014

Mark Bowden, Executive Director
Iowa Board of Medicine
400 SW Eighth Street, Suite C
Des Moines, IA 50309
mark.bowden@iowa.gov

Re: Proposed Rule ARC 1708C – Pain Medications and Vehicle Operation

Dear Director Bowden:

On behalf of the 6,400 physician and student members of the Iowa Medical Society (IMS), thank you for this opportunity to provide comment on the above-stated proposed rule of the Iowa Board of Medicine (IBM): While IMS understands the underlying intent of the proposed rulemaking, we oppose **ARC 1708** on the grounds that incorporating such a mandate in rule is an intrusion into the physician-patient relationship and is unnecessarily redundant given current practice.

Iowa physicians consistently deliver high quality medical care. Efforts to codify standards of care in statute or administrative rule are an intrusion into medical practice, and threaten quality care by failing to account for the unique healthcare needs of each patient. In recent years, the IBM has adopted numerous, burdensome pain management rules. The addition of this proposed rule would add another burden on Iowa prescribers and result in little added public benefit.

IMS questions the value of this proposed rule. It is current practice for physicians and pharmacists to have conversations with patients regarding the effects of any prescribed medications, including pain medications. Patients are warned if their medical conditions or prescribed medications might interfere with their ability to operate a motor vehicle. In addition, prescription packaging clearly contains warnings when a medication necessitates special precautions like not operating a motor vehicle. Mandating in rule that a prescribing physician have such conversations is unnecessarily duplicative of current practice and would expose Iowa physicians to additional, unnecessary liability.

The Iowa Medical Society urges the IBM to fully weigh the implications of **ARC 1708** and to not adopt this rule. Thank you again for the opportunity to offer comment and for your consideration.

Sincerely,

Clare Kelly

Clare M. Kelly
Executive Vice President

Iowa Osteopathic Medical Association
IOMA
950 - 12th Street • Des Moines, Iowa 50309
(515) 283-0002 • Fax (515) 283-0355
leah@ioma.org • www.ioma.org

November 17, 2014

Mark Bowden, MPA
Executive Director
Iowa Board of Medicine
400 S.W. 8th Street, Suite C
Des Moines, IA 50309-4686

Dear Mr. Bowden:

Subject: Comments on proposed amendment to IAC 653–13.2(8)

The Board cites a National Transportation Safety Board (NTSB) recommendation that states adopt **guidance** (emphasis added) for physicians to discuss with patients the effects that patients' medical conditions and the medication they use may have on their ability to safely operate a vehicle in any mode of transportation, as the rationale for the proposed rule.

The Board does not need to promulgate a rule, especially one that sets a standard of care, to provide "guidance" to physicians. There are multiple alternative methods the Board could use to accomplish the intended goal of the NTSB advisory. The Board could place the information on its website, provide the information to physicians at the time of license renewal, and/or provide the information to medical societies to forward to their members in their newsletters and include in their educational seminars.

The Iowa Osteopathic Medical Association stands ready to assist the Board in disseminating this information to physicians. Placing this requirement in rule will further discourage physicians from treating patients in pain. The Board may recall that in the past, rulemaking by the Board so dampened analgesic prescribing that the Board had to adopt rules stating that it is a violation of the standard of care to not address a patient's pain (653—13.2 preamble paragraphs 5 and 6). IOMA urges the Board to reconsider the need for this rule and seek alternative methods of providing this information to physicians.

Sincerely,

Leah McWilliams

Leah J. McWilliams, CAE
Executive Director

Fields of Opportunities

STATE OF IOWA

TERRY BRANSTAD, GOVERNOR
KIM REYNOLDS, LT. GOVERNOR

IOWA BOARD OF MEDICINE
MARK BOWDEN, EXECUTIVE DIRECTOR

FOR IMMEDIATE RELEASE: December 16, 2014
CONTACT: Mark Bowden, (515) 242-3268 or
mark.bowden@iowa.gov

Physicians urged to talk about effects of pain meds and medical conditions

DES MOINES, IA – The Iowa Board of Medicine is encouraging Iowa physicians to counsel their patients about the effects that pain medicines may on a their patients' ability to safely operate motor vehicles.

The Board's urging is prompted by a recent National Transportation Safety Board (NTSB) study that identified potential risks that prescription pain medicines and a patient's medical condition can create when a patient operates a vehicle in any mode of transportation. The NTSB's study and resulting recommendations are available at www.nstb.gov under report SS-14/01.

The Board in October initiated rulemaking (ARC 1708C) to require physicians to provide and document their consults with patients who are prescribed pain medicines. The proposed rule received several comments from physicians and healthcare organizations who said a mandated requirement was not necessary as it is standard practice for physicians and pharmacists to have conversations with patients about the effects of any prescribed medications, including pain medications.

After two public hearings on the proposed rule and the review of written comments, the Board on December 5 determined to discontinue the rulemaking process for ARC 1708C, which would have established the practice standard recommended by the NTSB.

In recent years, the Board has taken several steps to heighten physicians' awareness about the effects of pain medications, including addiction. The Board has adopted extensive standards of practice rules on treating acute pain and managing chronic pain. In addition, effective August 1, 2016, Iowa-license physicians will be required to complete continuing medical education activities on responsible opioid prescribing.

Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

MEMORANDUM

DATE: January 29, 2016

TO: Gerd Claibaugh
Director, Department of Public Health

FROM: Andrew Funk
Executive Director

SUBJECT: NTSB Letter Follow-up

In response to the NTSB Safety Recommendations addressed in Christopher Hart, Chairman's, letter dated November 12, 2015, the Board of Pharmacy offers the following:

1. Requirements for patient counseling on all new and changed prescriptions dispensed to any patient by Iowa-licensed pharmacists include addressing "special directions and precautions for preparation, administration, and use by the patient" and "common severe side effects or adverse effect…that may be encountered, including their avoidance…." Counseling is a requirement in Iowa-licensed pharmacies and is not restricted to a certain patient population nor an offer to counsel a patient sufficient to comply with the counseling requirement.

2. Periodic inspections of pharmacies and pharmacist practices include verifying compliance with the requirements for patient counseling. The Board periodically employs an inspection practice referred to as "shopper survey" wherein an individual, posing as a patient, will present a prescription for dispensing, often also purchasing another product such as an over-the-counter preparation that may create an adverse reaction or that may be contraindicated for use in combination with the prescription drug. The purpose of the "shopper survey" is to gauge the pharmacist's compliance with counseling requirements and drug use review.

3. The Board has published articles in the Board's quarterly newsletter, which is distributed to all currently licensed Iowa pharmacists and pharmacy technicians, reminding pharmacists of the requirement to appropriately counsel patients regarding their prescription drugs. Articles have focused on specific elements of patient counseling to ensure pharmacists are aware of the various elements of appropriate counseling, including a drug's potential impairment of the patient's ability to safely operate a vehicle or heavy machinery. The Board has also posted information on the Board's website, Facebook, and Twitter accounts reminding pharmacists of the importance of appropriate patient counseling.

Please let me know if you have any questions or if you need additional information. Thank you.

400 S.W. EIGHTH STREET, SUITE E ▪ DES MOINES, IA 50309-4688 ▪ PHONE: 515-281-6676
andrew.funk@iowa.gov ▪ https://pharmacy.iowa.gov ▪ FAX: 515-281-4609

Iowa Department of Public Health
Promoting and Protecting the Health of Iowans

Gerd W. Clabaugh, MPA
Director

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

TO: Gerd Clabaugh, Director, Iowa Department of Public Health
FROM: Sarah Reisetter, Bureau Chief, Professional Licensure
RE: National Transportation Safety Board (NTSB) Recommendations
DATE: January 15, 2016

The Bureau of Professional Licensure currently provides administration and regulation for the following professionals with prescriptive authority:

1. Physician Assistants
2. Optometrists
3. Podiatrists

The NTSB issued Safety Recommendations I-14-1 and I-14-2 and has asked how these recommendations are being implemented. The Bureau has taken the following implementation actions, with a goal of reaching as many prescribers as possible.

1. All newly licensed members of the professions listed above receive a printed reminder when the license is issued. The reminder is printed on colored paper and included in the envelope used to mail the license certificate. The text of the reminder is: "**A friendly reminder from the Iowa Department of Public Health and the National Transportation Safety Board:** Please remember to routinely discuss with patients the effect a person's diagnosed medical conditions or prescription medications may have on his or her ability to safely operate a vehicle in any mode of transportation."

2. All members of the professions listed above receive the same printed reminder with each biennial license renewal. The reminder is printed on colored paper and included in the envelope used to mail the renewal wallet cards. Each professional that renews a license will receive the reminder every 2 years.

3. The Bureau does not produce a newsletter at this time. The NTSB letter containing the recommendations has been provided to the professional associations for Iowa physician assistants, optometrists and podiatrists along with a request for inclusion of the material in the newsletters produced by the associations.

4. The Bureau also posted this reminder on each Board's website.

STATE OF IOWA
IOWA DENTAL BOARD

TERRY E. BRANSTAD, GOVERNOR
KIM REYNOLDS, LT. GOVERNOR

JILL STUECKER
EXECUTIVE DIRECTOR

To: Gerd Clabaugh
Director of the Iowa Department of Public Health

From: Jill Stuecker
Executive Director, Iowa Dental Board

Date: January 19, 2016

Re: Letter from the National Transportation Safety Board

In response to a letter addressed to The Honorable Terry Branstad, from the National Transportation Safety Board, the Iowa Dental Board has reviewed Iowa Administrative Code 650 (Dental Board), Chapter 16: Prescribing, Administering and Dispensing Drugs.

In response to recommendation I-14-1; Chapter 16 does not specifically state that the prescribing dentist must discuss with patients the effect their medical condition and medication use may have on their ability to safely operation a vehicle in any mode of transportation. These rules do state that all prescribing shall be done in accordance with applicable state and federal laws.

In response to recommendation I-14-2; the NTSB safety study has been shared with the Iowa Dental Association. The Iowa Dental Association has been an active participant on Iowa's Prescription Abuse Reduction Task Force.

The Iowa Dental Board has shared reminders to licensees through social media, regarding patient counseling, and plans to highlight this topic through the Dental Board list serve in February, 2016.

STATE OF IOWA

Governor Terry E. Branstad
Lt. Governor Kim Reynolds

BOARD OF NURSING
Kathleen R. Weinberg, MSN, RN
Executive Director

To: Gerd Clabaugh
Director of the Iowa Department of Public Health

From: Kathy Weinberg, MSN, RN
Executive Director

Date: January 7, 2016

Re: Letter from the National Transportation Safety Board

In response to the letter addressed to The Honorable Terry, November 12, 2015, the National Transportation Safety Board (NTSB) has issued two recommendations to the state of Iowa as a result of their safety study *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment.*

In response to recommendation I-14-1; the Iowa Board of Nursing currently does not have guidelines regarding the prescribing of controlled substances by an Advanced Registered Nurse Practitioner (ARNP). The Iowa Board of Nursing recently established an ARNP Advisory Committee and one of the goals and initiatives of this committee is to explore guidelines for the prescribing of controlled substances to be written in administrative rules. There is currently not a specific timeframe for this initiative, though it is a very important topic of conversation.

In response to recommendation I-14-2; the NTSB safety study has been published in the February, March, April, 2015 publication of the Iowa Board of Nursing's Newsletter. The study will once again be published in the February, March, April, 2016 publication in approximately a month. There is an editor's not stressing the importance of informing patients of the potential risks that drugs and medical conditions can cause while operating any mode of transportation.

For your reference I have included attachments of the Newsletter publications. If you have further questions please feel free to contact me. Thank you.

Renewal Reminder

Licenses that were due on January 15, 2015, are subject to the late fee listed below.

Licenses that expire February 15, 2015, are due by January 15, 2015, and can be renewed any time after December 15, 2014.

Licenses that expire March 15, 2015, are due by February 15, 2015, and can be renewed any time after January 15, 2015.

Licenses that expire April 15, 2015, are due by March 15, 2015, and can be renewed any time after February 15, 2015.

Licenses that expire May 15, 2015, are due by April 15, 2015, and can be renewed any time after March 15, 2015.

A $50 late fee is required for licensees who renew within the 30 days after the license lapses. Licenses that are not renewed will automatically be placed on inactive status on the 16th of the month following the expiration of the license.

The continuing education requirement for license renewal is 36 contact hours (3.6 CEUs) for renewal of a full three year license. Licensees renewing for the first time after the license was originally issued, or for the first time after a reactivation, will need 24 contact hours (2.4 CEUs) completed after the effective date printed on the wallet card.

Attention: Advanced Registered Nurse Practitioners

Safety Study Results Announced by the National Transportation Safety Board Washington, D.C.

SEPTEMBER 23, 2014 – WASHINGTON, D.C. – A safety announcement issued by the National Transportation Safety Board (NTSB) encourages all health care providers "who prescribe controlled substances for pain discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation" (NTSB, September 23, 2014).

Nurse practitioners should make it a practice to discuss these safety issues with their patients.

Evidence That Pilots Are Increasingly Using Over-the-Counter, Prescription, and Illicit Drugs

The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs.

The study found significantly increasing trends in pilots' use of all drugs, potentially impairing drugs (those with a US Food and Drug Administration warning about sedation or behavior changes in routine use), controlled substances, and illicit drugs (those defined as Schedule I by the US Drug Enforcement Administration). The final report, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*, is available on the NTSB's Safety Studies web page under report number SS-14/01.

In this study, the pilot was considered to be positive for a drug if it could be qualitatively or quantitatively identified in blood or tissue; drugs identified only in urine or used as part of resuscitative efforts were excluded.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 to 57 years over the study period.

Over the course of the study, for fatally injured pilots, the following was found:

The proportion of pilots testing positive for at least one drug increased from 10% to 40%.

More than 20% of all pilots from 2008-2012 were positive for a potentially impairing drug, and 6% of all pilots were positive for more than one potentially impairing drug.

Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating antihistamine (the active ingredient in many Benadryl and Unisom products).

During the most recent 5 years studied, 8% of all pilots tested positive for controlled substances; hydrocodone and diazepam each accounted for 20% of the positive findings.

The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.

These results highlight the importance of routine discussions between health care providers and pharmacists and their patients about the potential risks that drugs and medical conditions can create when patients are operating a vehicle in any mode of transportation.

Reminder: Advanced Registered Nurse Practitioners

Safety Study Results Announced by the National Transportation Safety Board Washington, D.C.

Editor's note: This article was initially published in the February, March, April 2015 Nursing Newsletter. *This important information is a reminder to practitioners to discuss with their patients the potential risks that drugs and medical conditions can cause while operating any mode of transportation. As a competent practitioner, ARNPs are accountable for keeping their patients informed.*

September 23, 2014 – Washington, D.C. - A safety announcement issued by the National Transportation Safety Board (NTSB) encourages all health care providers "who prescribe controlled substances for pain discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation" (NTSB, September 23, 2014).

Nurse practitioners should make it a practice to discuss these safety issues with their patients.

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- More than 20% of all pilots from 2008-2012 were positive for a potentially impairing drug, and 6% of all pilots were positive for more than one potentially impairing drug.
- Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating antihistamine (the active ingredient in many Benadryl and Unisom products).
- During the most recent 5 years studied, 8% of all pilots tested positive for controlled substances; hydrocodone and diazepam each accounted for 20% of the positive findings.
- The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

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These results highlight the importance of routine discussions between health care providers and pharmacists and their patients about the potential risks that drugs and medical conditions can create when patients are operating a vehicle in any mode of transportation.

National Transportation Safety Board

Washington, DC 20594

Office of the Chairman

November 12, 2015

The Honorable Terry Branstad
Governor of Iowa
State Capitol Building
Des Moines, IA 50319

Dear Governor Branstad:

The National Transportation Safety Board (NTSB) is an independent federal agency charged by Congress with investigating every civil aviation accident in the United States and significant accidents in other modes of transportation—railroad, highway, marine, and pipeline. We determine the probable cause of the accidents and issue safety recommendations aimed at preventing future accidents. In addition, we conduct special studies concerning transportation safety and coordinate the resources of the federal government and other organizations to provide assistance to victims and their family members impacted by major transportation disasters.

This letter addresses NTSB Safety Recommendations I-14-1 and -2. We issued these recommendations to the state of Iowa on September 23, 2014, as a result of our safety study *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*, SS 14/01, available at http://www.ntsb.gov/safety/safety-studies/Documents/SS1401.pdf. For your convenience, the background and bases for the recommendations may be found on pages 36-38 of the report.

I-14-1

Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

I-14-2

Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

We are interested in knowing whether and how our recommendations are implemented, both to ensure that the traveling public is provided the highest level of safety and to identify creative solutions that might be shared with others, and we normally expect actions to address our recommendations to be completed within 3 to 5 years. As we issued this recommendation more than a year ago and we have yet to hear from you regarding it, we would appreciate receiving a response within 90 days indicating actions you have taken or plan to take to implement it. In the meantime, the recommendation will retain its current classification of "Open—Await Response."

Please reply at correspondence@ntsb.gov. If your response, including attachments, exceeds 10 megabytes, please e-mail us at the same address for instructions. Please do not submit both an electronic and a hard copy of the same response.

If you have any questions, please contact Mr. Jeffrey Marcus, Safety Recommendation Specialist, at marcusj@ntsb.gov.

Thank you for your assistance in this matter.

Sincerely,

Christopher A. Hart
Chairman

cc: Mark Bowden, MPA, CMBE
Executive Director
Iowa Board of Medicine
mark.bowden@iowa.gov

Kathleen Weinberg, RN, MSN
Executive Director
Iowa Board of Nursing
Kathy.Weinberg@iowa.gov

Andrew Funk, PharmD
Executive Director
Iowa Board of Pharmacy
Andrew.funk@iowa.gov

Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

January 22, 2016

Governor Terry E. Branstad
Members of the 86th General Assembly
Iowa State Capitol
Des Moines, IA 50319

Honorable Governor and Members:

Re: Iowa Prescription Monitoring Program

Pursuant to the requirements of section 124.554, subsection 2, of the Iowa Uniform Controlled Substances Act, the Board of Pharmacy (Board) submits the following information.

The Iowa Prescription Monitoring Program (PMP) provides authorized prescribers and pharmacists with information regarding their patients' use of controlled substances and is used as a tool in determining appropriate prescribing and treatment of patients without fear of contributing to a patient's abuse of or dependence on addictive drugs or diversion of those drugs to illicit use. Iowa licensed pharmacies, both in-state and nonresident pharmacies, are required to report to the Iowa PMP all Schedule II, III, and IV controlled substances dispensed by the pharmacy to ambulatory patients.

The Iowa PMP became fully operational on March 25, 2009. The cost of initial implementation of the Iowa PMP was paid by federal grant and amounted to $411,250. Costs since implementation, amounting to approximately $112,000 annually, provide for the receipt and delivery of pharmacy data and software maintenance. Annual costs are paid from license fees retained by the Board for the support of Board programs and activities. No additional fees or surcharges have been imposed to pay for the activities or support of the Iowa PMP.

The Iowa PMP is administered by the Board with the assistance and guidance of an advisory council consisting of pharmacists and prescribers appointed by the Governor. The advisory council meets as needed to review the progress of the Iowa PMP, the cost of maintaining the Iowa PMP and the benefits of the program, possible enhancements to the program, and information, comments, and suggestions received from program users and the public.

The Board and the PMP Advisory Council also review statistics regarding the use of the Iowa PMP by prescribers, pharmacists, and law enforcement or regulatory agents; the number of prescriptions filled each year; the top drugs dispensed in Iowa each year; and indices of excessive pharmacy-shopping or doctor-shopping for controlled substances. Included with this report are some of the data compiled since the establishment of the Iowa PMP.

The data indicate steady increases in the number of pharmacists and prescribers registering to use the Iowa PMP and in the number of requests for patient prescription history being submitted and used by those authorized users. The data also demonstrate that the prescribing and dispensing of these

controlled substances has not been unnecessarily or adversely affected by the implementation of the Iowa PMP. The number of prescriptions dispensed and the number of doses dispensed increased during each year of the program. The number of patients obtaining prescriptions from multiple prescribers and multiple pharmacies decreased each year except 2014 when there was an increase in those numbers, likely attributable to the commencement of nonresident pharmacies reporting prescriptions dispensed to patients located in Iowa.

A number of regulatory and law enforcement agents have also registered to use the Iowa PMP. A member of this user community may receive Iowa PMP data only for an existing investigation or case where there has been a determination of probable cause for the information and the request for prescription information is accompanied by an order, subpoena, or other means of legal compulsion. Less than one percent of all processed requests are attributable to law enforcement or regulatory agents but those agents who have used information available from the Iowa PMP report improved efficiency and reduced investigative hours due to the central availability of the prescription information compiled in the Iowa PMP database. Use of the information available in the PMP database also reduces the demands on pharmacies and prescribers not involved with the prescribing or dispensing of controlled substances prescriptions to the subjects of law enforcement or regulatory agency investigations.

