

ARIZONA HOUSE OF REPRESENTATIVES
Fifty-second Legislature – Second Regular Session

MINUTES RECEIVED
CHIEF CLERK'S OFFICE

1-27-16

COMMITTEE ON HEALTH

Report of Regular Meeting
Tuesday, January 26, 2016
House Hearing Room 4 -- 2:00 p.m.

Convened 2:15 p.m.

Recessed

Reconvened

Adjourned 5:57 p.m.

Members Present

Mr. Boyer
Mr. Friese
Mr. Lawrence
Mr. Meyer
Mrs. Cobb, Vice-Chairman
Mrs. Carter, Chairman

Members Absent

Agenda

Original Agenda – Attachment 1

Request to Speak

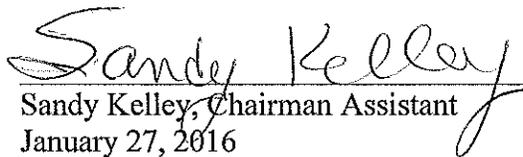
Report – Attachment 2

Presentations

<u>Name</u>	<u>Organization</u>	<u>Attachments (Handouts)</u>
Shannon Goldwater	Feeding Matters	3
Chris Linn		
W. C. Thompson, MD	Pain Management	None

Committee Action

<u>Bill</u>	<u>Action</u>	<u>Vote</u>	<u>Attachments (Summaries, Amendments, Attendance)</u>
HB2355	DPA	6-0-0-0	4,5,6,7,8,9
HB2310	DP	5-0-0-1	10,11,12,13,14
HB2265	DP	6-0-0-0	15,16
HB2225	DPA	6-0-0-0	17,18,19
HCM2001	DP	4-2-0-0	20,21
	Committee Attendance		22


Sandy Kelley, Chairman Assistant
January 27, 2016

(Original attachments on file in the Office of the Chief Clerk; video archives available at <http://www.azleg.gov>)

COMMITTEE ON HEALTH
Tuesday, January 26, 2016

Convened: 2:15 pm
adjourned: 5:57 pm

REVISED - 01/22/16

REVISED - 01/22/16

REVISED - 01/22/16

ARIZONA HOUSE OF REPRESENTATIVES
Fifty-second Legislature - Second Regular Session

REGULAR MEETING AGENDA

COMMITTEE ON HEALTH

DATE Tuesday, January 26, 2016

ROOM HHR 4

TIME 2:00 P.M.

Members:

Mr. Boyer
Mr. Friese

Mr. Lawrence
Mr. Meyer

Mrs. Cobb, Vice-Chairman
Mrs. Carter, Chairman

Presentations

Pain Management

- W. C. Thompson, MD

The Current Landscape of Pediatric Feeding Disorders

- Shannon Goldwater, Founder and Board Chair, Feeding Matters
- Chris Linn, Executive Director, Feeding Matters

Bills	Short Title	Strike Everything Title
HB2225	<u>dpa</u> radiologic technology; out-of-state licensed practitioners (Lawrence)	
	<u>6-0-0</u> HEALTH, RULES	
HCM2001	<u>dp</u> health insurance tax; repeal (Leach, Cobb; Norgaard)	
	<u>4-2-00</u> HEALTH, RULES	

ADDENDUM #1 - 01/22/16

HB2265	<u>dp</u> epinephrine auto-injectors (Cobb; Finchem, Weninger)	
	<u>6-0-0</u> HEALTH, RULES	
HB2310	<u>dp</u> biological products; prescription orders (Cobb, Coleman, Meza, et al)	
	<u>5-0-1</u> HEALTH, RULES	

Bills

Short Title

Strike Everything Title

*HB2355

dpa

opioid antagonists; prescription; dispensing;
administration

600-0

(Carter, Alston, Borrelli, et al)

* If first read and assigned

ORDER OF BILLS TO BE SET BY THE CHAIRMAN

slk

1/21/16

1/22/16

People with disabilities may request reasonable accommodations such as interpreters, alternative formats, or assistance with physical accessibility. If you require accommodations, please contact the Chief Clerk's Office at (602) 926-3032, TDD (602) 926-3241.

Information Registered on the Request to Speak System

House Health (1/26/2016)

HCM2001, health insurance tax; repeal

Testified in support:

Marc Osborn, AMERICA'S HEALTH INSURANCE PLANS (AHIP)

Support:

Farrell Quinlan, State Director, NATIONAL FEDERATION OF INDEPENDENT BUSINESS; Sara Sparman, AMERICA'S HEALTH INSURANCE PLANS (AHIP); Kathi Beranek, Blue Cross Blue Shield Of Arizona; Boaz Witbeck, AMERICANS FOR PROSPERITY AZ; Tom Jenney, AMERICANS FOR PROSPERITY AZ; Jaimie Kleshock, representing self; Kevin DeNomie, representing self; Joy Staveley, Chairman, Coconino County Republican Committee, representing self; Sara Sparman, AMERICA'S HEALTH INSURANCE PLANS (AHIP)

Oppose:

Brenda Thomas, ARIZONA FAMILY HEALTH PARTNERSHIP

All Comments:

Brenda Thomas, ARIZONA FAMILY HEALTH PARTNERSHIP: Arizona Family Health Partnership is opposed to HCM2001, the health insurance tax repeal of the ACA. We believe the ACA should be funded and that thousands of Arizonans who would otherwise not have health insurance are benefiting from the ACA.