A graphic comparing the top dispensed controlled substances for calendar year 2015 is also included. The substances ranking in the top doses dispensed have been fairly consistent since implementation of the Iowa PMP. This year, however, the recent classification of tramadol as a controlled substance has resulted in this substance ranking as the second most-dispensed controlled substance in Iowa, preceded only by hydrocodone products. Dispensing of codeine to patients in Iowa has decreased and dispensing of diazepam has increased; these substances have historically and consistently exchanged positions in the rankings of top substances dispensed to patients in Iowa.

Comments received from prescribers and pharmacists using the program indicate that the Iowa PMP is a valuable assistive tool in determining appropriate health care treatment for their patients. Many prescribers and pharmacists have taken advantage of the option to identify one or more authorized agents (a licensed, registered, or certified health professional under the direct supervision of the prescriber or pharmacist) to register for delegate or agent access to the Iowa PMP. Agents access the Iowa PMP, on the direction of the supervising practitioner and using credentials assigned to and identifying the specific agent, to request patient prescription history information for the use of the supervising practitioner in making a more informed decision regarding the patient's health care plan. Practitioners report that the use of agents improves work flow, encourages more consistent use of the PMP, and ensures the practitioner has information regarding a patient's use of controlled substances prior to the practitioner making a decision on the patient's drug therapy.

A frequent suggestion from users has been to provide a means of checking other states' PMP records at the time a query is submitted to the Iowa PMP. Practitioners along Iowa's borders have been especially supportive of such a program enhancement and Iowa Code amendments approved during the 2014 legislative session authorized the Board to enter into agreements for the exchange of PMP information with Kansas and the states bordering Iowa. Program enhancements were completed early in 2015 and data sharing with Illinois, Wisconsin, Minnesota, South Dakota, and Kansas is now possible. Authorized practitioner users of PMPs in those states that meet the requirements and limitations

imposed by Iowa law for practitioners using the Iowa PMP are now able to request from the Iowa PMP data on the practitioner's patient when the practitioner queries his/her home state PMP. Conversely, an Iowa PMP practitioner user may request patient records from those states' PMPs when submitting a query to the Iowa PMP.

In February 2015, the Board, the PMP Advisory Council, and the Governor's Office of Drug Control Policy, convened a one-day conference attended by PMP users, representatives of health professional boards, associations, and societies, law enforcement agencies, state and federal agencies, legislators, treatment counselors and providers, and other interested parties to discuss the current status of the Iowa PMP and the future direction or focus of the Iowa PMP. The agenda included identification and discussion of other state PMPs, PMP successes, difficulties, and "best practices," and future plans or recommendations for the Iowa PMP. The Board and the PMP Advisory Council will be considering those recommendations as they formulate plans for improvements and enhancements to the Iowa PMP.

Registered users of the Iowa PMP continue to express their appreciation for the program and the value of the program in planning the health care treatment of their patients. The Board and the PMP Advisory Council concur, and health professional boards, associations, and societies agree, that the Iowa PMP provides proportionally more value for the health care community and their patients than the program costs and that the Iowa PMP should continue.

Respectfully submitted,

Andrew R. Funk, Pharm.D.
Executive Director

ARF:tmw

Attachments

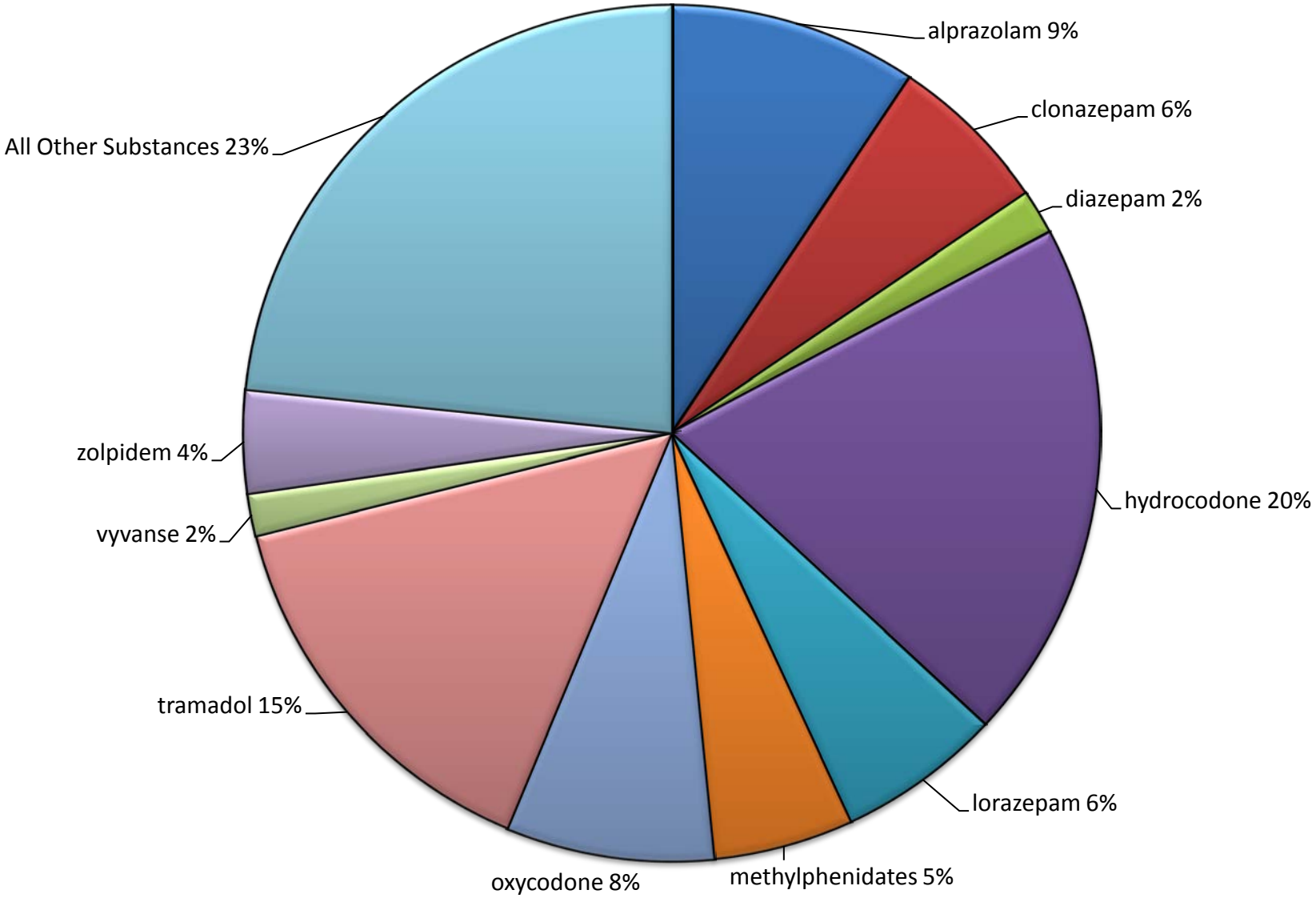
IOWA PRESCRIPTION MONITORING PROGRAM REPORT 2015

DATA COMPILATION

JANUARY 1, 2010, TO DECEMBER 31, 2015

Period:	1/1/2010 - 12/31/2010	1/1/2011 - 12/31/2011	1/1/2012 - 12/31/2012	1/1/2013 - 12/31/2013	1/1/2014 - 12/31/2014	1/1/2015 - 12/31/2015
Total CSA Registrant/Prescribers	13,472	14,008	14,547	14,891	15,491	16,012
Total Iowa Pharmacies*	943	948	942	1,520	1,708	1,703
Total Iowa-resident Pharmacists	3,314	3,372	3,410	3,489	3,523	3,568
Prescribers Registered	2,254	2,956	3,766	4,496	5,147	5,909
Pharmacists Registered	1,020	1,208	1,698	2,081	2,390	2,692
Regulators Registered	26	28	32	33	33	32
Law Enforcement Agents Registered	65	92	119	152	162	176
Practitioner Agents Registered	-	-	124	423	721	1,114
Prescriber Requests Processed	44,442	71,172	104,431	129,702	170,696	236,663
Pharmacist Requests Processed	7,988	8,173	12,327	48,040	68,669	91,174
LE/Regulator Requests Processed	340	423	644	484	487	459
Total # Requests Processed	52,770	79,768	117,402	178,226	239,852	328,296
**beginning 2013, includes nonresident pharmacies; required to report* effective 1/1/2013						
Filled prescriptions for period:	**1/1/2010 - 12/31/2010**	**1/1/2011 - 12/31/2011**	**1/1/2012 - 12/31/2012**	**1/1/2013 - 12/31/2013**	**1/1/2014 - 12/31/2014**	**1/1/2015 - 12/31/2015**
# Individual patients filling CII Rxs	297,424	322,950	332,908	425,604	769,937	905,146
...from 5 or more prescribers or pharmacies	217	249	186	42	303	169
...from 10 or more prescribers or pharmacies	4	7	3	-	2	1
...from 15 or more prescribers or pharmacies	-	-	1	-	-	-
# Individual patients filling CII or CIII Rxs	825,693	870,441	865,412	1,026,837	821,058	971,460
...from 5 or more prescribers or pharmacies	1,360	1,313	1,072	264	330	198
...from 10 or more prescribers or pharmacies	68	60	31	1	2	1
...from 15 or more prescribers or pharmacies	11	8	2	-	-	-
# Individual patients filling CII, III, IV Rxs	1,170,815	1,149,197	1,181,762	1,447,418	1,142,768	1,498,700
...from 5 or more prescribers or pharmacies	2,016	1,769	1,576	371	527	355
...from 10 or more prescribers or pharmacies	96	72	49	3	5	3
...from 15 or more prescribers or pharmacies	16	9	2	-	-	-
Total # Rxs dispensed for period:	4,442,017	4,581,643	4,668,502	4,679,271	4,800,912	5,183,996
Total # Doses dispensed for period:	242,691,025	253,631,899	254,137,229	260,092,453	269,466,402	303,030,950

CII-CIV CONTROLLED SUBSTANCES DOSES DISPENSED
JANUARY - DECEMBER 2015



From: Funk, Andrew [IBPE]
To: Jorgenson, Debbie [IBPE]
Cc: Witkowski, Terry [IBPE]
Subject: FW: HF 2049
Date: Tuesday, January 26, 2016 4:11:49 PM

Debbie,

See Dale's article below. Please put this on the Board agenda as an FYI…I think it pairs well with our PMP report.

Thanks,

Andrew Funk, Pharm.D.
Executive Director
Iowa Board of Pharmacy
RiverPoint Business Park
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688
515.281.5944 Main Line
andrew.funk@iowa.gov

From: Witkowski, Terry [IBPE]
Sent: Tuesday, January 26, 2016 12:37 PM
To: Woolery, Dale [ODCP]
Cc: Funk, Andrew [IBPE]
Subject: RE: HF 2049

Thanks, Dale, I had not seen that yet. Interesting.

Therese (Terry) Witkowski
Executive Officer
Iowa Board of Pharmacy
terry.witkowski@iowa.gov
515-281-6676

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code § 155A.2(1).

From: Woolery, Dale [ODCP]
Sent: Tuesday, January 26, 2016 11:24 AM
To: Witkowski, Terry [IBPE]
Subject: RE: HF 2049

Terry, I know Bruce wants to talk with you too, so hopefully you'll connect soon. BTW, I just saw news of the big national hydrocodone news. Dale

http://www.drugfree.org/join-together/one-billion-fewer-hydrocodone-combination-tablets-

dispensed-drug-rescheduled/?utm_source=Stay+Informed+-+latest+tips%2C+resources+and+news&utm_campaign=0f975e562c-JT_Daily_News_Naloxone_Offered_Free_to_High&utm_medium=email&utm_term=0_34168a2307-0f975e562c-222912789

From: Witkowski, Terry [IBPE]
Sent: Tuesday, January 26, 2016 10:32 AM
To: Woolery, Dale [ODCP]
Subject: RE: HF 2049

Dale,

I wish I could make that meeting but I have a prior commitment that I cannot change. I do want to talk to Bruce, however, and sent him an email earlier today with my questions.

Therese (Terry) Witkowski
Executive Officer
Iowa Board of Pharmacy
terry.witkowski@iowa.gov
515-281-6676

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code § 155A.2(1).

From: Woolery, Dale [ODCP]
Sent: Tuesday, January 26, 2016 9:53 AM
To: Witkowski, Terry [IBPE]
Subject: FW: HF 2049

Terry, DCI lab director Bruce Reeve plans to attend this meeting, as do I. If you are there, could we meet before or after to discuss strategy on HF 2049 and SSB 3004? Dale

Notice of Subcommittee Meeting
Committee: Public Safety (House)
Subcommittee: HF 2049
Bill Title: A bill for an act relating to controlled substances, including by modifying the penalties for controlled substances containing cocaine base, enhancing the penalties for imitation controlled substances, modifying the controlled substances listed in schedules I, III, and IV, and temporarily designating substances as controlled substances, and providing penalties.
Members: Klein-CH, Holt, Gaines

Date: 01/26/2016 1:15 PM
Location: RM 19
Agenda:
Discussion of HF 2049

Dale R. Woolery
Governor's Office of Drug Control Policy
Pape State Office Building, 5th Floor SW
215 East 7th Street, Des Moines, IA 50319
PH: 515.725.0310 / FX: 515.725.0304
*EM: **dale.woolery@iowa.gov***
*Web: **http://www.iowa.gov/odcp***

One Billion Fewer Hydrocodone Combination Tablets Dispensed After Drug Rescheduled

/ BY JOIN TOGETHER STAFF

January 26th, 2016 / 1

One billion fewer hydrocodone combination tablets were dispensed and 26.3 million fewer prescriptions were written after the Drug Enforcement Administration (DEA) enacted tighter controls on prescribing these products, a new study finds.

In 2014, the DEA announced it would reclassify hydrocodone combination products such as Vicodin. Under the new rules, patients can receive the drugs for only up to 90 days without receiving a new prescription.

The DEA reclassified hydrocodone combination products as Schedule II drugs. Until October 2014, these drugs were classified as Schedule III drugs, meaning they could be refilled up to five times, and prescriptions could cover a 180-day period. In most cases, patients who wish to refill their hydrocodone combination prescription now have to give their pharmacy a prescription from a healthcare provider, instead of having it phoned or faxed in.

In the new study, researchers from the Department of Health and Human Services analyzed data from IMS Health National Prescription Audit, which estimates the number of prescriptions dispensed from U.S. pharmacies. The findings are published in JAMA Internal Medicine.

Lead researcher Christopher Jones, PharmD, told MedPage Today the decline was substantial.

Andrew Kolodny, MD, Chief Medical Officer of the addiction rehabilitation program Phoenix House, said the DEA's rescheduling of hydrocodone combination products will likely have a dramatic impact on the opioid epidemic.

"I think when we look back on this 10 or 20 years from now, we'll see this was a very important policy change — maybe one of the most effective federal interventions to control the opioid addiction crisis," he said. "A billion fewer hydrocodone combination pills in circulation is a billion fewer pills that people might have consumed. That means we're reducing the exposure to a highly addictive drug."

1 Response to this article

LEAVE YOUR RESPONSE >

AdictionTherapist / *January 26, 2016 at 1:04 pm* REPLY

And only ten years past due! More evidence that Big Pharma owns the FDA.

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Opioid Painkiller Use For More Than One Month May Increase Depression Risk: Study

All Adults Should be Screened for Depression, Panel Advises

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Addiction is *finally* being talked about on the campaign trail. What are the presidential candidates saying? http://ow.ly/XyTUY We're rolling out a…

Please help us congratulate the winners of the Teens Make Music Contest! Listen to these talented young performers as they interpret what life is abov…

"Let's all continue the honest conversation that the presidential candidates have started, in order to bring addiction – how our family and friend…

"It would be a first step in a long and difficult struggle to get the national addiction crisis under control, and it deserves approval as soon as pos…

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Last year your donations helped us remove over 2 Million pounds of prescription drugs from America's medicine cabinets.

GIVE NOW

Join Together Staff

Candice Besson
Editor

Celia Vimont
Writer

*Key Findings**

90%

90 percent of addictions start in the teen years.

*2012 CASA Columbia

SHARE

1in4

One in four teens has misused or abused a prescription drug at least once in their lifetime.

*PATS 2013

SHARE

20%

Kids who learn about the risks of drugs from their parents are significantly less likely to use drugs, yet 20 percent report not getting that benefit.

*PATS 2013

SHARE

12YR

Prescription medicines are now the most commonly abused drugs among 12 to 13 year olds.

*NSDUH 2012

SHARE

Thanks to SAG-AFTRA and its members for their ongoing generosity and support of the organization and our cause.

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PATIENT CARE

Emergency Meds Act Would Fix Gap in EMS Law that Could Harm Patients

JAN 13, 2016 **SOURCE:** ACEP

January 13, 2016, WASHINGTON — Pending federal regulations threaten a longstanding practice that has allowed EMS personnel to administer controlled substances to patients who, for example, are suffering with severe pain or experiencing seizures. This practice will soon be prohibited unless the nation's Controlled Substances Act is amended accordingly.

The "Protecting Patient Access to Emergency Medications Act of 2015" (H.R. 4365), sponsored by Rep. Richard Hudson (R-NC), will allow EMS agencies to continue using standing orders from their medical director to administer approved medications to their patients under the Drug Enforcement Administration (DEA).

The legislation is strongly supported by the

American College of Emergency Physicians (ACEP) and five other national organizations representing EMS: the American Ambulance Association, Association of Air Medical Services, the Association of Critical Care Transport, International Association of Fire Chiefs (IAFC), the International Association of Fire Fighters (IAFF), National Association of EMS Physicians, National Association of Emergency Medical Technicians and the National Association of State EMS Officials.

“The proposed legislation will codify current practices into statute so that EMS practitioners, and most importantly patients, do not see any disruption in the provision of this critical and lifesaving care,” said Jay Kaplan, MD, FACEP, president of ACEP. “Emergency physicians appreciate the strong leadership of Rep. Hudson and the U.S. Drug Enforcement Administration in resolving this issue.”

The organizations supporting this legislation represent more than 350,000 physicians, firefighters and emergency medical services personnel.

“The IAFC thanks Representative Hudson for his work to ensure EMS personnel can continue providing the pre-hospital emergency patient care that may be needed,” said Fire Chief Rhoda Mae Kerr, president of the IAFC. “This legislation would simplify the registration process for thousands of fire and EMS agencies across the United States while cutting red tape that could jeopardize effective patient care.”

EMS provides critical care for patients while transporting them to hospitals. The ability to use controlled substances to administer medical care and medicines is essential to saving lives, managing pain and improving health outcomes.

“Citizens rely on emergency medical personnel to act on their behalf in times of crisis,” said Harold Schaitberger, General President of the International Association of Fire Fighters. “In an emergency, there is no time to waste. The Protecting Patient Access to Emergency Medications Act will help protect the ability of first

responders to treat patients with appropriate and necessary medications."

Specifically the proposed legislation would amend the Controlled Substances Act (21 USC 821 et seq) to:

- Permit EMS agencies to directly register with the DEA (rather than through their medical director);
- Allow a single registration for an EMS agency (rather than for each location);
- Ensure that an EMS agency has at least one physician medical director;
- Allow the medical director to use standing orders for EMS personnel for the delivery or administration of a controlled substance (Schedule II – V); and
- Update receipt, movement and storage rules for EMS agency controlled substances.

ACEP is the national medical specialty society representing emergency medicine. ACEP is committed to advancing emergency care through continuing education, research and public education. Headquartered in Dallas, Texas, ACEP has 53 chapters representing each state, as well as Puerto Rico and the District of Columbia. A Government Services Chapter represents emergency physicians employed by military branches and other government agencies.

The IAFC represents the leadership of firefighters and emergency responders worldwide. IAFC members are the world's leading experts in firefighting, emergency medical services, terrorism response, hazardous materials spills, natural disasters, search and rescue, and public safety legislation. Since 1873, the IAFC has provided a forum for its members to exchange ideas, develop professionally and uncover the latest products and services available to first responders.

The International Association of Fire Fighters represents more than 300,000 professional fire fighters and emergency medical personnel throughout the United States and Canada.

Loading

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Integrated Healthcare Delivery

MANY IOWA TEENS AND ADULTS HAVE A FALSE SENSE OF SECURITY ABOUT PRESCRIPTION AND OVER-THE-COUNTER (OTC) DRUGS:

"It's only medicine, so it's safe, right?"

Almost 1 out of 4 (24%) of Iowa middle school and high school students either do not know or do not believe using prescription drugs (not prescribed for them) puts them at risk of harm.[1]

Talking about using prescription and OTC medications needs to begin at an early age. Nearly half of young people who inject heroin surveyed in three recent studies reported abusing prescription opioids before starting to use heroin.[2]

[1] 2014 Iowa Youth Survey, www.iowayouthsurvey.iowa.gov
[2] www.drugabuse.gov./publications/research-reports/herioin
[3] http://www.cdc.gov/drugoverdose/

RESOURCES

Iowa Substance Abuse Information Center
1-866-242-4111
www.drugfreeinfo.org

Iowa Medicine Take Back
http://tinyurl.com/IowaRxTB

National Institute on Drug Abuse
www.nida.nih.gov

Partnership for Drug-Free Kids
www.drugfree.org

AC4C Alliance of Coalitions For Change
www.ac4c.org

Partnership @ DrugFreeIowa.org

Public Safety · Division of Narcotics Enforcement · Iowa

IDPH Iowa Department of Public Health

Governor's Office of Drug Control Policy · Iowa · Prevention · Treatment · Enforcement

www.iowa.gov/odcp

Project supported by Grant No. 2011-DD-BX-0002, awarded by the U.S. Dept. of Justice. Points of view represent the authors and do not necessarily represent the official position or policies of the U. S. Department of Justice.