HB2225, radiologic technology; out-of-state licensed practitioners

Testified in support:

Jason Bezozo, Senior Program Director, Government Relations, BANNER HEALTH ARIZONA

Support:

Steven Moortel, BANNER HEALTH ARIZONA; Jennifer Carusetta, HEALTH SYSTEM ALLIANCE OF ARIZONA; Boaz Witbeck, AMERICANS FOR PROSPERITY AZ; Tom Jenney, AMERICANS FOR PROSPERITY AZ; Jaimie Kleshock, representing self; Kevin DeNomie, representing self; Karen Mackean, representing self; Joy Staveley, Chairman, Coconino County Republican Committee, representing self; Stuart Goodman, DIGNITY HEALTH; Nancy Madezke, representing self

All Comments:

Karen Mackean, Self: I am in favor of opening up the barriers of licensing in Arizona!

HB2265, epinephrine auto-injectors

Testified in support:

Stuart Goodman, Mylan

Support:

Rory Hays, Arizona Nurses Association; Jeff Gray, AZ PHARMACY ALLIANCE; Pele Fischer, AZ MEDICAL ASSN; Kelly Ridgway, AZ PHARMACY ALLIANCE

HB2310, biological products; prescription orders

Testified in support:

Gino Grampp, representing self; Krystin Herr, ARTHRITIS FOUNDATION; Philip Schneider, representing self; Kaleo Ede, MD, representing self

Testified as neutral:

Pele Fischer, AZ MEDICAL ASSN

Testified as opposed:

Jeff Gray, AZ PHARMACY ALLIANCE

Support:

Gaspar Laca, Government Affairs Manager, Glaxosmithkline; Joan Koerber-Walker, representing self; Joseph Abate, PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA; Marcus Dell'Artino, AMGEN; Susie Stevens, Allergan, Genentech; Paul Senseman, Johnson & Johnson; Tom Farley, GENERIC PHARMACEUTICAL ASSOC, PFIZER INC; Amanda Rusing, BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO); Brian Hummell, American Cancer Society Cancer Action Network; Trish Hart, ELI LILLY & COMPANY; Pete Wertheim, Arizona Osteopathic Medical Association; Steven Zylstra, representing self; Barbara Lussenhop, Other; James Hamilton, BOEHRINGER INGELHEIM PHARMACEUTICALS INC, NOVARTIS PHARMACEUTICALS CO; Shelby Fletcher, Other

Neutral:

Janet Underwood, Arizona Community Pharmacy Committee; Deb Gullett, Arizona Association Of Health Plans

Oppose:

Kathi Beranek, Blue Cross Blue Shield Of Arizona; Farrell Quinlan, State Director, NATIONAL FEDERATION OF INDEPENDENT BUSINESS; Jaime Molera, AETNA INC; Kelly Ridgway, AZ PHARMACY ALLIANCE; Kelly Ridgway, AZ PHARMACY ALLIANCE; Sara Sparman, AMERICA'S HEALTH INSURANCE PLANS (AHIP)

All Comments:

Kathi Beranek, Blue Cross Blue Shield Of Arizona: BCBSAZ supports the availability of generics but has concerns that the notice requirement could be a barrier to the use of these less expensive prescriptions.; Farrell Quinlan, NATIONAL FEDERATION OF INDEPENDENT BUSINESS: The underlying policy is sound but how it is being implemented is flawed. The reporting requirements are too onerous for small, independent pharmacies.; Brian Hummell, American Cancer Society Cancer Action Network: HB2310 recognizes the evolving landscape of treatment and provides patient protections through communication with the entire care team.; Jaime Molera,

AETNA INC: .; Gino Grampp, Self: Representing Amgen; Kelly Ridgway, AZ PHARMACY ALLIANCE: error; Barbara Lussenhop, Other: Genentech; Shelby Fletcher, Other: Pfizer; Pele Fischer, AZ MEDICAL ASSN: ArMA is neutral on the bill. However, physician notification is imperative. Without physician notification, ArMA will likely be opposed.

HB2355, opioid antagonists; prescription; dispensing; administration

Support:

Rory Hays, Arizona Nurses Association; David Childers, PROPERTY CASUALTY INSURERS ASSOC OF AMERICA; Haley Coles, representing self; Tara Plese, AZ Alliance For Community Health Centers; Melody Glenn, representing self; Jeff Gray, AZ PHARMACY ALLIANCE; Pele Fischer, AZ MEDICAL ASSN; Kelly Ridgway, AZ PHARMACY ALLIANCE; Deb Gullett, Arizona Association Of Health Plans; Angela Geren, representing self; Lydia Larios, representing self; Janet Underwood, Arizona Community Pharmacy Committee; Erin Caldwell, representing self; Laura Cox, representing self; Josef Burwell, representing self; Kim Boardman, representing self; Erin Hoekstra, representing self; Pete Wertheim, Arizona Osteopathic Medical Association; Layal Rabat, representing self

All Comments:

Rory Hays, Arizona Nurses Association: With Carter amendment including Nurse Practitioners; Angela Geren, Self: Layperson access to naloxone is critical and the more people who have this medicine, the more lives can be saved!; Josef Burwell, Self: AZ PA medical license since 1995

PLEASE COMPLETE THIS FORM FOR THE PUBLIC RECORD



HOUSE OF REPRESENTATIVES

Please PRINT Clearly

Committee on HEALTH Bill Number 2310
 Date 1-26-2016 Support Oppose Neutral
 Name CATHY DALZECC Need to Speak? Yes No
 Representing ICAN Are you a registered lobbyist? NO
 Complete Address 6776 N. 63RD PL. PALM SPRING VALLEY, AZ
 E-mail Address CATHY@VALLEYRAIN.COM Phone Number 602-768-9272
 Comments: _____

FIVE-MINUTE SPEAKING LIMIT

PLEASE COMPLETE THIS FORM FOR THE PUBLIC RECORD



HOUSE OF REPRESENTATIVES

Please PRINT Clearly

Committee on Health Bill Number HB 2310
 Date 1/26/16 Support Oppose Neutral
 Name Kaleo Ede, MD Need to Speak? Yes No
 Representing Myself Are you a registered lobbyist? NO
 Complete Address 5434 E. Poinsettia Dr Scottsdale, AZ
 E-mail Address Kede@phoenixchildrens.com Phone Number 602-568-8332
 Comments: _____

FIVE-MINUTE SPEAKING LIMIT

PLEASE COMPLETE THIS FORM FOR THE PUBLIC RECORD

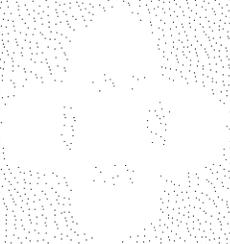


HOUSE OF REPRESENTATIVES

Please PRINT Clearly

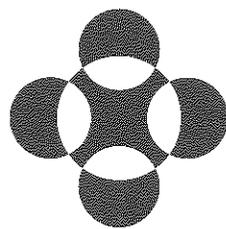
Committee on Health Bill Number 2355
Date 1-26-16 Support Oppose Neutral
Name Debbie Moak Need to Speak? Yes No
Representing self-NotMyKid Are you a registered lobbyist? No
Complete Address Governor's office
E-mail Address _____ Phone Number _____
Comments: _____

*****FIVE-MINUTE SPEAKING LIMIT*****



CONFIDENTIAL

MANY INFANTS AND
CHILDREN BATTLE WITH
THE FUNDAMENTALS OF
FEEDING—THEY ARE NOT
JUST PICKY EATERS.



feeding matters

*Conquering pediatric feeding struggles
to nourish healthy futures*

EATING IS INSTINCTUAL ONLY IN THE FIRST FEW WEEKS OF LIFE. AFTER THAT, IT IS A LEARNED BEHAVIOR. EARLY INTERVENTION IS CRITICAL.

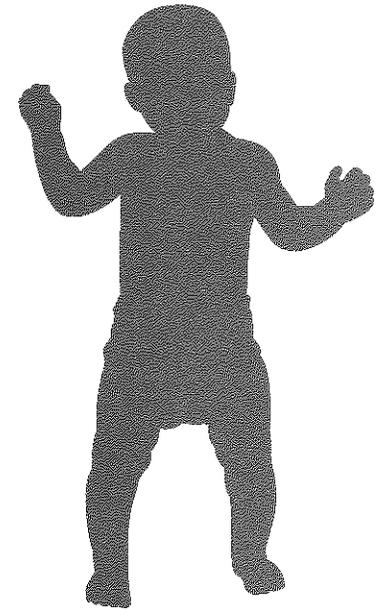
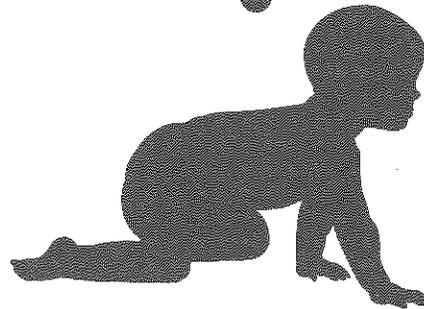
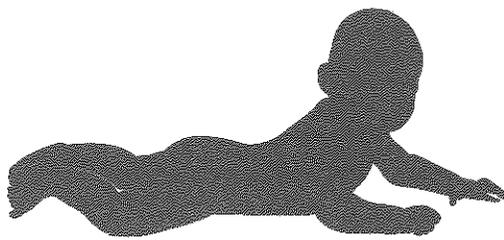
When children are unable to eat they **cannot thrive cognitively, physically, or emotionally.**

Eating is the body's **3rd priority**, only breathing and keeping one's head up are of greater importance.

Eating is **more difficult** than walking or talking.

A single swallow requires the use of **26 muscles** and **6 cranial nerves.***

Eating is the only bodily task that requires the use of **every organ and all of the senses.**

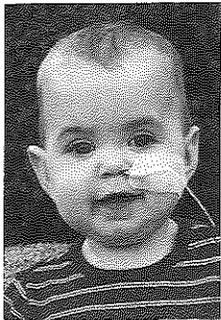


*Bass & Morrell, 1992

FEEDING IS COMPLEX

COLLABORATIVE APPROACH TO CARE

Feeding Matters® is spearheading the effort to conquer pediatric feeding struggles through a consortium of thought leadership.