1015

Medicine Abuse in Iowa

A FAMILY GUIDE TO PREVENTION

Commonly Abused Medicines

Opioids
Narcotic pain killers (e.g. morphine, codeine, oxycodone, fentanyl, hydrocodone, methadone)

Stimulants
Prescribed to treat narcolepsy and attention deficit or hyperactivity disorder (e.g. Adderall, Ritalin)

Central Nervous System Depressants
Used to treat anxiety or sleep disorders (e.g. Xanax, Valium)

Dextromethorphan (DXM)
A cough suppressant

There were 14.9 prescriptions filled per capita at Iowa retail pharmacies in 2014.[4] How many prescriptions are in your home?

Safety Tips

Take inventory and monitor the prescription and OTC drugs in your home. Store them in a locked area if you have concerns they are being abused.

Dispose of old and unused medications promptly and appropriately. Your pharmacist can provide information about how and where to dispose of OTC and prescription drugs.

Monitor your credit card statement and internet use in your home. It's easy for anyone to purchase a prescription drugs over the internet.

TALKING ABOUT MEDICINE USE

Discussion about medicine abuse presents a challenge, compared to talking about alcohol, tobacco, and illegal drug use-which are illegal for youth to use. Medicine is designed to help people. Make sure your child understands you are talking about intentionally using these drugs to get high.

Take time to learn about the abuse of these drugs. There's a wealth of information on the internet. Talk about specific drugs and how they affect the body and people's lives. Include information on side affects and symptoms of overdose. For older youth, discuss the risks of taking drugs and driving or riding with an impaired driver.

Use teachable moments, such as when a story is on the news about these drugs or when you and your child are on an extended ride. It's OK if you don't have all the answers. It's more important that you have an open dialogue, model responsible behavior around prescription and OTC use, and young people know your expectations around drug use.

[4] http://kff.org/other/state-indicator/retail-rx-drugs-per-capita/

Why are Young Iowans Abusing Medicines?

The Four "A's"

Availability: The number of prescription and over the counter (OTC) drugs that have potential for abuse is staggering.

Access: They are easy to get.

Off the Internet—With a credit card, youth can purchase almost any prescription drug they want.

From the Family Medicine Cabinet—Legitimate family member prescriptions can be stolen a few at a time, usually without notice.

From Friends—In a phenomenon known as Pharm Parties, youth bring whatever medicines they can find and take them together in a type of pill "trail mix" usually without knowing what they are taking.

Awareness: Teens know more about prescription drugs than ever before due to aggressive media advertising and the internet.

Attitude: Many youth believe there is low risk associated with taking prescription and OTC drugs, even though they can be just as dangerous as any illegal drug if used inappropriately.

Sharing or selling prescription medication is illegal. In some cases it is considered a felony punishable by up to 10 years in prison and a $10,000 fine.

From: Funk, Andrew [IBPE]
To: Jorgenson, Debbie [IBPE]
Subject: FW: Media Issues 1.13.16
Date: Friday, January 15, 2016 8:00:09 AM
Attachments: image002.png
image004.png
image006.png

Debbie,

Here is some information provided by IDPH for overdose deaths. Can we provide this to the Board in March as an FYI with Dale's map?

Andrew Funk, Pharm.D.
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From: Carver-Kimm, Polly [IDPH]
Sent: Wednesday, January 13, 2016 3:28 PM
To: Adams, Heather [AG]; Arndt, Elizabeth [IGOV]; Bettini, Christina [IGOV]; Briggs, Sandy [IDPH]; Carver-Kimm, Polly [IDPH]; Caskey, Jennifer [IDPH]; Garvey, Ann [IDPH]; Hammes, Ben [IGOV]; IDPH BureauChiefs; IDPH DivisionDirectors; Pottebaum, Nic [IGOV]; Thompson, Deborah [IDPH]
Subject: Media Issues 1.13.16

WHO radio (Sue Danielson) interviewed Eric Preuss about the Workplace Gambling Toolkit announced today in a press release from IDPH: http://bit.ly/1TVan2n

Moline Dispatch (Steve Elliot) inquired if there is an upcoming hearing about the Strategic Behavioral Health project in the Quad Cities. Reporter was directed to the agenda for the Health Facilities Council, which was posted to the IDPH website yesterday.

Will Kraft (Minnesota Public Radio) requested data on Iowa heroin overdose deaths. The following data was provided. He also requested dose data on naloxone; that information is pending.

2010

Code	Count	Description
T401	6	Heroin
T402	23	Other opioids
T403	16	Methadone
T404	14	Other synthetic narcotics
T406	5	Other and unspecified narcotics
T423	2	Barbiturates
T424	14	Benzodiazepines
T426	1	Other antiepileptic and sedative-hypnotic drugs
T427	1	Antiepileptic and sedative-hypnotic drugs, unspecified
T430	14	Tricyclic and tetracyclic antidepressants
T432	6	Other and unspecified antidepressants
T436	13	Psychostimulants with abuse potential
T438	1	Other psychotropic drugs, not elsewhere classified

2011

Code	Count	Description
T401	10	Heroin
T402	45	Other opioids
T403	17	Methadone
T404	14	Other synthetic narcotics
T406	10	Other and unspecified narcotics
T423	2	Barbiturates

T424	10	Benzodiazepines
T426	1	Other antiepileptic and sedative-hypnotic drugs
T430	3	Tricyclic and tetracyclic antidepressants
T432	11	Other and unspecified antidepressants
T433	1	Phenothiazine antipsychotics and neuroleptics
T435	4	Other and unspecified antipsychotics and neuroleptics
T436	4	Psychostimulants with abuse potential

2012

Code	Count	Description
T401	8	Heroin
T402	36	Other opioids
T403	16	Methadone
T404	12	Other synthetic narcotics
T406	5	Other and unspecified narcotics
T423	1	Barbiturates
T424	13	Benzodiazepines
T430	13	Tricyclic and tetracyclic antidepressants
T432	5	Other and unspecified antidepressants
T433	1	Phenothiazine antipsychotics and neuroleptics
T435	1	Other and unspecified antipsychotics and neuroleptics
T436	13	Psychostimulants with abuse potential

2013

Code	Count	Description
T40.1	20	Poisoning: Heroin
T40.2	44	Poisoning: Other opioids
T40.3	13	Poisoning: Methadone
T40.4	20	Poisoning: Other synthetic narcotics
T40.6	5	Poisoning: Other and unspecified narcotics
T42.4	10	Poisoning: Benzodiazepines
T42.6	1	Poisoning: Other antiepileptic and sedative-hypnotic drugs
T43.0	6	Poisoning: Tricyclic and tetracyclic antidepressants
T43.2	5	Poisoning: Other and unspecified antidepressants
T43.5	2	Poisoning: Other and unspecified antipsychotics and neuroleptics
T43.6	26	Poisoning: Psychostimulants with abuse potential

2014.

Code	Count	Description
T39.0	1	Poisoning: Salicylates
T39.1	4	Poisoning: 4-Aminophenol derivatives
T39.8	1	Poisoning: Other nonopioid analgesics and antipyretics, not elsewhere classified
T40.1	19	Poisoning: Heroin
T40.2	33	Poisoning: Other opioids
T40.3	2	Poisoning: Methadone
T40.4	7	Poisoning: Other synthetic narcotics
T40.5	5	Poisoning: Cocaine
T40.6	3	Poisoning: Other and unspecified narcotics
T41.2	1	Poisoning: Other and unspecified general anaesthetics
T42.3	1	Poisoning: Barbiturates
T42.4	4	Poisoning: Benzodiazepines
T42.6	2	Poisoning: Other antiepileptic and sedative-hypnotic drugs

T43.0	3	Poisoning: Tricyclic and tetracyclic antidepressants
T43.2	3	Poisoning: Other and unspecified antidepressants
T43.6	6	Poisoning: Psychostimulants with abuse potential
T45.0	4	Poisoning: Antiallergic and antiemetic drugs
T48.7	1	Poisoning: Other and unspecified agents primarily acting on the respiratory system
T50.9	10	Poisoning: Other and unspecified drugs, medicaments and biological substances

Tri States Radio (Jason Parrott) and **KHQA (Rajah Maples)** inquired about today's scheduled Board of Chiropractic meeting, at which a hearing was scheduled for Andrew Kearse, a Keokuk chiropractor. Response: A motion was to continue was filed and approved. The result is today's hearing was postponed to a yet to be determined date in the future.

Chicago Tribune (Harry Huggins) had several questions regarding concentrated animal feeding operations (CAFOs): Have there been any human or animal disease outbreaks linked to CAFOs or livestock facilities in Iowa? While public health does not conduct targeted human disease surveillance on livestock producers/employees, we are not aware of any human disease outbreaks linked to swine concentrated feeding operations. Animal disease outbreaks are tracked by IDALS so they could best respond to that part of the question.

Does Iowa follow the National Animal Identification System? This is IDAL's system, so the response would best come from them.

Are CAFOs identified in Iowa's emergency response plan? If you are referring to the statewide emergency operations plan, that would be a question for the Iowa Homeland Security and Emergency Management Department. If registration is voluntary, how many hog CAFOs in Iowa participate? IDALS would have this number.

Is it possible to quantify the dollar amount spent regulating CAFOs and the number of Full Time Equivalent workers who implement state statutory requirements? This answer will have to come from IDALS and DNR since they both play a regulatory role. IDPH does not dedicate any staff to CAFO surveillance/regulation, so we would not have any $ to add to this tally.

Reuters (Yasmeen Abutaleb) had a number of questions about antibiotic resistance in Iowa:

1. In aggregate, how many people have died from antibiotic-resistant infections [i.e. C. difficile, MRSA, CRE, VRSA, etc.] in the state over the past 10 years? Can you please give me a count for each year in the 10-year period beginning in 2004 and explain how you counted the cases? Is Clostridium Difficile included in this count? Deaths due to antibiotic resistance are not specifically reportable in Iowa.

2. What rules and procedures are in place to track and report antibiotic-resistant infections in the state? Which resistant infections have to be reported to state health officials? Vancomycin-resistant Staphylococcus(VRSA)has been reportable in Iowa for many years but none detected. Vancomycin intermediate-resistant Staphylococcus is reportable in Iowa starting this month. Any outbreak of any etiology is reportable to IDPH. Hospitals may report antibiotic resistant organisms through the National Healthcare Safety Network (NHSN) but only are now VRSA and VISA reportable directly to IDPH.

3. Does your state share that information with the CDC on a regular basis? How is that information communicated? No cases to share. We do share appropriate disease information to CDC

4. Is data or information on antibiotic-resistant infections and outbreaks shared with the public? Why or why not? If it is shared, then how so? General information on antibiotic resistance is shared through our website and press releases. The Iowa committee addressing antibiotic resistance publishes regular reports which is posted on our website and often a press release is issued.

5. Is CDC data on antibiotic-resistant infections in the state shared with the Iowa health department? We are able to access CDC information on these infections and receive specific consultations on Iowa situations as needed from CDC.

6. What is the definition of an outbreak? Any number of cases above the expected baseline. This could be one VRSA, or a hundred cases of influenza.

7. Can you provide descriptions of antibiotic-resistant infection outbreaks that occurred in Iowa over the past 10 years? Please include details on when and where each outbreak occurred; how many deaths were reported; and how many people got infected. We have seen small outbreaks in athletic team.

8. Are there any state incentives put in place to curb outbreaks of antibiotic-resistant infections? How about other healthcare-acquired infections? Yes, for example Iowa has used the CDC's Get Smart program, and other efforts

over the years can be found in the reports from Iowa's committee on antibiotic resistance.

9. Can you help me understand how deaths are recorded by the state, from the time of death to the point when a decedent's information appears as a row in your databases? In general, the funeral director in charge of arrangements enters the demographic information and assigns the record to a certifier or medical examiner as appropriate. Once all information has been entered and all parties (funeral director and certifier) has signed the record, the record may be registered and receive a state file number. At that point, the record is complete. The system for death registration has edits built in to accept records for registration if all information has been entered. If there is questionable information, state staff reviews the record prior to registration.

10. Who certifies the death? **641—97.6(144) Medical certification of death.** The funeral director shall submit the completed fact of

death portion of the certificate of death to the physician, physician assistant, advanced registered nurse practitioner, or medical examiner for the completion of the medical portion.
97.6(1) For a natural cause of death, the physician, physician assistant or advanced registered nurse practitioner in charge of the patient's care for the illness or condition which resulted in death shall complete and sign the medical certification within 72 hours after receipt of the death certificate from the funeral director or individual who initially assumed custody of the body.
97.6(2) If there is a non-natural cause of death, the state medical examiner or county medical examiner shall be notified and shall conduct an inquiry.

Are initial causes of death recorded in text descriptions only? Yes

If so, who converts the text descriptions to ICD codes? NCHS

Does the state use ICD-10 CM? ICD-10 is death coding and yes IDPH retains ICD-10 codes for the death records; ICD-10 CM are clinical codes and would apply in the hospital setting prior to death.

If not, which ICD-10 codes do you use in the records? See above

Do you rely on NCHS to code the death records? See above

10. Are autopsy records kept by the state or by counties? Are these considered public? How can I access them? Forensic autopsy reports are maintained by the Iowa Office of the State Medical Examiner and by the counties. They are not public record. Permission to view or obtain a copy of one of these reports must be provided by the decedent's immediate NOK. Cause and manner of death can be released as long as there is not an ongoing investigation or release of such information may jeopardize the safety of anyone in public.

11. Are death certificates considered public or private records? **641—95.5(144) Handling of vital records.**
95.5(1) State equipment and state vital records shall not be handled or accessed except by the state registrar, the state registrar's employees, or other authorized personnel for administrative purposes.
95.5(2) The county registrar shall provide assistance to the public in accessing vital records designated as public records in the custody of the county registrar.

641—95.7(144) General public access of vital records in the custody of the county registrar. A vital record may be in the custody of the county registrar if the event occurred in that county and the record is not excluded by statute or definition for purposes of confidentiality.
95.7(1) There shall be public access and the right to inspect in person all vital records in the custody of the county registrar after they are purged of confidential information.

Polly Carver-Kimm
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To Your Health

Early results of marijuana extract treatment for children with epilepsy prove promising

By Ariana Eunjung Cha December 8, 2015

For a number of years now, families of children with epilepsy have been relocating to Colorado from around the world to try to obtain a special marijuana extract known as "Charlotte's Web" that they had heard had an almost magical ability to reduce seizures. In late 2013 and early 2014, as the political movement to legalize medical marijuana was heating up, many of these parents traveled to state capitals around the country to plead for help in getting access to similar treatments. More than a few legislatures, regardless of their stance on marijuana, were so moved by the stories that they acquiesced.

The reaction from the scientific community was more cautious.

Some researchers dismissed the reports of recoveries — shared widely on social media — as wishful thinking. Others launched clinical trials to try to figure out what was going on.

Early results, unveiled at the American Epilepsy Society's annual meeting in Philadelphia this week, are encouraging.

The first study, led by Orrin Devinsky, director of the comprehensive epilepsy center at NYU Langone Medical Center, involved giving a drop of liquid cannabidiol (CBD), a key component of marijuana, to 261 patients with severe epilepsy for three months. The participants, most of whom were children with an average age of 11 and were at 16 different sites around the country, continued to take their regular anti-seizure medications as well.

By the end of that time period, their seizures were reduced by 45 percent on average. But the treatment wasn't without risks. Some 5 percent of the patients had side effects, such as changes in their liver enzymes or diarrhea. Twelve percent stopped taking the medication in the middle of the study because it didn't appear to help.

Devinsky called the data "promising" and said that they provide "hope to the children and their families who have been living with debilitating seizures."

The second study which was conducted at the University of California Benioff Children's Hospital involved fewer participants — only 25, and all children — but involved giving the drug for a longer time period — one year. The results were more mixed than in the previous study. Ten of those children experienced at least a 50 percent reduction in their seizures. But 12 of the children stopped taking the medication because it didn't work, and one because his seizures became more frequent.

Both studies used GW Pharmaceutical's investigational medicine Epidiolex, a liquid formulation of cannabidiol.

The scientists cautioned that their results are from a small sample, studies that did not have control groups, and that further research is needed before the results can be confirmed. Additional data is expected to be released in 2016.

Read more:

'Mommy lobby' emerges as a powerful advocate for medical marijuana for children

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Ariana Eunjung Cha is a national reporter. She has previously served as the Post's bureau chief in Shanghai and San Francisco, and as a correspondent in Baghdad.

January 15, 2016

Mark E. Bowden, MPA, CMBE
Executive Director
Iowa Board of Medicine
400 SW 8th St., Suite C
Des Moines, IA 50309-4686

Re: Compounded and Repackaged Medications for Office-use

Dear Mark E. Bowden:

Our organizations represent physicians, pharmacists, other healthcare providers, surgical centers, and patient advocates treating and providing care to patients with an array of conditions requiring a broad spectrum of treatments and also pharmacists that provide physicians, hospitals, and other health care professionals with compounded medications for administration to and treatment of patients within these practice settings (often called "office-use"). As such, we have been closely monitoring the Food and Drug Administration's (FDA) implementation of the *Drug Quality and Security Act* ("DQSA", P.L. 113-54) and remain concerned about the impact of the Agency's actions on patient access to compounded medications.

Specifically, we are deeply concerned about the implementation of the DQSA in regards to both compounded and repackaged medications for office-use. Recent implementation actions by the FDA and the information being provided by the Agency to States have caused confusion amongst State boards of medicine and pharmacy and have adversely impacted practitioner and patient access to vital medications.

Many medical professionals and healthcare facilities rely on various types of repackaged and compounded medications to treat their patients -- whether it is in their office, on a crash cart in an emergency department, or in another medical setting. These medications are essential for emergency situations as well as to initiate treatment immediately in response to a medical condition. Medications, including some biologics, are compounded or repackaged in order to meet specific dosage needs and are critical to the timely treatment of many patients when a prescriber determines that a FDA-approved drug product is neither available nor appropriate to treat their condition and achieve the best possible therapeutic outcome.

Currently, the majority of States provide for means by which prescribers may obtain both finished manufactured drug products and compounded preparations for the administration to or treatment of patients within their practice settings. When Congress re-enacted 503A within the DQSA, numerous Statements of the Record conveyed the intent that nothing within 503A was to intrude upon existing and well-established practices nor to circumvent the authority of individual

States to regulate the practice of medicine and pharmacy within their borders. Additionally, while Congress could have explicitly prohibited the compounding of medications for office-use, it did not. Despite this clear Congressional intent, FDA has conveyed a mixed message of whether office-use compounding is allowed.

Maintaining access to essential repackaged and compounded medications for office-use is not only vital for patients, but is consistent with the legislative intent of the DQSA.[136,137] While reinforcing Section 503A of the *Food, Drug and Cosmetic Act* (FDCA) through the passage of the DQSA, Congress came together in a bipartisan and bicameral fashion to make clear that pharmacists' ability to provide compounded medications for a prescriber's administration to or treatment of a patient within their practice should be left to the States -- office-use of compounded medications is currently regulated under state law.[138]

As with office-use, the DQSA did nothing to limit repackaging, and Congressional intent was that FDA would continue to allow the practice of repackaging of medications.[139] Actions by FDA to limit access to repackaged medications, either by requiring a patient-specific prescription in all cases or by not allowing pharmacists to engage in repackaging, would have significant consequences for patients who rely on these therapies.[140] As the DQSA did not explicitly provide for repackaging by either 503A pharmacies or the newly-created 503B outsourcing facilities, physicians and patients are now forced to rely on the FDA for issuance of further guidance on this issue.

Congress' multiple statements in the *Congressional Record* show clear and overwhelming intent that compounded preparations for office-use remain available after the passage of the DQSA. These numerous statements as well as the strong urging from physician and pharmacy stakeholders, directed the agency to not limit office-use medication preparation by 503A compounders. In addition, when FDA considered changes to the Compliance Policy Guide

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[136] Senator Isakson (GA), Senator Alexander (TN), and Senator Boozman (AR). "Drug Quality and Security Act." *Congressional Record* 159: 164 (November 18, 2013) p.S8071. Available from Thomas.gov; Accessed 11/24/2014.

[137] Representative Griffith (VA), Representative Burgess (TX), and Representative Green (TX). "Drug Quality and Security Act." *Congressional Record* p.H5963. Available from: Thomas.gov; Accessed 11/24/2014.

[138] Senator Isakson (GA), Senator Alexander (TN), and Senator Boozman (AR). "Drug Quality and Security Act." *Congressional Record* 159: 164 (November 18, 2013) p.S8071. Available from Thomas.gov; Accessed 11/24/2014.