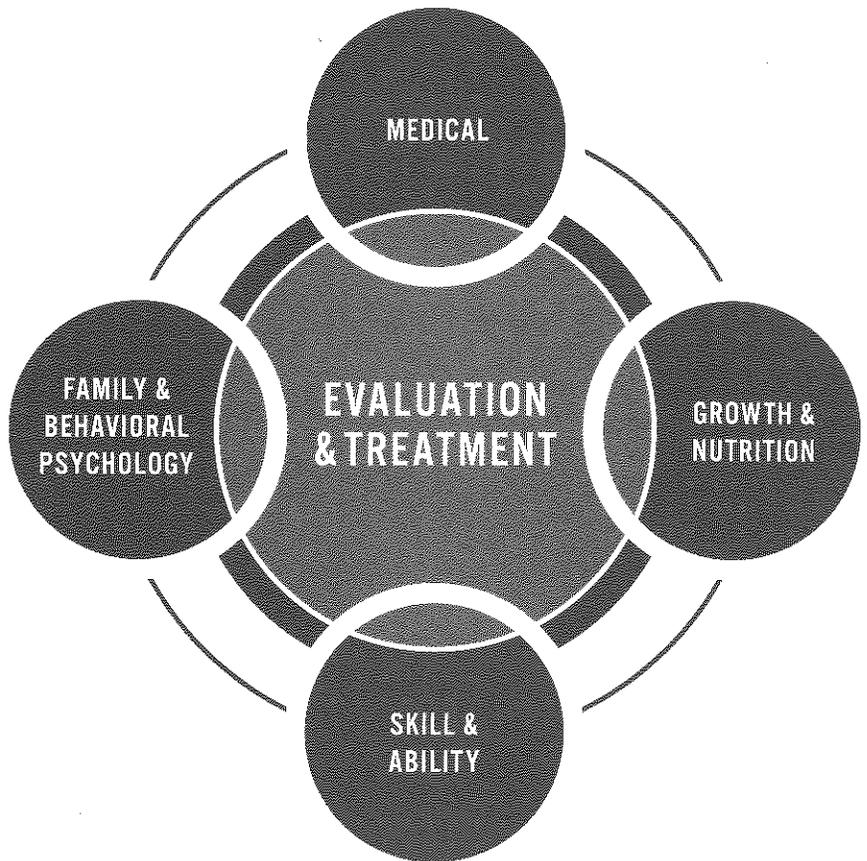
"Yes, it appears your daughter has the rare diseases that debilitate your son, and yes, she will also need a feeding tube in order to live." I couldn't believe my ears. The doctors were certain that the diseases our son has were so rare, that a second child with the same thing was highly unlikely. Yet there we were, alone in a world with questions that specialists could not

answer, and we had never seen a child with a feeding tube in our community, let alone a family with two. In our search for answers, my family was continuously passed from specialist to specialist. Some listened more than others but each provider's advice contradicted the next and our frustration continued.

My best friend said, "You need to meet others who will help you run this race." She told me about Feeding Matters®, and said that they would help us navigate my children's unique journey. Finding this organization changed our lives. Finally, I am surrounded by others who know first-hand the daily battles I am facing. They helped me understand collaborative care is crucial because pediatric feeding struggles are complex and no singular specialist will have all the answers.

With the help of Feeding Matters®, we've found a team of feeding experts who are working together to put the pieces of the puzzle together for our family.

Each team member has expertise in a specific field and our voice is heard and matters. My children have a long road ahead of them but without the help of Feeding Matters®, I would still be searching for answers and being passed from provider to provider getting nowhere. For the first time I know I'm not alone. I've found the kind of support and hope our family needs.



Feeding Matters® promotes coordinated care that addresses all aspects of a child's well-being.

“ This organization has harnessed the powerful voice and passions of parents to unify a formidable force of professionals and advocates to bring awareness and give voice to the large number of children and their families affected by feeding & swallowing problems. ”

- JULIE BARKMEIER-KRAEMER, PHD, CCC-SLP (UC DAVIS)

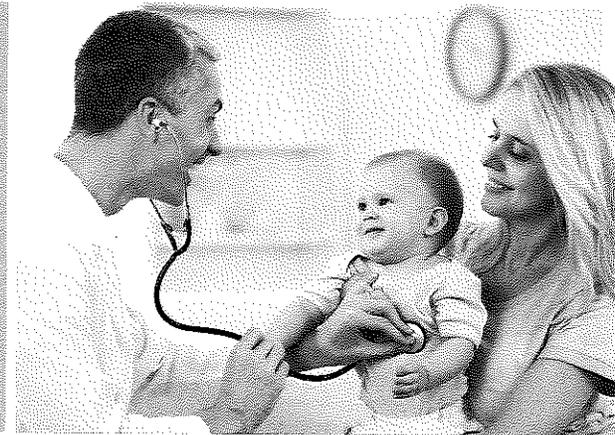
TAKE YOUR PLACE AT THE TABLE

Your role is crucial in continuing our efforts towards bringing this previously shadowed issue to the forefront.



PARENTS. We hear you — and your voice matters. Our dedication is driven by the necessity to minimize the challenge for families with feeding struggles. Between our personal experience with the problem and our partnership with the medical community, our hub of resources provides the support, expertise, and hope that families need.

MEDICAL COMMUNITY. Our thought leaders have created tools and resources to help establish best practices that foster collaborative approaches to care. With an increased understanding of the complexities of pediatric feeding struggles and the promotion of coordinated care, our medical community has the power to positively impact every child's well-being and future. Take your place at the table to transform the landscape of pediatric feeding struggles.



SUPPORTERS. Join the Feeding Matters® team on our mission to transform the landscape of feeding struggles to positively impact the lives of infants and children. Your role is crucial in continuing our efforts to bring a previously shadowed issue to the forefront. Your generosity matters; there's not a better time than now to take your place at the table.



ADVOCATE.

Spread the word to make a positive impact.



DONATE.

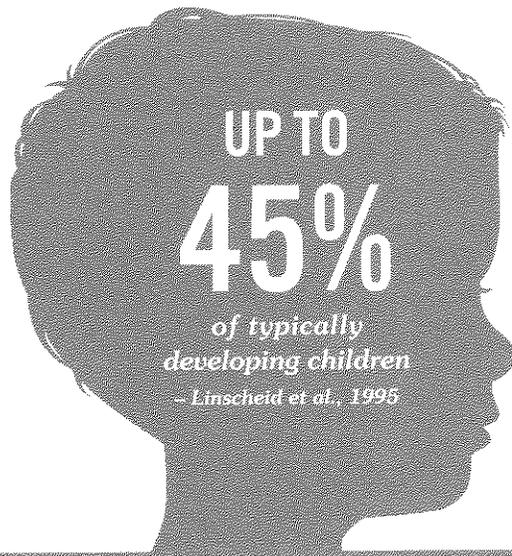
Contribute financially to support our mission.



VOLUNTEER.

Take the time to make a difference.

FEEDING STRUGGLES AFFECT



OVER A MILLION CHILDREN NATIONWIDE ARE IDENTIFIED WITH SEVERE FEEDING STRUGGLES. THOUSANDS MORE GO UNDIAGNOSED.

U.S. Census Data, 2010

*Feeding struggles
are often underlying
symptoms for over*

204
DIAGNOSES

Judarwanto; Picky Eaters Clinic, 2009

Diagnoses associated with feeding struggles:

Autism Spectrum Disorders

Cerebral Palsy

Congenital Heart Disease

Cystic Fibrosis

Down Syndrome

Eosinophilic Esophagitis (EoE)

Failure to Thrive

Mitochondrial Disease

Prematurity

Reflux

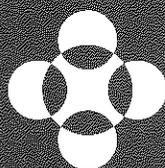
THE SUFFERING CONTINUES

There is a general lack of awareness on how to diagnose and treat infants and children with feeding struggles. Families are bounced from one medical professional to another trying to figure out what is wrong. Care is fragmented and families are challenged with facilitating the care for their child.

\$32k

ANNUAL COST
for a child on a feeding tube

Toomey, 2010



feeding matters

Feeding Matters® is bringing pediatric feeding struggles to the forefront so infants and children are identified early, families' voices are heard, and medical professionals are equipped to deliver collaborative care.

We overcome the complex issues of pediatric feeding struggles through our five mission pillars: education, advocacy, research, treatment, and support.

8711 E. PINNACLE PEAK RD. #333 • SCOTTSDALE, AZ 85255

P 602.222.6222 TF 800.233.4658 F 602.222.6225

feedingmatters.org • support@feedingmatters.org



feeding matters

CURRENT LANDSCAPE OF PEDIATRIC FEEDING DISORDERS

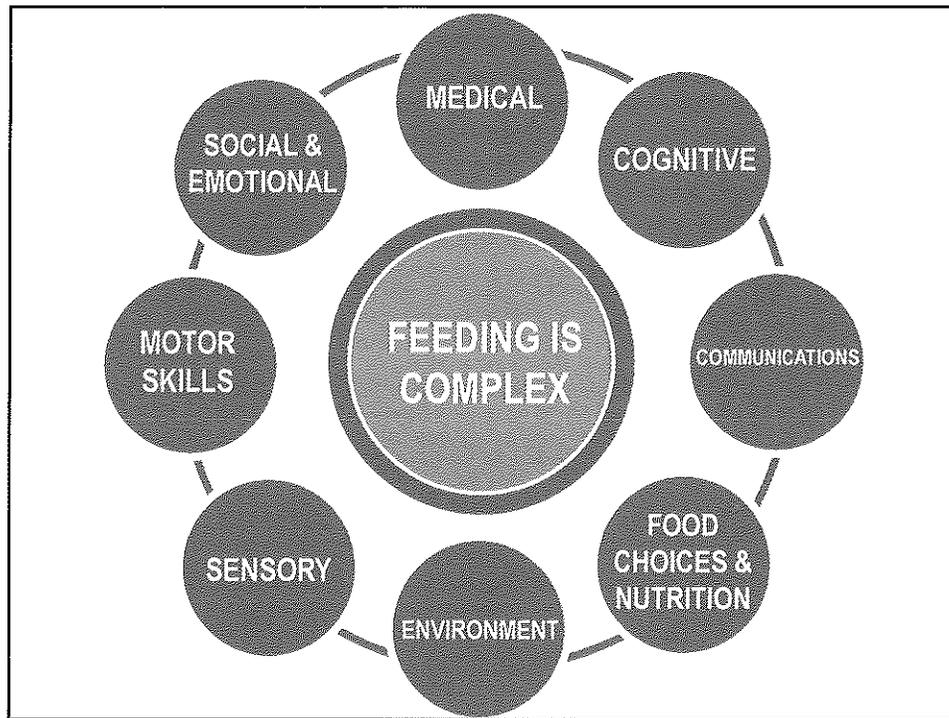
Shannon Goldwater, Founder & Board Chair

Chris Linn, Executive Director

WHAT ARE FEEDING DISORDERS

we are not talking about picky eaters

- A spectrum disorder that disrupts feeding, nutrition, and/or elimination.
- Impacts growth, cognitive development, physical strength, behavior, and nutritional status.
- A true debilitating condition that causes developmental delays with long lasting consequences.



WHO IS FEEDING MATTERS

thought leaders in pediatric feeding

- Founded in Scottsdale, AZ in 2006.
- Annually serves 40,000+ families and healthcare professionals across the country and internationally.
- Backed by a medical council comprised of 25+ world renowned feeding experts.
- Focused on education, advocacy, research, treatment, and support.

FEEDING DISORDERS TODAY

over a million children under age five are affected

- Approximately 5% of children in the United States who are under 5 years of age have severe feeding difficulties.
- 21,500 of these children are in Arizona.



EMILIE'S STORY

spent the first six years of her life on a feeding tube

- She would cry, arch, bat away the bottle, vomit and become listless.
- Her tiny body was instinctually trying to protect itself.
- I was told it was a phase and dismissed.
- Emilie was silently aspirating with every meal.
- It took three years for a referral to a feeding program.