[139] Senator Harkin (IA), Senator Alexander (TN), and Senator Boozman (AR). "Drug Quality and Security Act." *Congressional Record* 159: 164 (November 18, 2013) p.S8072. Available from Thomas.gov; Accessed 11/24/2014.

[140] Senator Isakson (GA), Senator Alexander (TN), Senator Harkin (IA), Senator Warner (VA), Senator Burr (NC), and Senator Boozman (AR). "Drug Quality and Security Act." *Congressional Record* 159: 164 (November 18, 2013) p.S8071. Available from Thomas.gov; Accessed 11/24/2014.

(CPG) for human compounding several years ago, the draft CPG specifically provided for office-use compounding.[141]

Despite these statements and its own draft guidance, FDA stated in a September 15, 2014 response to a bipartisan letter from Congress that in order to comply with 503A, a compounding pharmacist or physician may not dispense compounded medications for office-use, but rather, must obtain or issue a prescription for an individually identified patient.[142] As a result of these misleading statements by FDA, many States may have taken recent action related to office-use compounding.

The actions by FDA to prohibit all office-use compounding may result in drastically reducing patient access to vital medications. There are numerous examples of medications that 503A traditional compounders currently supply for office-use in quantities that are too small or limited to justify preparation and distribution by a 503B outsourcing facility.[143]

It is also important to recognize that at the present time, the only compounded preparations a 503B outsourcing facility may compound and distribute using bulk ingredients are those products which appear on the FDA shortage list. Until such time as the Pharmacy Compounding Advisory Committee completes its review of bulk ingredients submitted for use by 503B outsourcing facilities, very few of these medications will be legally allowed to be compounded and distributed by them.

Congress disagrees strongly with FDA's statements that the DQSA prohibits compounding and repackaging for office-use. In addition to the statements in the Congressional record and letters from key Members of Congress to the Agency, Congress has included in the House Report 114-2015 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill, 2016 language that states its concerns with FDA's interpretation of section 503A on office use that is inconsistent with the legislative intent of the DQSA and even the agency's own previous positions on office use compounding.

This past week, Congress approved House Report 114-2015. Within that, the Agency has now been directed to issue guidance which specifically addresses how office-use compounding will be permitted. That guidance must be issued within 90 days of the final enactment of the report.

Specifically, the language which will directly impact your Board's regulatory and rule-making activities related to office-use compounding is as follows:

> *Drug Compounding.*--The Committee is concerned that, since passage of the Drug Quality and Security Act (DQSA) of 2013, the FDA has interpreted provisions of Section 503A of the FDCA in a manner inconsistent with its legislative intent and with the

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[141] United States. Department of Health and Human Services. Food and Drug Administration. *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Draft Guidance.* Washington, DC: n.p. 2014. Print.

[142] United States. Department of Health and Human Services. Food and Drug Administration. *Response to Congressional Letter on Office Use.* September 15, 2014.

[143] See Appendix A for a compiled list of examples of medications supplied for office-use.

agency's own previous positions. Specifically, the FDA has taken the position that under 503A, a pharmacist may not compound medications prior to receipt of a prescription and transfer the drugs to a requesting physician or other authorized agent of the prescriber for administration to his or her patients without a patient-specific prescription accompanying the medication. This practice, which is often referred to as `office-use' compounding, is authorized in the vast majority of states and was intended to be allowable under DQSA. The Committee is aware that in 2012, prior to passage of the DQSA, FDA was working on a draft compliance policy guide for 503A of the FDCA that provided guidance on how `office-use' compounding could be done consistent with the provisions of 503A. ***The Committee understands the intent of the DQSA was not to prohibit compounding pharmacists from operation under existing 503A exemptions; therefore, the Committee directs the FDA to issue a guidance document on how compounding pharmacists can continue to engage in `office-use' compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A within 90 days after the enactment of this Act.*** *(emphasis added).* [144]

Our organizations urge the members of your Board to delay consideration of any pending regulatory or policy decisions on the ability of practitioners to obtain and use office-use compounded preparations until such time as the Agency issues its guidance in a manner that is consistent with this new Congressional directive. Additionally, given that FDA's previous position and information which may have been provided to your Board by the Agency may have been contradictory to Congress's intent, we urge you to review and potentially reconsider any recent decisions to prevent, eliminate or restrict office-use compounding within your State.

Sincerely,

Alaska Pharmacists Association (AKPhA)
Alabama Pharmacy Association (APA)
Alliance for Natural Health USA (ANH-USA)
Alliance of Independent Pharmacists of Texas
Ambulatory Surgery Center Association (ASCA)
American Academy of Dermatology Association (AADA)
American Academy of Ophthalmology (AAO)
American Association of Naturopathic Physicians (AANP)
American Pharmacists Association (APhA)
American Society of Cataract and Refractive Surgery (ASCRS)
American Society of Consultant Pharmacists (ASCP)
Arizona Pharmacy Association (AzPA)
Arkansas Pharmacists Association (APA)
California Pharmacists Association (CPhA)
Illinois Pharmacists Association (IPhA)
International Academy of Compounding Pharmacists (IACP)
Michigan Pharmacists Association (MPA)

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[144] See House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill, 2016. Page 67

Minnesota Pharmacists Association (MPhA)
Missouri Pharmacy Association (MPA)
National Alliance of State Pharmacy Associations (NASPA)
National Community Pharmacists Association (NCPA)
Nebraska Pharmacists Association (NPA)
New Hampshire Pharmacists Association (NHPA)
New Jersey Pharmacists Association (NJPhA)
New Mexico Pharmacists Association (NMPhA)
North Carolina Association of Pharmacists (NCAP)
PCCA
Pennsylvania Pharmacists Association (PPA)
South Carolina Pharmacy Association (SCPhA)
South Dakota Pharmacists Association (SDPhA)
Tennessee Pharmacists Association (TPA)
The Ohio Pharmacists Association (OPA)
Virginia Pharmacists Association (VPhA)
Washington State Pharmacy Association (WSPA)

Appendix A

The following are some examples of the medications that 503A traditional compounders currently supply for office-use in quantities that are too small or limited to justify preparation and distribution by a 503B outsourcing facility:

- Topical Phenol used by podiatrists and primary care physicians to treat in-grown toenails.
- Topical cantharidin (one strength is 52.5 mg / ml [0.7%]) used by podiatrists, primary care physicians, and dermatologists for the treatment of warts.
- Topical podophylline used by podiatrists, primary care physicians, and OB/GYNs.
- Topical Diphenylcypropenone in many strengths compounded from raw material and acetone for use by dermatologists treating alopecia areata.
- Topical Squaric acid for use by dermatologists in treating alopecia areata.
- Bleaching gels of various formulas used by dentists in teeth whitening procedures.
- Glycolic acid solutions used by dermatologists in skin peel procedures.
- Trichloroacetic acid solutions used by dermatologists in skin peel procedures.
- Lidocaine, Epinephrine, and Tetracaine (LET or LAT) gel/solution and derivatives used by ERs and Primary Care Physicians as a local anesthetic used to decrease pain while suturing patients – especially pediatric patients.
- Dextrose capsules #0, 00, 000, 1, 2, 3, and 4 for use by Social Work to teach pediatric patients how to swallow capsules.
- Tamsulosin 0.2 mg capsules (open up the 0.4 mg capsules, weigh total contents then weigh in half, pack into #4 capsules) used off-label for kidney stones in pediatric patients.
- Various powder-filled capsules - many formulations out in the industry with mixtures of 3-4 ingredients that may include ciprofloxacin, amphotericin, dexamethasone, clotrimazole, and lidocaine and others for use in Sheehy-House powder insufflators for insertion into the ear to treat refractory external ear infections.
- Topical Sodium Nitrate solution used in labs for diagnosis of cystic fibrosis via sweat testing.
- Topical Pilocarpine Nitrate solution used in labs for diagnosis of cystic fibrosis via sweat testing.
- Hydroxyzine pamoate suspension for use by pediatric dentists for mild sedation
- Combination antibiotic eye drop used by ophthalmology surgery centers.
- EDTA ophthalmic eye drops for surgery
- Bevacizamab (Avastin) repack used by ophthalmology clinics for treatment of wet macular degeneration.
- Alteplase 1 mg / ml syringes when commercial vials are on backorder and shortage from manufacturers.
- Oxymetazoline Nasal Spray + Lidocaine 4% injection compounded 1:1 in an ISO 5 environment and packaged into sterile oral syringes for storage in automated dispensing cabinets for ENT to use with an automizer prior to exam in office.
- Surgical Irrigations

- Bacitracin 50,000 units in 0.9% nacl 3000 ml (bag).
- Bacitracin 50,000 units in 0.9% nacl 1000 ml (bag or bottle).
- Bacitracin 25,000 units in 0.9% nacl 500 ml (bottle).
- Levofloxacin in 0.9% nacl 500 ml (bottle).
- Cefazolin in 0.9% nacl 500 ml (bottle).
- Bacitracin, Gentimicin and Cefazolin in 0.9% nacl 500 ml or 1000 ml (bottle).

- Organ Transplant Irrigations, Soaks and Baths
  - Cardioplegia solutions (mixtures of lidocaine, electrolytes, mannitol, dextrose, etc.).
  - Epinephrine in 0.9% nacl (bottle).
  - Phenylephrine in 0.9% nacl (bag).
- Crash/Emergency Cart drugs/ICU/Ambulance/Helicopter/Airplane
  - Phenylephrine syringes used for Anesthesia/ER crash carts, concentrations of 50 and 100 mcg / ml that are not commercially available; there is chronic backorder and shortage from manufacturers of vials 10 mg / ml to even compound the 50 and 100 mcg / ml syringes.
  - Sodium Bicarbonate used by Anesthesia/ER crash carts, a sterile drug that has been on chronic backorder and shortage from manufacturers.
  - Calcium Chloride used by Anesthesia/ER crash carts/dialysis centers – chronic backorder from manufacturers.
  - Calcium Gluconate used by icus /dialysis centers; chronic backorder from manufacturers.
  - Narcotic drug syringes; fentanyl, sufentanil used for anesthesia in outpatient surgery centers and physician offices.
  - Propofol repackaged into 10 and 20 ml syringes during shortages.
  - Dexmedetomidine straight from diluted commercial vial or compounded with 0.9% NS and concentrated vial, then packaged in syringes.
  - Heparin 500 units / ml (3 ml) compounded then packaged in syringes for dialysis.
  - Heparin 2,000 units / ml (3 ml) compounded then packaged in syringes for dialysis.
  - Heparin 1,000 units / ml (3 and 8 ml) packaged in syringes for dialysis.
  - Lidocaine 1% buffered with nabicarb (0.8 & 5 ml) packaged in syringes for IV starts and dialysis.
  - Lidocaine with nabicarb (0.2 ml) packaged in J-tip syringes for IV starts and shots in ER, surgery centers, inpatient and clinics.
  - Morphine 1 mg / ml compounded using commercial product and 0.9% nacl (1 ml) syringe for storage in automated dispensing cabinets, and anesthesia carts
  - Hydromorphone 0.2 mg / ml for PCA (50 ml) syringe for storage in automated dispensing cabinets within health systems and long term care facilities.
  - Hydromorphone 1 mg / ml for PCA (50 ml) syringe for storage in automated dispensing cabinets within health systems and long term care facilities.
  - Methadone 1 mg / ml compound from commercial product and 0.9% nacl (1 ml) syringe for storage in automated dispensing cabinets within health systems and long term care facilities.

- Morphine 2 mg / ml for PCA (25 ml) syringe prepared from commercial product and 0.9% nacl for storage in automated dispensing cabinets within health systems and long term care facilities.
- Fentanyl 10 mcg / ml NEONATAL (1 and 10 ml) compounded from commercial product and 0.9% nacl and packaged in bar-coded syringes for storage in automated dispensing cabinets within health systems and long term care facilities.
- Heparin 2 units / ml compounded from Heparin and 0.45% nacl commercial products (250, 500 and 1000 ml bags) for storage in automated dispensing cabinets within health systems and long term care facilities.
- Epinephrine 0.01 mg / ml compounded from epinephrine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Epinephrine 0.02 mg / ml compounded from epinephrine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Nicardipine 0.5 mg / ml compounded from Nicardipine and D5W commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Nicardipine 0.5 mg / ml compounded from Nicardipine and 0.9% nacl commercial products (50 ml syringe) for storage in automated dispensing machines within health systems and long term care facilities.
- Dextrose 10% plus 14.6% nacl or 23.4% nacl to prepare D10 and nacl 0.2% (250 ml) bag due to commercial product on chronic mfg b/o (prepared from commercial products).
- Dextrose 10% plus 14.6% nacl or 23.4% nacl plus heparin to equal 1 unit / ml to prepare D10 and nacl 0.2% and Heparin 1 unit / ml (250 ml) bag (prepared from commercial products) may be stored in automated dispensing cabinets.
- Bupivacaine 0.25 % + Epinephrine = 1:200,000 injection for use in surgery and surgery centers.
- Epinephrine 1:100,000 injection prepared from epinephrine and 0.9% nacl commercial products for use in surgery and surgery centers.
- Epinephrine 1:400,000 injection prepared from epinephrine and 0.9% nacl commercial products for use in surgery and surgery centers.
- Lidocaine 0.25% with Epinephrine 1:400,00 units injection prepared from commercial products in a vial for use in surgery and surgery centers.
- Lidocaine 1% with Epinephrine 1:10,000 units injection prepared from commercial products into a vial for use in surgery and surgery centers.
- Ropivacaine 0.2% with Epinephrine 1:200,000 units injection prepared from commercial products into a vial for use in surgery and surgery centers.
- Milrinone 0.2 mg / ml compounded or premix commercial product repackaged into 20 and 50 ml syringes for storage in automated dispensing cabinets.
- Pentobarbital 50 mg / ml commercial product repackaged into 1 ml syringe for cath lab and anesthesia surgery centers.
- Methadone 5 mg / 0.5 ml commercial product repackaged from large commercial vial into 0.5 ml syringes for storage in automated dispensing cabinets.

- Dopamine 1.6 and 3.2 mg / ml compounded or premix commercial product repackaged into 20 and 50 ml syringes for each for storage in automated dispensing cabinets.
- Nitroglycerin 0.4 mg / ml commercial product repackaged into 20 and 50 ml syringes during commercial product manufacturing back order and shortages.
- Fentanyl 50 mcg / ml injection repackaged from commercial product into 8, 24 and 50 ml syringes maybe stored in automated dispensing cabinets.
- Iopamidol (Isovue) 61% injection repackaged into 20 ml syringes during Manufacturing back order and shortages.
- Botulinium Toxin solution reconstituted commercial product and packaged in syringes for office use treatment of spasticity, diagnosis of gastrointestinal disorders and which dermatologists and plastic surgeons also use.
- Ceftriaxone mixed with lidocaine to 350 mg / ml, drawn up in 1.1, 1.4 and 2.2 ml volumes in an ISO 5 environment for storage in an automated dispensing cabinet refrigerator in ers and clinics.

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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

STRATEGIC PHARMACEUTICAL SOLUTIONS, INC., *d/b/a* VetSource Home Delivery, Plaintiff, v. NEVADA STATE BOARD OF PHARMACY, an administrative agency of the State of Nevada; LEO BASCH, an individual; KIRK WENTWORTH, an individual; JASON PENROD, an individual; KEVIN DESMOND, an individual; CHERYL BLOMSTROM, an individual; and TALLIE PEDERSON, an individual, Defendants.	CASE NO.: **COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF FOR VIOLATIONS OF THE SHERMAN ACT AND STATE LAW**

I. INTRODUCTION

1. Last year, the Supreme Court decided *North Carolina State Board of Dental Examiners v. Federal Trade Commission*, 135 S. Ct. 1101 (February 25, 2015) ("***N.C. Dental***"). In this landmark decision, the Supreme Court held that a state agency controlled by active market participants in the same occupation as regulated by the agency must be actively supervised by a politically accountable state official in order to enjoy immunity from federal antitrust laws, reasoning that "[w]hen a state empowers a group of active market participants to decide who can participate in its market, and on what terms, the need for supervision is manifest." 135 S. Ct. at 1114. Thus, the Supreme Court held that a state agency composed primarily of market participants is immune from the federal antitrust laws only if its anticompetitive actions are (i) in pursuit of a clearly articulated state policy and (ii) are actively supervised by the state.

2. The Nevada State Board of Pharmacy is nominally a state agency (the Board and its members, collectively, the "**Pharmacy Board**"), but is controlled by private individual members who as licensed pharmacists actively participate and compete in the market for the sale and distribution of Pet Medications in Nevada ("**Relevant Market**") ("**Pet Medications**", for the purpose of this action, means and includes, prescription veterinary medicines prescribed and intended for household pets and companion animals, including privately owned horses, but not including medicines for commercial livestock, animals kept in and by zoos or other commercial establishments, and not including over-the-counter pet medicines). These Pharmacy Board members are misusing their position to seek to exclude innovative competitors such as Plaintiff from effectively competing in the distribution of Pet Medications in Nevada. In doing so, the Pharmacy Board is both (i) exceeding the limited authority granted to them by the State of Nevada (*i.e.*, not acting pursuant to any clearly articulated state policy) and (ii) exercising their authority over competitors without adequate (indeed, without any) state oversight and supervision. Accordingly, the Pharmacy Board's conduct is not entitled to immunity from the federal antitrust laws. Absent state-action immunity, the Defendants' actions violate the Sherman Act, 15 U.S.C. §§ 1 and 2.

3. Plaintiff Strategic Pharmaceutical Solutions Inc. d/b/a VetSource Home Delivery ("**VetSource**" or "**Plaintiff**") is an out-of-state pharmacy, registered with the Defendant Pharmacy Board (license number PH02320). VetSource competes in the Relevant Market by shipping Pet Medications directly to pet owners at the direction and prescription of licensed veterinarians ("**Direct Shipping**") ("**veterinarians**" as used in this Complaint includes individual veterinarians, veterinary practices, and veterinary hospitals). VetSource's business model benefits consumers in the form of increased choice and convenience, more competitive pricing for Pet Medications, and increased safety and quality. VetSource's business model also provides veterinarians and pet owners with an alternative to the less efficient and increasingly cost-prohibitive practice of veterinarians directly disbursing Pet Medications to their patient-clients (which the veterinarians are permitted to do under state law), and merely applies to Pet Medications the "drop-shipping" model of disbursing veterinary medicines that has long been permitted under Nevada state law.

4. VetSource's innovative Direct Shipping business model, however, threatens individual and traditional pharmacists and pharmacies with increased competition and potential loss of business and profits. To stifle this innovative competition, the Board and its members have taken actions, based on unfounded allegations that VetSource's business model violates regulations of the Nevada State Board of Veterinary Medical Examiners ("**Veterinary Board**"), effectively seeking that VetSource either stop its innovative competitive practices or face having its statutorily required pharmacy license revoked by the Pharmacy Board (thus forcing VetSource out of the market).

5. The Pharmacy Board's unlawful and unreasonable exclusion of VetSource as a competitor in the state has injured competition in the Relevant Market and, by seeking to wrongfully exclude a major competitor and exclude innovative, pro-consumer, competitive Direct Shipping practices, has caused and will cause antitrust injury to VetSource. Accordingly, VetSource brings this action under the federal antitrust laws (and corresponding state competition laws) to challenge and seek redress from the anticompetitive, exclusionary,

monopolistic conduct and conspiracy in restraint of trade of the Board and its members (the Pharmacy Board or "**Defendants**") by having the Pharmacy Board's actions declared illegal and a violation of the Sherman Act and state law; to obtain a permanent injunction against the anticompetitive conduct complained of herein; and to recover from the Defendants actual and treble damages suffered by VetSource.

II. THE PARTIES

6. Plaintiff VetSource is an Oregon corporation headquartered in Portland, Oregon and licensed to operate in Nevada under Nevada State Board of Pharmacy license number PH02320.

7. Defendant Nevada State Board of Pharmacy is an agency of the State of Nevada.

8. a. Defendant Leo Basch, Pharmacy Board member, (Nevada Pharmacy License number 12431), resides in Las Vegas, Nevada. He is sued in his individual and official capacities.

b. Defendant Kirk Wentworth, Pharmacy Board member, (Nevada Pharmacy License number 07247), resides in Las Vegas, Nevada. He is sued in his individual and official capacities.

c. Defendant Jason Penrod, Pharmacy Board member, (Nevada Pharmacy License number 16876), resides in Reno, Nevada. He is sued in his individual and official capacities.

d. Defendant Kevin Desmond, Pharmacy Board member, (Nevada Pharmacy License number 08731), resides in Reno, Nevada. He is sued in his individual and official capacities.

e. Defendant Cheryl Blomstrom, Pharmacy Board member, resides in Carson, City, Nevada. She is sued in her individual and official capacities.

f. Defendant Tallie Pederson, Pharmacy Board member, (Nevada Pharmacy License number 17431), resides in Las Vegas, Nevada. She is sued in her individual and official capacities.

9. a. Co-conspirator Larry L. Pinson, Pharmacy Board Executive Secretary, (Nevada Pharmacy License number 06015), resides in Reno, Nevada.

b. Co-conspirator Dave Wuest, Deputy Pharmacy Board Executive Secretary, (Nevada Pharmacy License number 11245), resides in Reno, Nevada.

10. Upon information and belief, others have encouraged and conspired with the Pharmacy Board to commit the exclusionary conduct complained of herein.

11. At all relevant times, each Defendant and co-conspirator was an agent of each of the remaining Defendants and their co-conspirators and, in performing the acts alleged in this Complaint, was acting within the course and scope of such agency. Each Defendant and co-conspirator ratified or authorized the wrongful acts of each of the other Defendants and their co-conspirators. Defendants are individually and collectively sued as participants, co-conspirators, and aiders and abettors in the improper acts and transactions that are the subject of this action.

III. JURISDICTION AND VENUE

12. VetSource brings this lawsuit against Defendants seeking declaratory judgment pursuant to 28 U.S.C. § 2201 and monetary and injunctive remedies related to the Defendants' violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2 pursuant to 15 U.S.C. §§ 15(a) and 26 and for violations of corresponding state law, including N.R.S. § 598A.060.

13. This Court has subject matter jurisdiction over the claims asserted in this lawsuit pursuant to 28 U.S.C. §§ 1331 and 1337 and 15 U.S.C. §§ 15(a) and 26, and pendant and supplementary jurisdiction

14. This Court has personal jurisdiction over each Defendant because each Defendant resides in Nevada and has substantial, continuous contacts with Nevada.

15. Venue is proper in this District because all Defendants are residents of Nevada. 28 U.S.C. § 1391(b)(1). Venue is also proper in this District because a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District. 28 U.S.C. § 1391(b)(2).

IV. UNITED STATES TRADE AND COMMERCE, THE RELEVANT MARKET, BARRIERS TO ENTRY AND INJURY TO COMPETITION

16. The Pharmacy Board's activities and the conduct of Defendants and their co-conspirators occurred in and affected a substantial portion of interstate commerce, including trade and commerce to, from, and within Nevada. The sale and distribution of Pet Medications occurs in the interstate commerce of the United States.

17. VetSource competes with individual pharmacists and traditional pharmacies in the distribution of Pet Medications in the State of Nevada. The distribution of Pet Medications is the relevant product market ("**Product Market**"). The relevant geographic market is the State of Nevada ("**Geographic Market**"). The Relevant Market is thus the distribution of Pet Medications in the State of Nevada. Direct Shipping is part of the Relevant Market.

18. By law, to distribute Pet Medications in Nevada, an individual or entity must have a license from the Pharmacy Board and abide by other Pharmacy Board regulations. Obtaining such a license is a lengthy process, limited by education and other qualifications, and constitutes a barrier to entry to the Relevant Market.

19. Even for licensed pharmacists or pharmacy companies, a significant investment of time, resources and effort is needed to enter the Relevant Market by Direct Shipping (including contracting with veterinarians), which time, resources and effort are also a barrier to entry to the Relevant Market. The current proceeding of the Pharmacy Board – which would have the effect of excluding under color of state law any competitor seeking to distribute Pet Medications through Direct Shipping – is an additional significant barrier to entry. These barriers to entry, individually and collectively, are such that any new competition by a Direct Shipping or similar method is unlikely to occur at all or would not be likely, timely and sufficient to provide effective competition to existing market participants and members of the Pharmacy Board.

20. The Pharmacy Board, through its ability to exclude competitors from the market under color of state law, has market power in the Relevant Market.

21. The Pharmacy Board's actions complained of herein have and will have the direct effect of excluding a major competitor from providing Pet Medications in the State of Nevada; excluding competition by the Direct Shipping method; causing or tending to cause a monopoly; thus reducing competition and lowering consumer choice for purchasers of Pet Medications in the Relevant Market.

22. The Pharmacy Board's actions will also have a direct, negative effect on quality, safety and efficiency in the distribution of Pet Medications in the Relevant Market.

23. These illegal and exclusionary actions will have a direct impact on and cause injury to VetSource. This constitutes injury of the type the antitrust laws were intended to prevent.

V. ADDITIONAL FACTUAL ALLEGATIONS

A. The VetSource Business Model

24. In 2008, VetSource began its primary business as an outsourced pharmacy services provider for veterinarians that contract for VetSource to provide its services at fair market value.

25. As stated in each of VetSource's contracts with its veterinarian customers, the following key events occur each time a veterinarian – who is licensed to and can legally prescribe and dispense Pet Medications in Nevada – prescribes a Pet Medication and the veterinarian's pet owner client requests or agrees that the Pet Medication prescription be filled and delivered to his/her home through Direct Shipping. First, upon receiving a request from a contracted veterinarian to process a transaction, VetSource Wholesale (a separate division of VetSource) sells the Pet Medication, wholesale, to the veterinarian. In Nevada, this occurs under Nevada Board of Pharmacy wholesale license number WH01459 or WH01461. The contracted veterinarian takes title to the Pet Medication, but not physical possession.

26. Next, the contracted veterinarian sells the Pet Medication to the pet owner at a retail price set by the veterinarian. The Pet Medication is then consigned by the veterinarian to VetSource Home Delivery Pharmacy for processing pursuant to an authorized prescription. In

Nevada, this processing occurs under VetSource's Nevada Board of Pharmacy license number PH02320.

27. Then, at the direction of the licensed, prescribing veterinarian, VetSource Home Delivery Pharmacy mails the prescribed and consigned Pet Medication directly to the pet owner. VetSource collects the total cost of the transaction, including the retail price of the product (which is set individually by each veterinarian), plus applicable shipping charges and retail taxes from the pet owner, and then deposits these sums into the individual veterinarian's e-Merchant account.

28. The veterinarian pays VetSource an agreed fair market price for the product and for the services provided by VetSource via separate charges by VetSource to the individual veterinarian's e-Merchant account. The charges include one for the wholesale cost of the Pet Medication and one for VetSource's pharmacy processing fee plus delivery charges. The remainder of the funds in the veterinarian's account represents the retail taxes due by the veterinarian to the State of Nevada and the veterinarian's profit margin on the sale to the pet owner, which is property of the veterinarian. The contracted veterinarian may choose to charge a pet owner an amount for any given prescription that is more or less than the wholesale cost of the product and the services provided by VetSource.

29. No veterinarians or pet owners are required to use VetSource to fill their prescriptions, and a contracted veterinarian may choose to use VetSource for some but not all of its patients' prescriptions. Those who do use VetSource as an outsourced pharmacy service provider pay fair market value for the product and services, just as they would for any third-party fill service and delivery service.

30. VetSource currently operates in all 50 states. It is licensed and in good standing in each of these states as required and purchases all of its veterinary pharmaceutical products directly from leading animal health manufacturers and distributors.

31. VetSource's business model and relationships with veterinarians (the same business model under attack by the Pharmacy Board in this case) have been reviewed in detail by

various state boards of pharmacy, expert legal counsel for these boards, trade and professional associations, and regulatory agencies. These entities have specifically examined issues related to kickbacks, rebates, and fee-splitting on a state-by-state basis. None of these reviewing entities have concluded that VetSource's business model violates any applicable laws, including applicable pharmacy statutes and regulations substantially similar to those the Pharmacy Board claims to be enforcing against VetSource now. At least eight of these entities have found VetSource's business model to be lawful and proper; the Nevada Pharmacy Board's actions aside, none have found VetSource's business model to be unlawful or improper.

B. The Use of VetSource's Services

32. VetSource's business model results in more competitive pricing, greater efficiency in the delivery of Pet Medications, and increased quality and safety for Pet Medication purchasers, including better patient compliance and lower error rates.

33. VetSource contracts with just under 5,000 veterinarians nationwide, including at least 35 in Nevada, involving approximately $200,000 in annual revenue in Nevada.

34. VetSource distributes Pet Medications to over 250,000 consumers nationwide.

35. Pet Medications are an approximately $14 billion (retail) industry nationwide.

C. Composition of the Pharmacy Board

36. The Pharmacy Board is an agency of the State of Nevada that has primary jurisdiction over the licensing and regulation of persons operating or engaging in the practice of pharmacy.

37. Under Nevada Revised Statute 639.030, the Pharmacy Board shall be comprised of seven members, six of which "are registered pharmacists in the State of Nevada, are actively engaged in the practice of pharmacy in the State of Nevada and have had at least 5 years experience as registered pharmacists preceding the appointment" and one of which "is a representative of the general public and is not related to a pharmacist registered in the State of Nevada by consanguinity or affinity within the third degree." N.R.S. § 639.030. Six of the

seven defendant members of the Pharmacy Board are competitors in the Relevant Market, and have business relationships with others in the market.

38. No politically accountable state official has or exercises the power to review the Pharmacy Board's acts and disapprove those that do not accord with state policy. Indeed, no state official outside the Pharmacy Board has any such review power.

D. Defendants' Anticompetitive Conduct

39. The Pharmacy Board has a history of engaging in anticompetitive conduct under the guise of enforcing the state's pharmacy regulations. For instance, upon information and belief, for years the Pharmacy Board has engaged in anticompetitive investigations and/or letter-writing campaigns against other outsourced pharmacy competitors designed to restrict competition.

40. On February 5, 2015, co-conspirator Dave Wuest, Deputy Executive Secretary of the Pharmacy Board (also an active participant in the Relevant Market), contacted VetSource's pharmacy manager, Laura Hysen, to solicit information about VetSource. After a very brief explanation of the VetSource business model, co-conspirator Wuest communicated to Ms. Hysen that he was certain the VetSource model violated the Pharmacy Board's anti-kickback regulation and, in an attempt to intimidate VetSource into ceasing operations in Nevada, stressed that the Pharmacy Board would win if VetSource tried to fight its position.

41. Co-conspirator Wuest's conclusions on behalf of the Pharmacy Board were made before complete materials factually documenting VetSource's legitimate business model were provided or reviewed by the Pharmacy Board, demonstrating the pretextual nature of the Pharmacy Board's unreasonable anticompetitive conduct.

42. On February 9, 2015, counsel for VetSource had a telephone conference with counsel for the Pharmacy Board to again discuss VetSource's business model. Following this discussion, Pharmacy Board counsel noted that he was inclined to issue VetSource a "cease and desist" letter. In response, VetSource's counsel requested the opportunity to submit in writing a detailed explanation of VetSource's business model. Pharmacy Board counsel agreed. That

same day, counsel for VetSource submitted a detailed explanation of VetSource's business model to Pharmacy Board counsel and co-conspirator Wuest.

43. On February 27, 2015, without calling VetSource's counsel to discuss or ask questions about the substance of VetSource's submission, the Pharmacy Board, in furtherance of the conspiracy to eliminate VetSource from the Relevant Market, issued a letter to VetSource stating "Strategic Pharmaceutical Solutions Inc. and/or VetSource must discontinue their 'outsourced hospital pharmacy service' immediately." As a pretext for its illegal and unreasonable anticompetitive exclusionary conduct, the February 27 letter alleged violations primarily based on a flawed (and improper) interpretation of regulations promulgated by the Veterinary Board.

44. On March 12, 2015, in response to the Pharmacy Board's February 27 letter, VetSource submitted to the Pharmacy Board a Petition for Declaratory Order or Advisory Opinion ("**Petition**") to create an opportunity for VetSource to meaningfully defend against the allegations in the February 27 letter. In a cover email accompanying VetSource's Petition, VetSource also requested an informal review and interpretation from the Pharmacy Board regarding its business model prior to being forced to discontinue its business in Nevada.

45. The same day (March 12, 2015), Pharmacy Board counsel called counsel for VetSource to inform him that, despite the clear language in the February 27, 2015 letter (directing VetSource to "discontinue their 'outsourced hospital pharmacy service' immediately"), the Pharmacy Board did not intend the letter to be a cease and desist letter.

46. The filing of VetSource's Petition and the apparent misunderstanding with regard to the intent behind the February 27 letter prompted the Pharmacy Board to schedule informal meetings between representatives of VetSource, the Pharmacy Board, and the Veterinary Board, all of which took place on April 30, 2015.

47. As part of the April 30, 2015 meetings, the parties agreed that VetSource should attend the July meetings of both the Pharmacy Board and the Veterinary Board to provide additional evidence demonstrating VetSource's compliance with Nevada law. In reliance on this

agreement, VetSource submitted a request that its Petition be held in abeyance and initiated contact with both Boards to arrange to appear at their respective July meetings.

48. Despite the understandings VetSource believed had been reached at the April 30 meetings, on May 29, 2015, the Pharmacy Board issued another cease and desist letter in furtherance of the conspiracy to eliminate VetSource from the Relevant Market.

49. Thereafter, on or about June 18, 2015, the Pharmacy Board, again, in furtherance of the conspiracy to eliminate VetSource from the Relevant Market, filed an Accusation and Notice of Intended Action, initiating a proceeding to have VetSource's pharmacy license revoked or suspended based on the unfounded allegation that VetSource's business model violates the Pharmacy Board's anti-kickback regulation.

50. On September 18, 2015, the Pharmacy Board filed an Amended Accusation and Notice of Intended Action, reviving its unfounded accusation that VetSource's business model violates certain Veterinary Board regulations.

51. Upon information and belief, the Pharmacy Board through its members and staff have also communicated to veterinarians (including both veterinarians with whom VetSource had existing contracts and veterinarians with whom VetSource was seeking and reasonably expected to have contractual relations) in Nevada that the veterinarians are prohibited from doing business with VetSource and that VetSource's Direct Shipping violates Nevada law. These comments have caused certain veterinarians to cease or to avoid doing business with VetSource.

52. VetSource responded to both of the Pharmacy Board's Accusations denying the allegations and defending its business model as lawful and proper under Nevada law. VetSource has also taken steps to inform the Pharmacy Board of the Pharmacy Board's lack of authority to interpret and enforce the Veterinary Board's regulations and of the illegal anticompetitive nature of the Pharmacy Board's conduct.

53. A hearing on the Pharmacy Board's Amended Accusation, originally scheduled for December 3, 2015, has been continued to March 3, 2016; and the Pharmacy Board has

indicated its intent to go forward with the hearing and possibly impose immediate sanctions on VetSource on that date.

54. While VetSource has refused to be intimidated by the Pharmacy Board's unlawful and anticompetitive tactics and has continued to distribute Pet Medications to consumers in the Relevant Market, upon information and belief, at least two other outsourced pharmacy competitors targeted by the Pharmacy Board either limited their pharmacy activities in Nevada to those acceptable to the Pharmacy Board or stopped distributing Pet Medications in Nevada altogether.

55. If carried through, the Pharmacy Board's current actions would have the effect of eliminating the ability of VetSource to compete in the market for Pet Medications in Nevada through its innovative, competitive and consumer friendly Direct Shipping model.

56. Because of pharmacy regulations in other states, known to the Pharmacy Board, any adverse (but unfounded) finding against VetSource by the Pharmacy Board would have a foreseeable impact on VetSource's ability to continue to compete and distribute Pet Medications in other states.

E. No Clearly Articulated State Policy

57. The Pharmacy Board's anticompetitive activity is not, and has not been, in pursuit of a clearly articulated state policy. In fact, the Pharmacy Board's anticompetitive activity both exceeds its statutory authority and has been in direct contravention of state policy.

58. That the Pharmacy Board is acting in direct contravention of state policy is demonstrated by the fact that the State of Nevada has allowed, and state statutes and regulations specifically permit, licensed pharmacies to ship medications prescribed by offsite veterinarians directly to farms and ranches using business models substantially similar to VetSource's Direct Shipping. VetSource has simply adapted this practice for domestic Pet Medications.

59. The Pharmacy Board's Amended Accusation and Notice of Intended Action, and other actions and communications claiming to be under color of state law, are a pretext for the Pharmacy Board's illegal and unreasonable anticompetitive exclusionary conduct.

60. Absent a clearly articulated state policy (and active state supervision), the Pharmacy Board has no authority to exclude current competitors or potential new entrants from the Relevant Market in which the professional Pharmacy Board members actively compete.

61. The Pharmacy Board has no legislative authority to interpret or enforce regulations promulgated by the Veterinary Board. *See* N.R.S. 639.090 ("The members of the [Pharmacy] Board, its inspectors and investigators are designated and constituted agents for the enforcement and carrying out of the provisions of this chapter [639][.]") (emphasis added); N.R.S. 639.097 ("The [Pharmacy] Board may bring an action to enjoin any act which would be in violation of the provisions of this chapter [639].") (emphasis added).

62. Accordingly, the Pharmacy Board and its staff have unlawfully usurped power not granted to the Pharmacy Board by Nevada law by attempting to interpret and enforce the Veterinary Board's regulations, contained in Chapter 638 of the Nevada Revised Statutes.

63. By taking these actions in excess of its statutory authority, the Pharmacy Board is not acting pursuant to any clearly articulated state policy.

64. Being outside of any clearly articulated state policy, the Defendants' actions are not entitled to state-action immunity from antitrust liability under *N.C. Dental.*

F. Not Actively Supervised

65. Even if one could find that the Pharmacy Board has been acting pursuant to a clearly articulated state policy (which one could not), the Pharmacy Board is not actively supervised by politically accountable officials of the State of Nevada.

66. No politically accountable state official has or exercises the power to review the Pharmacy Board's acts and disapprove those that do not accord with state policy. No politically accountable state official reviews the substance of the Pharmacy Board's decisions or has the power to veto or modify particular decisions of the Pharmacy Board to ensure they accord with state policy.

67. For lack of active state supervision, the Defendants' actions are not entitled to state-action immunity from antitrust liability under *N.C. Dental.*

G. Impact on and Injury to VetSource

68. While VetSource has continued to provide its services to its contracted veterinarians in the Relevant Market in the face of the Pharmacy Board's unlawful and anticompetitive conduct, other competitors in the Relevant Market have been, and potential new entrants are likely to be, dissuaded by the Pharmacy Board's anticompetitive conduct.

69. If the Pharmacy Board succeeds in imposing its position, (i) a significant, effective and innovative competitor would be eliminated from the Relevant Market, in whole or in significant part, (ii) Direct Shipping as an effective and innovative method of competition would be eliminated from the Relevant Market, and (iii) competition in the distribution of Pet Medications would be reduced, consumer choice in the purchase of Pet Medications would be limited, and quality and safety in the distribution of Pet Medications in the Relevant Market would decrease. Allowing the Pharmacy Board's anticompetitive conduct to continue would also increase barriers to entry in the Relevant Market.

70. These results are the direct, intended and foreseeable result of the Pharmacy Board's conduct in restraint of trade and would be to the detriment of Pet Medication consumers in Nevada and competitors in the Relevant Market.

71. The impact of the Pharmacy Board's actions would also cause dramatic and irreparable injury to VetSource, which will effectively be put out of business in Nevada and have its business nationwide placed in jeopardy.

72. The loss of VetSource's ability to lawfully distribute Pet Medications in the Relevant Market and to continue its proper Direct Shipping method of business would cause irreparable injury to VetSource.

73. In addition to such irreparable injury, the Pharmacy Board's illegal actions, conspiracy and activities in restraint of trade will cause significant monetary damage to VetSource.

COUNT I

Declaratory Judgment

74. VetSource incorporates by reference as if fully set forth here the allegations in all the foregoing paragraphs of this Complaint.

75. There is an actual, current dispute and controversy between VetSource and the Pharmacy Board as to the Pharmacy Board's actions alleged herein being in violation of the Sherman Act and Nevada state law.

76. VetSource seeks a determination and declaration that (i) the Pharmacy Board's actions complained of herein are an illegal restraint of trade and may tend to cause a monopoly, and thus are in violation of the Sherman Act (sections 1 & 2); (ii) that the Board and its members are not entitled to state action immunity in carrying out the actions complained of herein; and (iii) that Board and its members may not continue the activities complained of herein against VetSource.

COUNT II

Combination and Conspiracy in Restraint of Trade In Violation of Section 1 of the Sherman Act

77. VetSource incorporates by reference as if fully set forth here the allegations in all the foregoing paragraphs of this Complaint.

78. As described above, beginning at least as early as February 2015 and continuing through at least the date of this Complaint, the Pharmacy Board, its members and their co-conspirators entered into a continuing agreement, understanding, combination and/or conspiracy in restraint of trade, resulting in harm both to competition generally and to Plaintiff VetSource specifically, in violation of Section 1 of the Sherman Act.

79. The Defendants' conduct complained of herein constitutes (i) an illegal attempt to exclude VetSource as a lawful competitor from the Relevant Market; and (ii) an illegal attempt to exclude the innovative, efficient and pro-consumer practice of Direct Shipping as a means of competition in the Relevant Market.

80. The direct, foreseeable and intended result of this conduct is to reduce competition in the distribution of Pet Medications in Nevada, limit consumer choice in the purchase of Pet Medications, and decrease quality and safety in the distribution of Pet Medications in the Relevant Market, all in violation of the Sherman Act.

81. Defendants' actions have forced other competitors to withdraw from the Relevant Market, have caused some veterinarians to cease or avoid doing business with VetSource and have raised barriers to entry in the Relevant Market.