CURRENT SERVICES IN ARIZONA

services are limited

- High demand but limited quality help available.
- The wait time is 6+ plus months, creating a narrow window for critical brain development.
- Economic impact of lost jobs, unnecessary medical interventions, etc.

WHY HAVEN'T I HEARD OF THIS

over 200 diagnoses place children at higher risk

- It's more common than most people realize.
- Parents feel like failures and don't want to talk about it.
- It's difficult to explain and parents feel judged.
- It is often mislabeled without its own classification.



WHAT IS THE SOLUTION

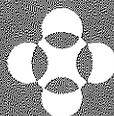
to recognize feeding struggles as a stand alone diagnosis

- Identify this disorder a recognized household name.
- Incorporate feeding questions into well-check visits.
- Cover costs through state programs and early intervention services.
- Shorten the wait time and increase the availability of feeding programs.

HOW YOU CAN HELP

we have some of the leading experts in the country



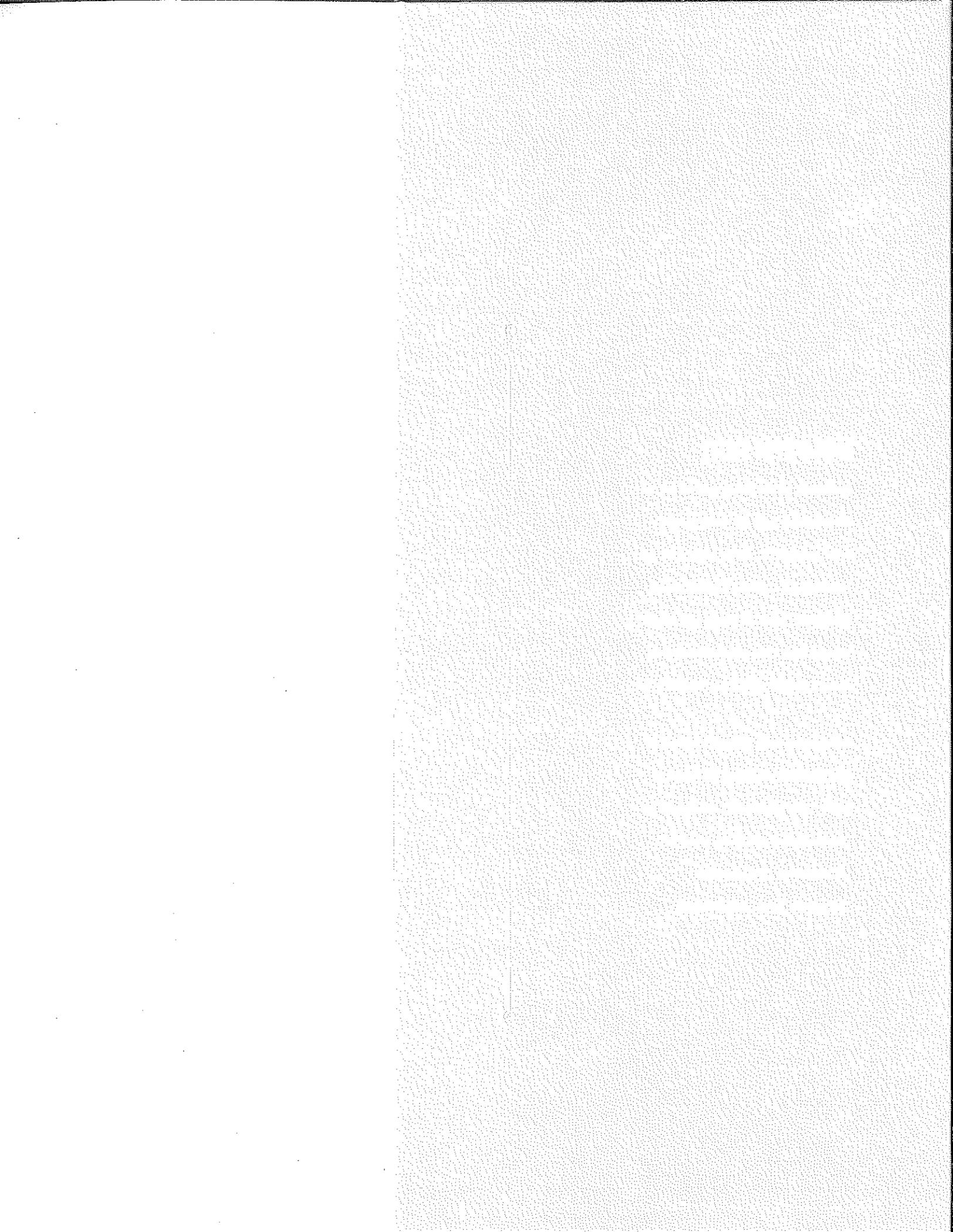


feeding matters

P 623.242.5234

support@feedingmatters.org

feedingmatters.org



Your role is crucial in continuing our efforts towards bringing this previously shadowed issue to the forefront.

SHANNON GOLDWATER

board chair & founder

P. 623.242.5234 C. 602.697.0840

SGOLDWATER@FEEDINGMATTERS.ORG

7650 E REDFIELD RD, SUITE C4 • SCOTTSDALE, AZ 85260



feedingmatters.org

REVISED

REVISED

REVISED



HOUSE OF REPRESENTATIVES

HB 2355

opioid antagonists; prescription; dispensing; administration

Prime Sponsor: Representative Carter, et al., LD 15

X Committee on Health

Caucus and COW

House Engrossed

OVERVIEW

HB 2355 allows a pharmacist to dispense naloxone hydrochloride (Naloxone) without a prescription to a person at risk of experiencing an opioid-related overdose or to a family member in a position to assist that person. Allows a physician to prescribe and dispense Naloxone to a person at risk, a family member in a position to assist a person at risk or a community organization that provides services to persons addicted to opioids that may be is a position to assist.