82. Defendants' actions constitute a boycott, a collective refusal to deal and the exclusion of a competitor from the Relevant Market by market participants with market power, and thus are a *per se* antitrust violation. In the alternative, the Defendants' conduct constitutes an unreasonable restraint of trade. The actions of Defendants complained of herein violate section 1 of the Sherman Act. 15 U.S.C. § 1.

83. Defendants' unlawful combination and conspiracy injured or will injure competition in the Relevant Market and proximately caused or will cause VetSource economic loss and damages. This damage by reason of reduced competition, injury to competition, reduced consumer choice and decreased quality and safety, is the type of injury the antitrust laws were intended to prevent. VetSource has thus suffered, will suffer and will continue to suffer antitrust injury.

84. VetSource is entitled to damages equal to three time its economic losses, in an amount to be demonstrated, jointly and severally from each Defendant, plus the cost of this action including attorneys' fees.

COUNT III

Monopolization and Attempted Monopolization In Violation of Section 2 of the Sherman Act

85. VetSource incorporates by reference as if fully set forth here the allegations in all the foregoing paragraphs of this Complaint.

86. The Board and its members have market power, including the ability to exclude competition, in the Relevant Market.

87. As described above, beginning at least as early as February 2015 and continuing through at least the date of this Complaint, Defendants and their co-conspirators have monopolized, through the willful acquisition, maintenance, and/or enhancement of monopoly power; attempted to monopolize; and/or combined and conspired to monopolize the Relevant Market, resulting in harm both to competition generally and to Plaintiff VetSource specifically, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

88. Defendants' unlawful monopolization, attempted monopolization, and/or combination and conspiracy to monopolize threaten to injure competition in the Relevant Market and will result in the unlawful exclusion of Plaintiff from that Market. Defendants' unlawful monopolization, attempted monopolization, and/or combination and conspiracy to monopolize will result in the elimination of the innovative and efficient Direct Shipping method of competition from the Relevant Market.

89. The direct, foreseeable and intended result of this unlawful monopolization, attempted monopolization, and/or combination and conspiracy to monopolize is to reduce competition in the distribution of Pet Medications, reduce consumer choice in the purchase of Pet Medications, and decrease quality and safety in the distribution of Pet Medications, all in violation of the Sherman Act.

90. Defendants' actions have forced other competitors to withdraw from the Relevant Market, have caused some veterinarians to cease or avoid doing business with VetSource and have raised barriers to entry in the Relevant Market.

91. Defendants' monopolization, attempted monopolization, and/or combination and conspiracy to monopolize injured or will injure competition in the Relevant Market and proximately caused or will cause VetSource economic loss and damages. This damage by reason of reduced competition, injury to competition, reduced consumer choice and decreased

quality and safety, is the type of injury the antitrust laws were intended to prevent. VetSource has thus suffered, will suffer or will continue to suffer antitrust injury.

92. VetSource is entitled to damages equal to three time its economic losses, in an amount to be demonstrated, jointly and severally from each Defendant, plus the cost of this action including attorneys' fees.

COUNT IV

Nevada Unfair Trade Practices

93. VetSource incorporates by reference as if fully set forth here the allegations in all the foregoing paragraphs of this Complaint.

94. Defendants' actions complained of herein also violate the Nevada Unfair Trade Practices Act, N.R.S. § 598A.060.

95. The Nevada Unfair Trade Practices Act is construed in conformity with the federal antitrust laws.

96. Defendants' violation of the Nevada Unfair Trade Practices Act has caused and will cause injury to VetSource.

97. VetSource is entitled to damages for Defendants' violation of the Nevada Unfair Trade Practices Act, in an amount to be demonstrated.

COUNT V

Injunctive Relief

98. VetSource incorporates by reference as if fully set forth here the allegations in all the foregoing paragraphs of this Complaint

99. VetSource has a right to compete lawfully in the Relevant Market.

100. VetSource's Direct Shipping method is a legal, innovative, competitive and efficient method of competition.

101. The loss or infringement of VetSource's right to compete lawfully in the Relevant Market cannot, or cannot be fully, be measured or compensated in money damages.

102. The harm to competition in the Relevant Market resulting from VetSource's exclusion from competition, or from the exclusion of the Direct Shipping method of competition, cannot be fully remedied by money damages.

103. The impact of Defendants' attempt to exclude VetSource from the Relevant Market, and the impact of such action on VetSource's ability to do business as a licensed distributor of pharmaceutical products in other states, cannot reasonably be measured in money damages, and cannot be remedied by, or solely remedied by, an award of money damages.

104. If the activities of the Board and its members complained of herein are allowed to continue, VetSource will be irreparably injured.

105. VetSource is entitled to a permanent injunction against the activities of the Board and its members seeking to illegally exclude VetSource from competing and participating in the Relevant Market. If Defendants continue or attempt to continue their actives during the pendency of this case, VetSource may also seek and be entitled to a preliminary injunction against such activity by Defendants.

RELIEF REQUESTED

WHEREFORE, for all the above reasons, VetSource asks this Court to enter its judgment in favor of VetSource and against Defendants:

(i) Finding and declaring that the activities of the Board and its members in attempting and seeking to exclude VetSource from competing in the Relevant Market are a contract, combination and conspiracy in restraint of trade in violation of section 1 of the Sherman Act;

(ii) Finding and declaring that the activities of the Board and its members in attempting and seeking to exclude VetSource from competing in the Relevant Market, including excluding Direct Shipping as a method of competition in the Relevant Market, monopolizes, attempts to monopolize, and/or is a combination and conspiracy to monopolize in violation of section 2 of the Sherman Act;

(iii) Finding that the activities of the Board and its members in attempting and seeking to exclude VetSource from competing in the Relevant Market, are actions of active market participants in the same market, not acting pursuant to a clearly articulated state policy, and not actively supervised by politically accountable state officials, and are thus not entitled to state action immunity under the antitrust laws of the United States;

(iv) Finding that the activities of the Board and its members complained of herein in violation of the Sherman Act sections 1 and 2 have caused damages to VetSource and awarding VetSource, jointly and severally against all Defendants, treble the amount of such damages, as may be demonstrated;

(v) Awarding VetSource, jointly and severally against all Defendants, the cost of this action, including its reasonable attorneys' fees;

(vi) Finding that the activities of the Board and its members complained of herein are in violation of the Nevada State Unfair Competition Act, and awarding VetSource damages, in an amount to be demonstrated, caused by such violations;

(vi) Permanently enjoining the Board and its members from attempting to exclude VetSource, including its innovative and efficient Direct Shipping method of competition, from competing in the Relevant Market;

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(vii) Awarding such other and further relief as this Court may find to be just and proper.

DATED this 29th day of January, 2016.

HOLLEY DRIGGS WALCH
FINE WRAY PUZEY & THOMPSON

/s/ James D. Boyle

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Nevada Bar No. 08384
BRITTANY W. PUZEY, ESQ.
Nevada Bar No. 13745
400 South Fourth Street, Third Floor
Las Vegas, Nevada 89101

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1101 Connecticut Ave., NW – Suite 1000
Washington D.C. 20036

KEVIN E. BURR, ESQ.
PAUL GWILT, ESQ
1650 Farnam Street
Omaha, Nebraska 68102

(Pro Hac Vice Applications Forthcoming)

Attorneys for Plaintiff

State of Iowa
Board of Pharmacy

400 S.W. Eighth Street, Suite E, Des Moines, IA 50309-4688
https://pharmacy.iowa.gov/
Telephone: (515)281-5944 Facsimile: (515)281-4609

January 22, 2016

Helen Eddy, AVP, Pharmacy Services
Hy-Vee, Inc.
5820 Westown Parkway
West Des Moines, IA 50266

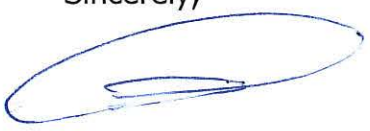
Dear Ms. Eddy,

Thank you for submitting Hy-Vee Pharmacy Fulfillment Center's (IA License #1472) Fourth Quarter 2015 Error Report for dates ranging from October 1, 2015 through December 31, 2015. While the Board appreciates this information and believes Hy-Vee should continue to provide this information, this Error Report does not address the elements required to be addressed when the Board initially granted Hy-Vee's waiver request:

"The Board requires that the Pharmacy document and report to the Board, on a quarterly basis, information and evidence of the redirection of pharmacist and pharmacy services and of pharmacist activities including growth of medication therapy management activities, administration of immunizations, and other redirected pharmacist services in the retail pharmacies being served by the Central Fill Pharmacy."

Please revise your 2015 Fourth Quarter report to include the required elements. All future quarterly reports submitted to the Board must also comply with this requirement.

Sincerely,



Andrew Funk

Fields of Opportunities

STATE OF IOWA

TERRY BRANSTAD
GOVERNOR
KIM REYNOLDS
LT. GOVERNOR

BOARD OF PHARMACY
LLOYD K. JESSEN, RPh, JD
EXECUTIVE DIRECTOR

June 26, 2013

COPY

Kristin Williams, R.Ph., Pharm.D.
Assistant Vice-President, Pharmacy Services
Pharmacist in Charge, Central Fill Pharmacy
Hy-Vee, Inc.
5820 Westown Parkway
West Des Moines, IA 50266

Dear Ms. Williams:

The Iowa Board of Pharmacy (Board), at their regularly scheduled meeting on June 26, 2013, approved the request for waiver of Board rules pursuant to 657 IAC 9.17(155A). The Petition for Waiver relates to practices at the proposed Hy-Vee Central Fill Pharmacy in West Des Moines.

The project has been approved for a period of five (5) years from the date the pharmacy opens for business. The project is subject to compliance with the policies and procedures and assurances included in and with the submitted request for waiver. Further, the Board prohibits the dispensing of controlled substances through the Central Fill Pharmacy.

The Board requires that the Pharmacy document and report to the Board, on a quarterly basis, information and evidence of the redirection of pharmacist and pharmacy services and of pharmacist activities including growth of medication therapy management activities, administration of immunizations, and other redirected pharmacist services in the retail pharmacies being served by the Central Fill Pharmacy.

Any proposed change to the information submitted to the Board in support of or in addenda to the Petition for Waiver must be submitted to the Board for prior approval by submitting an amended Petition for Waiver. The amended Petition must include a detailed explanation of the reason for the proposed change and must respond to all elemental issues to be addressed by a Petition for Waiver.

Sincerely,

Therese Witkowski
Executive Officer

A Helpful Smile In Every Aisle

February 3, 2016

Andrew Funk, Executive Director
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, IA 50309-4688

*Re: Hy-Vee Pharmacy Fulfillment Center's 2015 Q4 Error Report**Revised***

Dear Mr. Funk

Hy-Vee Pharmacy Fulfillment Center (IA License #1472) respectfully submits our Fourth Quarter 2015 Error Report, for dates ranging from October 1, 2015, through December 31, 2015. All prescriptions dispensed through our Automatic Distribution Dispensing System (ADDS) from the Hy-Vee Pharmacy Fulfillment Center are monitored through the Pharmacy Quality Commitment Program and are reflected in the error report.

During the fourth quarter of 2015, the Hy-Vee Pharmacy Fulfillment Center dispensed 1,724,767 prescriptions utilizing our ADDS to our retail Hy-Vee pharmacies in seven states. During this fourth quarter period, we had 657 errors associated with ADDS, resulting in an error-free percentage of 99.9% for prescriptions dispensed through ADDS. Of the 657 errors, 2 prescriptions reached the patient and no patients were harmed as a result of the errors. The errors reaching a patient were the result of a miscount by the Parata robot, as fully discussed below.

Summary

Number of Prescriptions dispensed through ADDS	1,724,767
Number of Errors associated with ADDS	657
Error Free Percentage	99.9%
Number of Errors Reaching the Patient	2
Percentage of Errors Reaching the Patient	0.0001%
Number of Patients harmed as a result of errors	0

Categories of Errors

The ten distinct categories of errors are listed below, along with the number of errors in each category.

Category	Number of Errors	Percentage of Prescriptions
Incorrect Drug	2	0.0001%
Incorrect Quantity	267	0.015%
Incorrect Dose	0	0%
Incorrect Dosage Form	0	0%

Hy-Vee, Inc.
5820 Westown Parkway, West Des Moines, Iowa 50266
Phone: (515) 267-2800

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Incorrect Directions	0	0%
Incorrect Patient Name	0	0%
Other Incorrect Label Information	0	0%
Computer Order Entry	0	0%
Incorrect Safety Cap	131	0.0075%
Other Errors	257	0.0149%

Please see the attached reports for a detailed description of each error, the category, and corrective action adopted by the Hy-Vee Pharmacy Fulfillment Center.

Quantity Errors

Quantity errors are caused by the calibration of the scale or the air pressure in our ADDS. The Hy-Vee Pharmacy Fulfillment Center continues to monitor particular NDC's that are miscounted or damaged by the ADDS. We adjust the calibration of our scales and air pressure in our ADDS with respect to the applicable drug to optimize the settings and reduce the incidence of incorrect quantities or broken tablets and capsules. We are exploring changing manufacturers for the NDC's that consistently are damaged or miscount.

Incorrect Safety Caps

The process for providing non-safety caps is a manual process. We continue to work daily with our packing team to ensure that they do not forget to include the snap caps for patients requesting a snap cap. The computer screen places a large red message on the screen, alerting the packer to add the snap caps before sealing the bag.

Other Errors

Errors, such as the barcode cutting off on the prescription label, capping issues, or bag seals, are the result of our mechanical process for automatically filling prescriptions. We respond to these errors immediately and continue to adjust and refine our mechanical systems. For example, adjustments are made to the automated capper machines to ensure that the caps are securely put on the prescription vials.

Errors related to Replenishment and Inventory

We experienced 32 errors with replenishment and 9 with inventory in the 4th quarter. We reviewed the importance of removing all foil and cotton with the replenishment staff. In addition, we have modified the cycle counting procedure at replenishment to include separating the 2 sections of the cycle count container and placing it upside down in specific location. We determined that the inventory errors were the result of an employee placing the product in the wrong location on the shelf. The inventory team has been instructed and trained to use the scan technology and pay better attention when placing product on the shelf. Our quality system immediately caught all of these errors at the replenishment stations.

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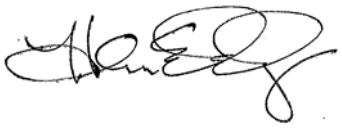
Redirection of Pharmacist and Pharmacy Services

Utilization of the Hy-Vee Pharmacy Fulfillment Center by Hy-Vee's retail pharmacies has facilitated the expansion of pharmacy services. Hy-Vee retail pharmacies administered 22% more immunizations from October 1, 2015, through December 31, 2015, as compared to the same time frame in 2014. Hy-Vee retail pharmacies completed 51% of Mirixa and 74% of Outcomes medication therapy management cases from October 1, 2015, through December 31, 2015. Hy-Vee retail pharmacies increased the number of Mirixa MTM cases completed by 250% and the number of Outcomes MTM cases completed by 10.6% in the 4th quarter of 2015, compared to the 4th quarter of 2014. In addition, Hy-Vee pharmacies launched a new educational program for Medicare-eligible patients, iMedicare, during the Medicare Open enrollment period. The iMedicare program served patients in all 8 states served by Hy-Vee pharmacies. The Hy-Vee pharmacies provided Medicare Part D plan comparison reports for eligible patients.

Quality Training

The Hy-Vee Pharmacy Fulfillment Center Director and Pharmacy Manager are consistently looking at all reported errors and addressing and training staff immediately when an error is identified. We are constantly refining our procedures and equipment to ensure that our level of quality is never compromised.
All registered pharmacy employees working at the Hy-Vee Pharmacy Fulfillment Center have completed the Quality Assurance training. We are committed to continual monitoring and improvement of our quality at the Hy-Vee Pharmacy Fulfillment Center.

Respectfully submitted,
Hy-Vee, Inc.



Helen E. Eddy, R.Ph., MBA
AVP, Pharmacy Services

Hy-Vee, Inc.
5820 Westown Parkway, West Des Moines, Iowa 50266
Phone: (515) 267-2800

Briefing on EMMA E-Kit

Version 1.0

Presented to

Iowa State Board of Pharmacy

Prepared by:

Christopher E. Bossi, President

Date: February 21, 2016

PURPOSE

The purpose of this document is to inform the Iowa State Board of Pharmacy ("Board") of a new storage and retrieval system offered by INRange Systems, Inc. ("INRange"). INRange would like to offer for sale to LTC pharmacies their EMMA E-Kit as a First Dosing / Emergency Kit (E-Kit) for Long Term Care Facilities (LTCF). INRange E-Kit solution is similar to other secure E-Kit Solutions offered by other vendors.

THE ISSUE

The storage and control of first dosing and emergency medications in LTCFs in compliance with Iowa Administrative Code 657-22.7.

CURRENT PRACTICE

In order to service newly admitted patients and emergency situations, the LTC pharmacy provides to the LTCF an emergency stock of medications to be used on new patients or in emergency situations. These medications are typically stored in small e-kit boxes that are filled at the pharmacy with a standard configuration of medications. These e-kits are then stored in a cabinet in the LTCF's med room.

When a patient needs a medication, the nurse removes one of the E-Kit boxes, breaks the seal and utilizes the box for the patient until the pharmacy can deliver the needed prescriptions. These e-kit boxes are then cycled back to the pharmacy along with the administration records for reconciliation.

The key shortcomings with this practice include:

1. The opportunity for diversion is great.
2. Often the documentation showing the medications removed and administered to a patient is missing and the pharmacy must work with the home to recreate this paperwork.
3. An electronic, real-time chain of custody record does not exist.
4. It is very cumbersome for the nurse to use.
5. It puts the nurse in charge of the pharmacy's inventory with very little control.

EMMA E-KIT

The EMMA E-Kit solution provides the **identical function** as the current practice:

- In a more secure storage and retrieval enclosure
- Better medication tracking and control
- Less risk of diversion

The EMMA unit is a storage cabinet that holds up to thirty (30) different medications and a total of 300 unique doses. It retrieves individual medications and delivers them in individual unit dose containers, each of which is labeled.

The EMMA E-Kit practice includes:

Medications are packaged in blister cards by the pharmacy. This blister cards allow for a visual count and inspection of the medications.	 
The blister cards are inserted into the EMMA device, which electronically inventories and verifies the medications in the card.	
The administering nurse makes a request in consultation with the physician using the system software. All required information is kept electronically and in real time.	
The nurse retrieves the medications from the EMMA storage unit, receiving only the doses requested. The EMMA storage unit does not allow the nurse to access any other medications.	

Each dose is delivered in its own individually labeled and sealed blister.	
The pharmacy is notified of the transaction through system alerts or through its DocuTrack System.	DocuTrack eRx MODULE

The EMMA delivery unit is a secured storage unit with the following key features:

- The unit videos all transactions, which can be recalled by the pharmacy
- The nurse only has access to the doses requested and approved – minimizing diversion
- A complete chain of custody by individual dose of medication
- Unit has anti-theft (movement) and tamper alarms and alerts
- Provides convenience for the nurse and complete control for the pharmacy
- Monitors and alerts for expired medications

A Pharmacy Pilot or Demonstration Research Project for a

New Practice Model for Community Pharmacy

A Demonstration Project to Study the Effects of Implementing Tech-Check-Tech Programs in Community Practice to Engage Community Pharmacists in Clinical Pharmacy Services in Iowa

PHASE ONE (7TH QUARTER)/PHASE TWO (4TH QUARTER)

QUARTERLY REPORT

Iowa Pharmacy Association &
Drake University College of Pharmacy and Health Sciences

Primary Contact:

Megan Myers, PharmD.
New Practice Model Program Manager
Iowa Pharmacy Association
8515 Douglas Avenue, Suite 16
Des Moines, IA 50322
515-270-0713 (office)
mmyers@iarx.org

Secondary Contact:

Anthony Pudlo, PharmD, MBA, BCACP
Vice President of Professional Affairs
Iowa Pharmacy Association
8515 Douglas Avenue, Suite 16
Des Moines, IA 50322
515-270-0713 (office)
630-816-5716 (cell)
apudlo@iarx.org

Submitted to the Iowa Board of Pharmacy

March 9, 2016

LEADERSHIP TEAM MEMBERS

Megan Myers, PharmD, will serve as Project Coordinator. She will oversee the project, conduct regular on-site visits with each site, coordinate the study activities, chair the regular team meetings, and lead the writing of the study reports to the Board of Pharmacy.

Michael Andreski, RPh, MBA, PhD, Assistant Professor of Social and Administrative Pharmacy, Drake University College of Pharmacy and Health Sciences serves as research consultant and principal investigator, participates in regular team meetings, and participates in the writing of the study report.

T.J. Johnsrud, NuCara Health Management, Inc., provides a pharmacy management perspective for coordinating the community pharmacy clinical services and Tech-Check-Tech programs within the community pharmacy sites. He participates in regular team meetings.

Anthony Pudlo, PharmD, MBA, BCACP, Vice-President of Professional Affairs, and Kate Gainer, PharmD, Executive Vice President/CEO, Iowa Pharmacy Association, will oversee coordination of clinical pharmacy services available to community pharmacy sites in this study.