PROVISIONS

1. Permits a pharmacist to dispense Naloxone or any other opioid antagonist without a prescription to a person who is at risk of experiencing an opioid-related overdose or to a family member who is in a position to assist that person.
2. Requires a pharmacist who dispenses Naloxone or any other opioid antagonist to do the following:
 - a. Document the dispensing consistent with the Pharmacy Board rules; and
 - b. Instruct the individual to whom the opioid antagonist is dispensed to summon emergency services as soon as practicable either before or after administering the drug.
3. Clarifies that the authority of a pharmacist to fill or refill a prescription for Naloxone will not be affected.
4. Specifies that a pharmacist who dispenses an opioid antagonist is immune from professional liability and criminal prosecution for any decision, act, omission or injury that results if the pharmacist acts with reasonable care and in good faith, except in cases of wanton or willful neglect.
5. Allows for a licensed physician to prescribe or dispense Naloxone or any other opioid antagonist to a person who is at risk of experiencing an opioid-related overdose, to a family member who is in a position to assist that person or to a community organization that provides services to persons addicted to opioids and that may be in a position to assist a person who is at risk of experiencing an opioid-related overdose.
6. Specifies that a physician who prescribes or dispenses an opioid antagonist will be immune from professional liability and criminal prosecution for any decision, act, omission or injury that results if the physician acts with reasonable care and in good faith, except in cases of wanton or willful neglect.

HB 2355

7. Allows a person to administer an opioid antagonist that is dispensed by a pharmacist or prescribed or dispensed by a physician to a person who is experiencing an opioid-related overdose.
8. Specifies that a person who administers an opioid antagonist in good faith and without compensation to a person who is experiencing an opioid-related overdose is not liable for any civil or other damages as the result of any act or omission by the person rendering care or as the result of any act or failure to act to arrange for further medical treatment or care for the person experiencing the overdose, unless the person rendering the care is guilty of gross negligence.
9. Makes technical changes.

CURRENT LAW

A.R.S. §36-2228 states that an emergency medical care technician or peace officer who is trained in the administration of Naloxone or any other opiate antagonist that is approved by the United States Food and Drug administration and designated by the director of the Arizona Department of Health Services may administer to a person who they believe are suffering from an opiate-related drug overdose.

Licensed physicians, licensed nurse practitioners, emergency medical care technicians and peace officers who administer Naloxone or any other opiate antagonist are immune from professional liability and criminal prosecution for any decision made, act, omission or injury that results from that act if those persons act with reasonable care and in good faith, except in cases of wanton or willful neglect. The statute does not create a duty to act or a standard of care for peace officers to administer an opiate antagonist.

The director shall designate opiate antagonists that may be used based on an evaluation of the opiate antagonist's safety and efficacy.

PROPOSED

HOUSE OF REPRESENTATIVES AMENDMENTS TO H.B. 2355

(Reference to printed bill)

- 1 Page 21, line 5, after "17" insert ", A NURSE PRACTITIONER LICENSED PURSUANT TO
- 2 TITLE 32, CHAPTER 15 AND AUTHORIZED BY LAW TO PRESCRIBE DRUGS OR ANY OTHER
- 3 HEALTH PROFESSIONAL WHO HAS PRESCRIBING AUTHORITY AND WHO IS ACTING WITHIN
- 4 THE HEALTH PROFESSIONAL'S SCOPE OF PRACTICE"
- 5 Line 8, after "PHYSICIAN" insert ", NURSE PRACTITIONER OR OTHER HEALTH
- 6 PROFESSIONAL"
- 7 Line 10, strike "OR" insert a comma
- 8 Line 12, after "OVERDOSE" insert "OR TO ANY OTHER PERSON WHO IS IN A POSITION TO
- 9 ASSIST A PERSON WHO IS AT RISK OF EXPERIENCING AN OPIOID-RELATED OVERDOSE"
- 10 Lines 13 and 17, after "PHYSICIAN" insert ", NURSE PRACTITIONER OR OTHER HEALTH
- 11 PROFESSIONAL"
- 12 Line 23, after "PHYSICIAN" strike "OR" insert ", NURSE PRACTITIONER,"; after
- 13 "PHARMACIST" insert "OR OTHER HEALTH PROFESSIONAL"
- 14 Amend title to conform

HEATHER CARTER

2355CARTER3
01/25/2016
09:11 AM
H: BG/rca

2355CARTER3*
01/22/2016
04:10 PM
C: MJH

Attachment 5

Adopted <input checked="" type="checkbox"/>	# of Verbals _____
Failed _____	Withdrawn _____
Not Offered _____	Analysts Initials _____

Health Committee

1/26/15

Rep. Carter: Without objection, I move the following verbal amendment to HB 2355.

Page 21, line 13, strike "WANTON OR WILFUL NEGLECT" insert "GROSS NEGLIGENCE,
WILFUL MISCONDUCT OR INTENTIONAL WRONG DOING"

Page 21, line 31, strike "IS GUILTY OF" insert "ACTS WITH"; after "NEGLIGENCE" insert
", WILFUL MISCONDUCT OR INTENTIONAL WRONGDOING"

Attachment 6

Adopted <input checked="" type="checkbox"/>	# of Verbals <u>1</u>
Failed <input type="checkbox"/>	Withdrawn <input type="checkbox"/>
Not Offered <input type="checkbox"/>	Analysts Initials <input type="text"/>

Randy Friese
Verbal Amendment
1/28/16

see amendment

Without objection, I move the following verbal amendment to the proposed Friese Amendment dated 1/15/16 to HB2355 (opioid antagonists; prescription; dispensing; administration) :

Line 2- after "prescribes" insert "or dispenses".