IPA'S NPM GOALS:

1) Sites are using Tech-Check-Tech (TCT) at least 75% of business days (M-F).
2) Sites to submit data collected for both research aims within 7 days of the end of the month.
3) Sites to increase time spent counseling patients on both new and refilled prescriptions.
4) Pharmacists are providing expanded patient care services including increasing volume of established services and successful implementation of new services.

PHARMACY SITE-SPECIFIC INFORMATION

***Pharmacy Site #1*:**
Towncrest Pharmacy
2306 Muscatine Avenue
Iowa City, IA 52240
319.337.3526
License #838
Mike Deninger, Pharmacist-In-Charge
License #17620
Randy McDonough, On-Site Responsible Pharmacist
License #16918

***Pharmacy Site #2*:**
Mercy Family Pharmacy
1111 3rd Street SW
Dyersville, IA 52040
563.875.7624
License #129
Julie Panosh, Pharmacist-In-Charge
License #19527

***Pharmacy Site #3*:**
Medicap Pharmacy #8003
105 Lincoln Way
Ames, IA 50010
515.232.1653
License #123
Stephanie McCollom, Pharmacist-In-Charge
License #21189

***Pharmacy Site #4*:**
NuCara Pharmacy #11
120 E. Madison Street
Washington, IA 52353
319.653.5404
License #342
Rachel Clemens, Pharmacist-In-Charge
Participated June 2, 2014 – July 31, 2015

***Pharmacy Site #5*:**
NuCara Pharmacy #30
107 N Main Street
Lenox, IA 50851
641.333.2260
License #1454
Alicia Lynn, Pharmacist-In-Charge
License #21963

***Pharmacy Site #6*:**
NuCara Pharmacy #12
500 2nd Street
Traer, IA 50675
319.478.8711
License #467
Phyllis A. McKee, Pharmacist-In-Charge
License #13929

***Pharmacy Site #7*:**
NuCara Pharmacy #10
621 Broad Street
Story City, IA 50248
515.733.2233
License #78
Betty Grinde, Pharmacist-In-Charge
License #15568

***Pharmacy Site #8*:**
Thrifty White Pharmacy #42
400 Grand Ave
Spencer, IA 51301
712-262-1523
License #504
Amy Fitch, Pharmacist-In-Charge
License #17211

***Pharmacy Site #9*:**
Hy-Vee Pharmacy #1192
115 South 29th Street
Fort Dodge, IA 50501
515-576-5320
License #981
Thomas F. Donner, Pharmacist-In-Charge
License #16040
Christine Donner-Tiernan, On-Site Responsible Pharmacist

***Pharmacy Site #10*:**
Walgreens Pharmacy #12108
2719 Grand Ave
Ames, IA 50010
515-232-8276
License #804
Anne Stover Garcia, Pharmacist-In-Charge
License #20768

***Pharmacy Site #11*:**
Hartig Drug #3
2255 JFK Road
Dubuque, IA 52002
563-588-8708
License #767
Emily Vyverberg, Pharmacist-In-Charge
License #21065

***Pharmacy Site #12*:**
Main at Locust Pharmacy and Medical Supplies
129 W Locust St
Davenport, IA 52803
563-324-1641
License #774
Lisa C Ploehn, Pharmacist-In-Charge
License #16831

***Pharmacy Site #13*:**
Target Pharmacy
3400 Edgewood Rd SW
Cedar Rapids, IA 52404
319-396-4777
License #1135
Sarah Lewis, Pharmacist-In-Charge
License #21575
Participated Feb. 2, 2015 – Dec. 15, 2015

***Pharmacy Site #14*:**
Wester Drug; License #399
315 E 2nd Street
Muscatine, IA 52761
563-263-7044
Cory Garvin, Pharmacist-In-Charge
License #20245
Michelle Garvin, Pharmacy Owner, Certified Pharmacy Technician
CPhT#38010161153651; Registration # 2016

***Pharmacy Site #15*:**
Medicap Pharmacy #8036
208 E. Euclid Ave.
Indianola, IA 50125
515-961-5303
License # 495
Shanna Zwanziger, Pharmacist-In-Charge
License #19096

***Pharmacy Site #16*:**
Thrifty White Pharmacy #56
1320 Broadway
Denison, IA 51442
712-263-4646
License #157
Tim Weber, Pharmacist-In-Charge
License #17699

***Pharmacy Site #17*:**
Walgreens Pharmacy #07967
15601 Hickman Rd
Clive, IA 50325
515-961-5303
License #1257
Kori Nagel, Pharmacist-In-Charge
License #20047

Aim 1: Implement and assess the impact of a Tech-Check-Tech program in community pharmacies in Iowa on patient safety measures. "50 refills per month for the remainder of the project will be double checked for errors."

	Aggregate data from Technician checked prescriptions Dec 1st – Jan 31st		**Aggregate data from Baseline collection (pharmacist-checked prescriptions)**	
	Phase 1	**Phase 2**	**Phase 1**	**Phase 2**
Total Rx Refills Checked	613	1,371	5,565	7,884
Wrong Drug	0	1	1	0
Wrong Strength	0	0	0	0
Safety Cap Error	0	2	8	18
Wrong Amount	0	1	2	19
Other Errors	1 (right drug, wrong NDC)	0	4	13
Total Errors	**1**	**4**	**15**	**50**
Patient-Safety Errors	*0*	*1*	*2*	*4*
Administrative Errors	*1*	*3*	*13*	*46*

For Aggregate Data from Technician checked prescriptions collected Dec 1st – Jan. 31st :

	Total Errors		**Patient-Safety Errors**		**Administrative Errors**	
	Phase 1	Phase 2	Phase 1	Phase 2	Phase 1	Phase 2
Error Rate	0.16%	0.29%	0%	0.07%	0.16%	0.22%
Mean	0.167% (±0.41%)	0.48% (±0.82%)	0%	0.09% (±0.28%)	0.167% (±0.41%)	0.39% (±0.69%)
p-value compared to baseline	0.57	0.66	0.19	0.69	0.77	0.54
Range	0 – 1%	0 – 2%	0%	0 - 0.9%	0 – 1%	0 – 2%

Discussion:

All error rates were non-significantly lower than baseline. Patient-safety has most likely not been compromised with technician-verification of refill prescriptions. The overall error rates (p=0.57 & 0.66)), patient-safety error rates (p=0.19 & 0.69), and administrative error rate (p=0.77 & 0.54) showed no statistically significant differences compared to baseline.

*Please see appendix A for individual site data.

Aim 2: Implement and assess the impact of a Tech-Check-Tech program in community pharmacies in Iowa and in facilitating the provision of community pharmacist-provided medication therapy management.

"The primary data sources will be self-reported pharmacist daily activity logs and numbers of both compensated and identified opportunities for MTM and other patient care services. Once the Tech-Check-Tech procedures have been initiated and are performing adequately as defined above, the pharmacist(s) at the participating pharmacies will begin to focus on increasing the amount of MTM services provided."

Aggregate data: Composition of Pharmacist Day

Pharmacist Time Spent in:	**Phase 1**			**Phase 2**		
	Baseline	**TCT Dec 1st – Jan 31st**	**p-value***	**Baseline**	**TCT Dec 1st – Jan 31st**	**p-value***
Dispensing	67.3% Range= 38.73% - 80.81%	51.65% Range= 27.05% – 75.84%	*0.081*	74.23% Range= 52.63% - 85.99%	53.75% Range= 22.17% – 76.7%	**0.019**
Patient Care	15.9% Range= 11.03% - 19.39%	33.56% Range= 19.49% – 45.00%	**0.009**	16.40% Range= 8.23% - 32.16%	32.61% Range= 1.36% – 59.15%	**0.020**
Practice Development	3.5% Range= 0.25% - 14.43%	3.68% Range= 0% – 15.47%	0.944	1.89% Range= 0% - 5.54%	1.56% Range= 0% – 5.05%	0.352
Management	9.2% Range= 5.81% - 12.79%	9.90% Range= 2.50% – 21.19%	0.816	6.83% Range= 2.16% - 24.56%	7.80% Range= 2.04% – 24.35%	0.764
Other activities**	4.1% Range= 0% - 14.66%	1.21% Range= 0% – 7.26%	0.290	0.65% Range= 0% - 4.32%	4.27% Range= 0% – 34.87%	0.308

*Bold indicates statistically significant and italicized indicates trending towards significant

*Other Activities included precepting pharmacy students, specialty compounding, setting up medication planners and providing in-services to other providers. Sites were guided to re-classify to other categories when appropriate.

Discussion:

The amount of time pharmacists spend in dispensing has decreased with a corresponding increase in patient care activities and no significant change in other categories. This is consistent with results from previous quarters. There was a statistically significant increase in the amount of pharmacist time spent in patient care in both groups.

*Please see appendix A for individual site data.

Aggregate data: Number of Services Provided

Number of Patient Care Services Per Pharmacist Hour	**Phase 1**			**Phase 2**		
	Baseline	**TCT Dec 1st – Jan 31st**	**p-value**	**Baseline**	**TCT Nov 1st – Jan 31st**	**p-value**
Average Reimbursed Services	0.11 *Range= 0 – 0.51*	0.17 *Range= 0.06 – 0.36*	0.495	0.46 *Range= 0.15 - 1.98*	0.25 *Range= 0.002 – 0.62*	0.283
Average Non-Reimbursed Services	2.77 *Range= 0.13 – 11.24*	4.59 *Range= 2.51 – 6.44*	0.297	1.49 *Range= 0.41 - 3.18*	2.39 *Range= 0.06 – 4.71*	0.160
Average Total Patient Care Services	2.88 *Range= 0.14 – 11.75*	4.76 *Range= 2.56 – 6.59*	0.302	1.95 *Range= 0.99 - 4.36*	2.63 *Range= 0.6 – 5.83*	0.337

Discussion:

The amount of overall services continues to grow, though the data collected was not statistically significantly different than baseline measure for this quarter. Numerical trends are similar to previous quarters. The amount of reimbursed services was lower than last quarter, which is likely due to the majority immunizations for flu season being captured last quarter. The lack of growth in services with the increased time in patient care suggests that time more time might need to be spent in practice development in developing new services and relationships with providers.

*Please see appendix A for individual site data.

PHASE 1 Aggregate Data: Number of services per pharmacist hour:

Service Type	Baseline	TCT (12/1/15 – 1/31/16)	p-value compared to baseline*
Prescription Counseling Reimbursed	Avg. = 0.0735 Range= 0 – 0.51 2/7 Pharmacies Provided	Avg. = 0 Range = 0 0/6 pharmacies provided	p=0.371
Prescription Counseling Non-Reimbursed	Avg. = 2.3780 Range= 0.0304 – 10.45 7/7 Pharmacies Provided	Avg. = 3.84 Range= 1.55 – 6.20 6/6 pharmacies provided	p=0.400
Drug Therapy Problems Identified Through Dispensing DUR Reimbursed	Avg. = 0.0014 Range= 0 – 0.01 1/7 Pharmacies Provided	Avg. = 0 Range = 0 0/6 pharmacies provided	p=0.356
Drug Therapy Problems Identified Through Dispensing DUR Non-Reimbursed	Avg. = 0.1333 Range= 0.3 – 0.47 7/7 Pharmacies Provided	Avg. = 0.43 Range = 0.05 – 2.12 6/6 pharmacies provided	p=0.429
Drug Information Request Reimbursed	Avg. = 0.0003 Range= 0 – 0.002 1/7 Pharmacies Provided	Avg. = 0 Range = 0 0/6 pharmacies provided	p=0.356
Drug Information Request Non-Reimbursed	Avg. = 0.6995 Range= 0.012 – 0.1724 7/7 Pharmacies Provided	Avg. = 0.10 Range = 0.02 – 0.20 6/6 pharmacies provided	p=0.424
Patient Education Reimbursed	Avg. = 0.0031 Range= 0 – 0.02 2 1/7 Pharmacies Provided	Avg. = 0 Range = 0 0/6 pharmacies provided	p=0.356
Patient Education Non-Reimbursed	Avg. = 0.0899 Range= 0.021 – 0.192 7/7 Pharmacies Provided	Avg. = 0.09 Range = 0 – 0.19 5/6 pharmacies provided	p=0.785
Immunizations Reimbursed	Avg. = 0.005 Range= 0 – 0.013 1/7 Pharmacies Provided	Avg. = 0.11 Range = 0.02 – .20 6/6 pharmacies provided	**p=0.01**
Immunizations Non-Reimbursed	Avg. = 0.0034 Range= 0 – 0.019 2/7 Pharmacies Provided	Avg. = 0.0 Range = 0 0/6 pharmacies provided	p=0.251
Injection Administration Reimbursed	Avg. = 0.0032 Range= 0 – 0.0086 4/7 Pharmacies Provided	Avg. = 0.04 Range = 0 – 0.18 4/6 pharmacies Provided	p=0.211
Injection Administration Non-Reimbursed	Avg. = 0.00 Range= 0 0/7 Pharmacies Provided	Avg. = 0.0 Range = 0 0/6 pharmacies Provided	p=n/a (the same result)

*Bold indicates statistically significant, and italicized indicates trending towards statistical significance.

PHASE 1 Aggregate Data: Number of services per hour (continued):

Service Type	Baseline	TCT (12/1/15 – 1/31/16)	p-value compared to baseline*
Patient Screening/Testing Reimbursed	Avg. = 0.0018 Range = 0 – 0.013 1/7 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.02 1/6 pharmacies provided	p=0.651
Patient Screening/Testing Non-Reimbursed	Avg. = 0.0018 Range= 0 – 0.105 5/7 Pharmacies Provided	Avg. = 0.03 Range = 0.0 – 0.09 3/6 pharmacies provided	p=0.731
MTM Current Medication List/History Reimbursed	Avg. = 0.0047 Range= 0 – 0.02 0 2/7 Pharmacies Provided	Avg. = 0 Range = 0 0/6 pharmacies provided	p=0.184
MTM Current Medication List/History Non-Reimbursed	Avg. = 0.0066 Range= 0 – 0.022 3/7 Pharmacies Provided	Avg. = 0. 01 Range = 0 – 0.06 2/6 pharmacies provided	p=0.717
MTM Medication Reconciliation Reimbursed	Avg. = 0.0078 Range= 0 – 0.042 2/7 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.03 1/6 pharmacies provided	p=0.794
MTM Medication Reconciliation Non-Reimbursed	Avg. = 0.0226 Range= 0 – 0.076 3/7 Pharmacies Provided	Avg. = 0.02 Range = 0 – 0.05 3/6 pharmacies provided	p=0.755
MTM Patient Follow-up Reimbursed	Avg. = 0.0025 Range= 0 – 0.017 1/7 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.04 1/6 pharmacies provided	p=0.527
MTM Patient Follow-up Non-Reimbursed	Avg. = 0.0133 Range= 0 – 0.084 2/7 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.02 2/6 pharmacies provided	p=0.605
MTM Patient Interview Reimbursed	Avg. = 0.0012 Range= 0 – 0.086 1/7 Pharmacies Provided	Avg. = 0 Range = 0 – 0.004 1/6 pharmacies provided	p=0.729
MTM Patient Interview Non-Reimbursed	Avg. = 0.0061 Range= 0 – 0.035 2/7 Pharmacies Provided	Avg. = 0.02 Range = 0 – 0.04 3/6 pharmacies provided	p=0.320
MTM Provider Consult Reimbursed	Avg. = 0.0003 Range= 0 – 0.002 1/7 Pharmacies Provided	Avg. = 0.0 Range = 0 0/6 pharmacies provided	p=0.356
MTM Provider Consult Non-Reimbursed	Avg. = 0.0190 Range= 0 – 0.133 1/7 Pharmacies Provided	Avg. = 0.05 Range = 0 – 0.18 3/6 pharmacies provided	p=0.388
MTM Other Services Reimbursed	Avg. = 0.0051 Range= 0 – 0.036 1/7 Pharmacies Provided	Avg. = 0.00 Range = 0 0/6 pharmacies provided	p=0.356
MTM Other Services Non-Reimbursed	Avg. = 0.0172 Range= 0 – 0.089 2/7 Pharmacies Provided	Avg. = 0 Range = 0 0/6 pharmacies provided	p=0.224

*Bold indicates statistically significant, and italicized indicates trending towards statistical significance.

PHASE 2 Aggregate Data: Number of services per hour:

Service Type	Baseline	TCT (12/1/15 – 1/31/16)	p-value compared to baseline*
Prescription Counseling Reimbursed	Avg. = 0.0173 Range= 0 – 0.10 4/10 Pharmacies Provided	Avg. = 0.04 Range = 0 – 0.23 2/10 pharmacies provided	p=0.502
Prescription Counseling Non-Reimbursed	Avg. = 1.160 Range= 0.218 – 3.069 10/10 Pharmacies Provided	Avg. = 1.78 Range= 0.04 – 4.71 10/10 pharmacies provided	p=0.255
Drug Therapy Problems Identified Through Dispensing DUR Reimbursed	Avg. = 0.00486 Range= 0 – 0.0455 2/10 Pharmacies Provided	Avg. = 0.003 Range = 0 – 0.03 2/10 pharmacies provided	p=0.824
Drug Therapy Problems Identified Through Dispensing DUR Non-Reimbursed	Avg. = 0.119 Range= 0.21 – 0.51 10/10 Pharmacies Provided	Avg. = 0.13 Range = 0 – 0.41 9/10 pharmacies provided	p=0.815
Drug Information Request Reimbursed	Avg. = 0.014 Range= 0 – 0.136 2/10 Pharmacies Provided	Avg. = 0.0004 Range = 0 – 0.004 1/10 pharmacies provided	p=0.345
Drug Information Request Non-Reimbursed	Avg. = 0.0823 Range= 0.0054 – 0.191 10/10 Pharmacies Provided	Avg. = 0.16 Range = 0.01 – 0.35 10/10 pharmacies provided	*p=0.09*
Patient Education Reimbursed	Avg. = 0.0049 Range= 0 – 0.049 1/10 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.08 1/10 pharmacies provided	p=0.735
Patient Education Non-Reimbursed	Avg. = 0.0549 Range= 0 – 0.189 9/10 Pharmacies Provided	Avg. = 0.12 Range = 0 – 0.53 9/10 pharmacies provided	p=0.279
Immunizations Reimbursed	Avg. = 0.361 Range= 0.107 – 1.74 10/10 Pharmacies Provided	Avg. = 0.09 Range = 0 – 0.21 9/10 pharmacies provided	*p=0.098*
Immunizations Non-Reimbursed	Avg. = 0.00277 Range= 0 – 0.0186 2/10 Pharmacies Provided	Avg. = 0.09 Range = 0 – 0.88 2/10 pharmacies provided	p=0.336
Injection Administration Reimbursed	Avg. = 0.00261 Range= 0 – 0.0182 3/10 Pharmacies Provided	Avg. = 0.03 Range = 0 – 0.15 3/10 pharmacies Provided	p=0.199
Injection Administration Non-Reimbursed	Avg. = 0.00 Range= 0 0/10 Pharmacies Provided	Avg. = 0.0 Range = 0 0/10 pharmacies Provided	p=n/a (the same result)

*Bold indicates statistically significant, and italicized indicates trending towards statistical significance.

PHASE 2 Aggregate Data: Number of services per hour (continued):

Service Type	Baseline	TCT (12/1/15 – 1/31/16)	p-value compared to baseline*
Patient Screening/Testing Reimbursed	Avg. = 0.00494 Range = 0 – 0.0453 2/10 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.06 1/10 pharmacies provided	p=0.909
Patient Screening/Testing Non-Reimbursed	Avg. = 0.00668 Range= 0 – 0.0394 5/10 Pharmacies Provided	Avg. = 0.00 Range = 0.0 – 0.006 2/10 pharmacies provided	p=0.165
MTM Current Medication List/History Reimbursed	Avg. = 0.0104 Range= 0 – 0.0491 4/10 Pharmacies Provided	Avg. = 0.03 Range = 0 – 0.26 3/10 pharmacies provided	p=0.432
MTM Current Medication List/History Non-Reimbursed	Avg. = 0.0115 Range= 0 – 0.0806 5/10 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.06 3/10 pharmacies provided	p=0.829
MTM Medication Reconciliation Reimbursed	Avg. = 0.0104 Range= 0 – 0.0491 4/10 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.05 4/10 pharmacies provided	p=0.896
MTM Medication Reconciliation Non-Reimbursed	Avg. = 0.0166 Range= 0 – 0.0549 6/10 Pharmacies Provided	Avg. = 0.02 Range = 0 – 0.15 3/10 pharmacies provided	p=0.905
MTM Patient Follow-up Reimbursed	Avg. = 0.0071 Range= 0 – 0.0526 4/10 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.06 4/10 pharmacies provided	p=0.523
MTM Patient Follow-up Non-Reimbursed	Avg. = 0.00138 Range= 0 – 0.0077 2/10 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.08 3/10 pharmacies provided	p=0.376
MTM Patient Interview Reimbursed	Avg. = 0.00112 Range= 0 – 0.0494 4/10 Pharmacies Provided	Avg. = 0.02 Range = 0 – 0.09 5/10 pharmacies provided	p=0.315
MTM Patient Interview Non-Reimbursed	Avg. = 0.00745 Range= 0 – 0.0434 3/10 Pharmacies Provided	Avg. = 0.00 Range = 0 – 0.01 2/10 pharmacies provided	p=0.223
MTM Provider Consult Reimbursed	Avg. = 0.00511 Range= 0 – 0.0165 4/10 Pharmacies Provided	Avg. = 0.01 Range = 0 – 0.04 3/10 pharmacies provided	p=0.895
MTM Provider Consult Non-Reimbursed	Avg. = 0.0365 Range= 0 – 0.192 6/10 Pharmacies Provided	Avg. = 0.05 Range = 0 – 0.18 8/10 pharmacies provided	p=0.686
MTM Other Services Reimbursed	Avg. = 0.00035 Range= 0 – 0.0035 1/10 Pharmacies Provided	Avg. = 0.00 Range = 0 – 0.01 1/10 pharmacies provided	p=0.331
MTM Other Services Non-Reimbursed	Avg. = 0 Range= 0 0/10 Pharmacies Provided	Avg. = 0.02 Range = 0 – 0.17 2/10 pharmacies provided	p=0.315

*Bold indicates statistically significant, and italicized indicates trending towards statistical significance.

Discussion:

This quarter, there appeared to be an increase in patient counseling, answering drug information requests, and immunizations. Anecdotally, pharmacists have reported having more time with each patient, providing a better quality service than prior to TCT. Details on length and type of counseling may need to be further examined in future phases of the Pilot Program.

*Please see appendix A for individual site data.

SUMMARY

- Tech-Check-Tech portion of the study in Phase I sites went live on June 2, 2014. Tech-Check-Tech portion of the study in Phase II sites went live on February 2, 2015.
    - On average, Phase I sites used the Tech-Check-Tech model approximately 65.9*%* of the time in December and January, not including weekends and holidays. The range was 42.5 – 100%. This is an improvement from previous quarters
    - On average, Phase II sites used the Tech-Check-Tech model approximately 77.3% of the time November through January, not including weekends and holidays. The range was 27.5% to 100%. This is comparable to previous quarters.

- A small group from the NPM task force met on December 22, 2014 to establish guidelines on when to consider discontinuation of the project due to a site's inability to fully participate in the NPM project requirements (see Appendix B). The group recognized the importance of reviewing each site on a case-by-case basis.

    - Two sites from Phase II are in need of a formal action plan, to be developed this quarter

        - One based on low number of TCT days

        - One based on low number of patient care services and difficulty submitting data on time

- IPA supported the sites throughout the pilot with multiple live meetings and frequent site visits.
    - The IPA project manager did not visit sites this quarter due to maternity leave. Site visits resumed in February 2016, with a live meeting planned for March 31, 2016.

EXPANDING PHARMACIST-PROVIDED PATIENT CARE SERVICES

- Sites are working on:

    - Expanding MTM opportunities

    - Expanding immunizations offered

    - Expanding Med Sync, compliance packaging and adherence programs

    - Pursuing collaborative practice agreements

    - Reaching out to other providers to let them know about pharmacy services

    - Site 5 has successfully incorporated formal diabetes education classes

PHARMACIST AND TECHNICIAN TRAINING

- Required pharmacist and technician training modules were completed by all initial participating staff by November 14, 2014.
    - Additional staff have been trained throughout quarter three (Appendix C).
- Revised CEI modules are available for future staff additions. Modules are being used for phase I and phase II sites. The modules are on-demand and accredited for C.P.E.
    - Modules were available starting September 9, 2014.

CONCLUSION

There has been no statistical difference in error rates on refills for Phase I or Phase II sites with Tech-Check-Tech as compared to the traditional Pharmacist-Check-Tech model. The Tech-Check-Tech intervention continues to be a successful approach to increasing the amount of time pharmacists spent in patient care in a statistically significant amount. Patient care services per pharmacist hour have not increased in a statistically significant manner this quarter, and continued efforts will be made to support sites in growing services.

FUTURE DIRECTION/GOALS

Combined data will be available with the next report.

While not included in the original proposal, IPA will study any possible relationship between the amounts of time spent doing TCT and changes in pharmacist workday composition and number of services provided.

Quantitative and/or Qualitative examination of the “increased time spent on patient counselling” may need to be performed to better understand the use of time made available to the pharmacist for patient care.

Other TCT models should be considered with additional pilot and research demonstration projects.

PHASE ONE PROJECT TIMELINE

Month 1-3	Project start-up; Finalize procedures for MTM service delivery and data collection
Month 2	Submit proposal to Iowa Board of Pharmacy for pilot/demonstration project – *Approved March 12, 2014*
Month 5	Community pharmacies implement Tech-Check-Tech programs; pharmacists engage in collaborative practice agreements for patient care delivery – *Implemented TCT June 2, 2014*
Month 23	Pilot project authority expires for Tech-Check-Tech *Pilot ends December 2, 2015* *Approved September 2, 2015 to renew pilot through Aug 2, 2016*
Month 22-24	Data analyses and report writing

PHASE TWO PROJECT TIMELINE

Month 1-3	Project start-up; Identify sites
Month 2	Submit proposal to Iowa Board of Pharmacy for pilot/demonstration project – *Approved November 19, 2014*
Month 5	Community pharmacies implement Tech-Check-Tech programs; pharmacists engage in collaborative practice agreements for patient care delivery – *Implemented TCT February 2, 2015*
Month 23	Pilot project authority expires for Tech-Check-Tech *Pilot ends August 2, 2016*
Month 22-24	Data analyses and report writing

APPENDIX A

In order to protect the confidentiality of each site, there is no correlation between the order of the individual site reports A-Q and the numerical designation on pages 3 - 4 of this report.

Individual Site Data for *Site A*:

Site A Data from Technician checked prescriptions collected (12/1/15 -1/31/16):	
Total Rx Refills Checked	100
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0.0%

Site A data from Baseline collection (Pharmacist-checked prescriptions):	
Total Prescription Refills Checked	752
Wrong Drug	1
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	1
Overall Error Rate	0.13%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 -1/31/16)**
Time Spent in Dispensing	71.02%	47.29%
Time Spent in Management	10.25%	2.50%
Time Spent in Patient Care	16.60%	45.00%
Time Spent in Practice Development	0.62%	5.21%
Time Spent in Other Activities	1.50%	0.0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 -1/31/16)**
Reimbursed Patient Care Services	0.000	0.24
Non-Reimbursed Patient Services Care	1.99	4.60
Total Patient Care Services	1.99	4.84

Percent time utilizing TCT: 65.0%

Individual Site Data for *Site B*:

Site B Data from Technician checked prescriptions collected (12/1/15 -1/31/16):		**Site B data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	100	Total Prescription Refills Checked	758
Wrong Drug	0	Wrong Drug	0
Wrong Strength	0	Wrong Strength	0
Safety Cap Error	0	Safety Cap Error	3
Wrong Amount	0	Wrong Amount	0
Other Errors	0	Other Errors	0
Total Errors	0	Total Errors	3
Overall Error Rate:	0%	Overall Error Rate	0.396%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 -1/31/16)**
Time Spent in Dispensing	69.56%	49.40%
Time Spent in Management	9.17%	6.94%
Time Spent in Patient Care	17.44%	44.53%
Time Spent in Practice Development	0.71%	1.13%
Time Spent in Other Activities	3.11%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 -1/31/16)**
Reimbursed Patient Care Services	0.086	0.15
Non-Reimbursed Patient Services Care	1.84	3.82
Total Patient Care Services	1.93	3.97

Percent time utilizing TCT: 87.5%

Individual Site Data for *Site C*:

Site C Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):		**Site C data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	113	Total Prescription Refills Checked	752
Wrong Drug	0	Wrong Drug	0
Wrong Strength	0	Wrong Strength	0
Safety Cap Error	0	Safety Cap Error	0
Wrong Amount	0	Wrong Amount	0
Other Errors	0	Other Errors	1
		Days' Supply =1	
Total Errors	0	Total Errors	1
Overall Error Rate	0%	Overall Error Rate	0.13%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 -1/31/16)**
Time Spent in Dispensing	74.47%	55.81%
Time Spent in Management	9.26%	10.39%
Time Spent in Patient Care	14.95%	33.52%
Time Spent in Practice Development	1.32%	0.82%
Time Spent in Other Activities	0.00%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 -1/31/16)**
Reimbursed Patient Care Services	0.00	0.06
Non-Reimbursed Patient Services Care	1.99	2.50
Total Patient Care Services	1.99	2.56

Percent time utilizing TCT: 72.5%

Individual Site Data for *Site D*:

Site D Data from Technician checked prescriptions collected (12/1/15 -1/31/16):		**Site D data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	100	Total Prescription Refills Checked	750
Wrong Drug	0	Wrong Drug	0
Wrong Strength	0	Wrong Strength	0
Safety Cap Error	0	Safety Cap Error	4
Wrong Amount	0	Wrong Amount	0
Other Errors	0	Other Errors	0
Total Errors	0	Total Errors	4
Overall Error Rate	0.0%	Overall Error Rate	0.53%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 -1/31/16)**
Time Spent in Dispensing	80.81%	75.84%
Time Spent in Management	5.81%	4.67%
Time Spent in Patient Care	13.13%	19.49%
Time Spent in Practice Development	0.25%	0%
Time Spent in Other Activities	0.00%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 -1/31/16)**
Reimbursed Patient Care Services	0.015	0.12
Non-Reimbursed Patient Services Care	0.13	6.44
Total Patient Care Services	0.14	6.56

Percent time utilizing TCT: 42.5%

***Site E*: No longer in project.**

Individual Site Data for *Site F*:

Site F Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):	
Total Rx Refills Checked	100
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	1
(right drug, wrong NDC)	
Total Errors	1
Overall Error Rate	1%

Site F data from Baseline collection (Pharmacist-checked prescriptions):	
Total Prescription Refills Checked	854
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	2
Other Errors	3
Wrong Data Entry =1 Wrong Place in Cassette=2	
Total Errors	5
Overall Error Rate	0.5854%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 -1/31/16)**
Time Spent in Dispensing	38.73%	27.05%
Time Spent in Management	12.79%	13.68%
Time Spent in Patient Care	19.39%	36.53%
Time Spent in Practice Development	14.43%	15.47%
Time Spent in Other Activities	14.66%	7.26%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.15	0.10
Non-Reimbursed Patient Services Care	0.85	3.93
Total Patient Care Services	0.99	4.04

Percent time utilizing TCT: 100%

Individual Site Data for *Site G*:

Site G Data from Technician checked prescriptions collected (12/1/15 -1/31/16):	
Total Rx Refills Checked	100
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0.0%

Site G data from Baseline collection (Pharmacist-checked prescriptions):	
Total Prescription Refills Checked	926
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0.00%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	71.39%	56.51%
Time Spent in Management	6.93%	21.19%
Time Spent in Patient Care	19.20%	22.30%
Time Spent in Practice Development	2.33%	0%
Time Spent in Other Activities	0.15%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 -1/31/16)**
Reimbursed Patient Care Services	0.51	0.36
Non-Reimbursed Patient Services Care	11.24	6.23
Total Patient Care Services	11.75	6.59

Percent time utilizing TCT: 93.75%

Individual Site Data for *Site H*:

Site H Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):		**Site H data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	100	Total Prescription Refills Checked	750
Wrong Drug	0	Wrong Drug	0
Wrong Strength	0	Wrong Strength	0
Safety Cap Error	0	Safety Cap Error	1
Wrong Amount	0	Wrong Amount	1
Other Errors	0	Other Errors	0
Total Errors	0	Total Errors	2
Overall Error Rate	0%	Overall Error Rate	0.27%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	75.36%	55.81%
Time Spent in Management	2.16%	3.06%
Time Spent in Patient Care	21.61%	40.37%
Time Spent in Practice Development	0.86%	0.76%
Time Spent in Other Activities	0%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.35	0.34
Non-Reimbursed Patient Services Care	0.87	2.09
Total Patient Care Services	1.22	2.43

Percent of time utilizing TCT = 75.0%

Individual Site Data for *Site I*:

Site I Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):

Total Rx Refills Checked	100
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	1
Other Errors	0
Total Errors	1
Overall Error Rate	1%

Site I data from Baseline collection (Pharmacist-checked prescriptions):

Total Prescription Refills Checked	750
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	2
Wrong Amount	1
Other Errors	0
Total Errors	3
Overall Error Rate	0.4%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	71.71%	22.17%
Time Spent in Management	13.48%	24.35%
Time Spent in Patient Care	8.23%	47.39%
Time Spent in Practice Development	2.26%	2.90%
Time Spent in Other Activities	4.32%	3.20%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.40	0.19
Non-Reimbursed Patient Services Care	1.78	2.38
Total Patient Care Services	2.18	2.57

Percent of time utilizing TCT – 95.0%

Individual Site Data for *Site J*:

Site J Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):		**Site J data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	50	Total Prescription Refills Checked	750
Wrong Drug	0	Wrong Drug	0
Wrong Strength	0	Wrong Strength	0
Safety Cap Error	1	Safety Cap Error	1
Wrong Amount	0	Wrong Amount	1
Other Errors	0	Other Errors Wrong patient identification = 2	2
Total Errors	1	Total Errors	4
Overall Error Rate	2%	Overall Error Rate	0.53%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	76%	58.97%
Time Spent in Management	4.71%	10.26%
Time Spent in Patient Care	17.92%	30.77%
Time Spent in Practice Development	1.37%	0%
Time Spent in Other Activities	0	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.22	0.21
Non-Reimbursed Patient Services Care	1.32	2.31
Total Patient Care Services	1.54	2.52

Percent of time utilizing TCT – 100%

Individual Site Data for *Site K*:

Site K Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):	
Total Rx Refills Checked	102
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0%

Site K data from Baseline collection (Pharmacist-checked prescriptions):	
Total Prescription Refills Checked	909
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	1
Wrong Amount	0
Other Errors	0
Total Errors	1
Overall Error Rate	0.11%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	59.29%	50.16%
Time Spent in Management	3.02%	4.44%
Time Spent in Patient Care	32.16%	43.43%
Time Spent in Practice Development	5.54%	0.75%
Time Spent in Other Activities	0%	1.21%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	1.98	0.62
Non-Reimbursed Patient Services Care	2.37	5.22
Total Patient Care Services	4.35	5.84

Percent of time utilizing TCT – 57.5%

Individual Site Data for *Site L*:

Site L Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):	
Total Rx Refills Checked	107
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0%

Site L data from Baseline collection (Pharmacist-checked prescriptions):	
Total Prescription Refills Checked	857
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	4
Wrong Amount	6
Other Errors	0
Total Errors	10
Overall Error Rate	1.17%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 - 1/31/16)**
Time Spent in Dispensing	81.6%	68.33%
Time Spent in Management	3.96%	4.64%
Time Spent in Patient Care	12.03%	23.73%
Time Spent in Practice Development	2.41%	3.30%
Time Spent in Other Activities	0%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.15	0.25
Non-Reimbursed Patient Services Care	1.06	1.61
Total Patient Care Services	1.21	1.86

Percent of time utilizing TCT = 52.5%

Individual Site Data for *Site M*:

Site M Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):			**Site M data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	110		Total Prescription Refills Checked	750
Wrong Drug	1		Wrong Drug	0
Wrong Strength	0		Wrong Strength	0
Safety Cap Error	1		Safety Cap Error	2
Wrong Amount	0		Wrong Amount	2
Other Errors	0		Other Errors	1
Total Errors		2	Total Errors	5
Overall Error Rate		1.8%	Overall Error Rate	0.67%

Composition of Pharmacist Day

	Baseline	**TCT Aug. (12/1/15 – 1/31/16)**
Time Spent in Dispensing	79.57%	76.72%
Time Spent in Management	3.76%	5.17%
Time Spent in Patient Care	14.52%	13.79%
Time Spent in Practice Development	0%	0.86%
Time Spent in Other Activities	2.15%	3.45%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.33	0.002
Non-Reimbursed Patient Services Care	1.76	0.6
Total Patient Care Services	2.10	0.602

Percent of time utilizing TCT = 27.5%

Individual Site Data for *Site N*:

Site N Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):	
Total Rx Refills Checked	500
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0%

Site N data from Baseline collection (Pharmacist-checked prescriptions):	
Total Prescription Refills Checked	868
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	1
Other Errors	0
Total Errors	1
Overall Error Rate	0.12%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	79.4%	73.90%
Time Spent in Management	5.32%	7.90%
Time Spent in Patient Care	13.95%	16.26%
Time Spent in Practice Development	1.33%	1.94%
Time Spent in Other Activities	0%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.21	0.20
Non-Reimbursed Patient Services Care	1.06	1.43
Total Patient Care Services	1.27	1.63

Percent of time utilizing TCT – 100%

Individual Site Data for *Site O*:

Site O Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):	
Total Rx Refills Checked	100
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0%

Site O data from Baseline collection (Pharmacist-checked prescriptions):	
Total Prescription Refills Checked	750
Wrong Drug	0
Wrong Strength	0
Safety Cap Error	0
Wrong Amount	0
Other Errors	0
Total Errors	0
Overall Error Rate	0%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	85.99%	61.73%
Time Spent in Management	3.26%	2.04%
Time Spent in Patient Care	10.13%	1.36%
Time Spent in Practice Development	0.62%	0%
Time Spent in Other Activities	0%	34.87%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.16	0.14
Non-Reimbursed Patient Services Care	1.18	0.31
Total Patient Care Services	1.34	0.44

Percent of time utilizing TCT – 80.0%

Individual Site Data for *Site P*:

Site P Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):		**Site P data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	100	Total Prescription Refills Checked	750
Wrong Drug	0	Wrong Drug	0
Wrong Strength	0	Wrong Strength	0
Safety Cap Error	0	Safety Cap Error	1
Wrong Amount	0	Wrong Amount	2
Other Errors	0	Other Errors	0
Total Errors	0	Total Errors	3
Overall Error Rate	0%	Overall Error Rate	0.4%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	52.63%	32.47%
Time Spent in Management	24.56%	12.60%
Time Spent in Patient Care	18.25%	49.86%
Time Spent in Practice Development	4.56%	5.04%
Time Spent in Other Activities	0%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.58	0.54
Non-Reimbursed Patient Services Care	0.41	4.88
Total Patient Care Services	0.99	5.41

Percent of time utilizing TCT = 95.0%

Individual Site Data for *Site Q*:

Site Q Data from Technician checked prescriptions collected (12/1/15 – 1/31/16):		**Site Q data from Baseline collection (Pharmacist-checked prescriptions):**	
Total Rx Refills Checked	102	Total Prescription Refills Checked	750
Wrong Drug	0	Wrong Drug	0
Wrong Strength	0	Wrong Strength	0
Safety Cap Error	0	Safety Cap Error	6
Wrong Amount	0	Wrong Amount	5
Other Errors	0	Other Errors Broken tablet = 1 Refrigerated item not in fridge = 1	2
Total Errors	0	Total Errors	13
Overall Error Rate	0%	Overall Error Rate	1.73%

Composition of Pharmacist Day

	Baseline	**TCT (12/1/15 – 1/31/16)**
Time Spent in Dispensing	80.75%	37.28%
Time Spent in Management	4.04%	3.57%
Time Spent in Patient Care	15.22%	59.15%
Time Spent in Practice Development	0%	0%
Time Spent in Other Activities	0%	0%

Number of Services Provided per Pharmacist Hour

	Baseline	**TCT (12/1/15 – 1/31/16)**
Reimbursed Patient Care Services	0.17	0.02
Non-Reimbursed Patient Services Care	3.18	3.58
Total Patient Care Services	3.35	3.60

Percent of time utilizing TCT – 90.0%

APPENDIX B

Site Requirements for New Practice Model (NPM) Project

The following is a guideline of requirements asked of sites in the NPM project. If a site struggles to meet the requirements, members from the NPM task force will review the site's progress and develop a plan of action to help the site succeed. If the site continues to be unable to meet the requirements, the members from the task force will provide a recommendation to the board of pharmacy to consider withdrawing the site from the study.

Sites that consistently struggle with:

1) Submitting data on time
2) Changing workflow to incorporate Tech-Check-Tech
3) Ongoing staffing issues including low number of hours doing Tech-Check-Tech
4) Using freed up time to reduce pharmacist hours or engage in non-patient care activities

APPENDIX C

New Staff addition to project since December 2015					
Site	Position	Name	Signed Letter	Signed study consent	Completed training
Walgreens Clive & Ames	Relief RPh	Evan Hammer	1/6/2016	1/6/2016	1/18/2016
Walgreens Clive	Relief RPh	Julie Lindgren	12/14/2015	12/14/2015	1/18/2016
Walgreens Ames	Relief RPh	Doyle Tweet	1/22/2016	1/22/2016	1/22/2016
Walgreens Clive	Relief RPh	Quang Phan	1/26/2016	1/26/2016	1/25/2016
Walgreens Clive	Relief RPh	Jennifer Elliff	1/11/2016	1/11/2016	1/26/2016
Nucara Story City	CPhT	Verona Parr	2/19/2016	2/19/2016	n/a (filling tech)

Staff that has left since December 2015 – None.