Attachment 7

Adopted # of Verbals 2
Failed _____ Withdrawn _____
Not Offered _____ Analysts Initials _____

PROPOSED

HOUSE OF REPRESENTATIVES AMENDMENTS TO H.B. 2355

(Reference to printed bill)

1 Page 21, between lines 12 and 13, insert:

2 "B. A PHYSICIAN WHO PRESCRIBES NALOXONE HYDROCHLORIDE OR ANY OTHER
3 OPIOID ANTAGONIST PURSUANT TO SUBSECTION A OF THIS SECTION, SHALL INSTRUCT
4 THE INDIVIDUAL TO WHOM THE OPIOID ANTAGONIST IS DISPENSED TO SUMMON EMERGENCY
5 SERVICES AS SOON AS PRACTICABLE EITHER BEFORE OR AFTER ADMINISTERING THE
6 OPIOID ANTAGONIST."

7 Reletter to conform

8 Amend title to conform

RANDALL FRIESE

2355FRIESE
01/25/2016
10:35 AM
H: JH/rca

Attachment 8

Adopted <input checked="" type="checkbox"/>	# of Verbals _____
Failed _____	Withdrawn _____
Not Offered _____	Analysts Initials _____

**ARIZONA HOUSE OF REPRESENTATIVES
Fifty-second Legislature - Second Regular Session**

ROLL CALL VOTE

COMMITTEE ON HEALTH BILL NO. HB 2355

DATE January 26, 2016 MOTION: dpa

	PASS	AYE	NAY	PRESENT	ABSENT
Mr. Boyer		✓			
Mr. Friese		✓			
Mr. Lawrence		✓			
Mr. Meyer		✓			
Mrs. Cobb, Vice-Chairman		✓			
Mrs. Carter, Chairman		✓			
		6	0	0	0

APPROVED:



 HEATHER CARTER, Chairman
 REGINA COBB, Vice-Chairman



 COMMITTEE SECRETARY

ATTACHMENT _____



HOUSE OF REPRESENTATIVES

HB 2310

biological products; prescription orders

Prime Sponsor: Representative Cobb, et al., LD 5

X Committee on Health

Caucus and COW

House Engrossed

OVERVIEW

HB 2310 permits a pharmacist to substitute a biological product for a prescribed biological product when certain conditions are met.

PROVISIONS

1. Allows a pharmacist to substitute a biological product for a prescribed biological product only if all the following conditions are met:
 - a. The United States Food and Drug Administration (FDA) have determined the substituted product to be an interchangeable biological product.
 - b. The prescribing physician does not designate in writing or electronically that substitution is prohibited.
 - c. The pharmacy informs the patient or person presenting the prescription of the substitution.
 - d. Within five business days after dispensing a biological product, the dispensing pharmacist or their designee makes an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication must be conveyed by making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system or a pharmacy record. Communication is not required if:
 - i. There is no interchangeable biological product approved by the FDA for the prescribed product.
 - ii. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.
 - e. The pharmacy retains a record of the biological product dispensed.
2. Requires pharmacy staff to notify the person presenting the prescription of the price difference between the brand name drug or biological product prescribed and the generic drug or interchangeable biological product when the medical practitioner does not indicate intent to prevent substitution with a generic equivalent drug or interchangeable biological product.
3. Includes labeling requirements when a biological product or an interchangeable biological product is used.
4. Prohibits an employer or agent of an employer of a pharmacist from requiring the pharmacist to dispense an interchangeable biological product or to substitute an interchangeable

HB 2310

biological product for a biological product against the professional judgment of the pharmacist or the order of the prescriber.

5. Restricts a pharmacist's ability to make a substitution unless the manufacturer or distributor of the interchangeable biological product has shown that:
 - a. All products dispensed have an expiration date on the original package.
 - b. The manufacturer or distributor maintains recall and return capabilities for unsafe or defective biological products.
6. Requires the Arizona State Board of Pharmacy to maintain on its website a link to the current list of each biological product determined by the FDA to be an interchangeable product.
7. Includes interchangeable biological products in the worker's compensation statute (A.R.S. § 23-908).
8. Defines *biological product* and *interchangeable biological product*.

CURRENT LAW

A.R.S. § 32-1963.01 provides that if a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution, a pharmacist is permitted to fill the prescription with a generic drug. Pharmacy staff must notify the person presenting the prescription of the cost differential between a name brand and generic drug and in addition statute outlines labeling instructions.

A prescription must be dispensed as written only if the prescriber writes or clearly displays "DAW", "dispense as written", "do not substitute", "medically necessary" or any statement by the prescriber that clearly indicates an intent to prevent substitution. An out-of-state prescription must be dispensed as written only if the prescriber clearly writes or clearly displays "do not substitute", "dispense as written", "medically necessary" or any statement by the prescriber that clearly indicates intent to prevent substitution.

**ARIZONA HOUSE OF REPRESENTATIVES
Fifty-second Legislature - Second Regular Session**

ROLL CALL VOTE

COMMITTEE ON HEALTH BILL NO. HB 2310

DATE January 26, 2016 MOTION: df

	PASS	AYE	NAY	PRESENT	ABSENT
Mr. Boyer					✓
Mr. Friese		✓			
Mr. Lawrence		✓			
Mr. Meyer		✓			
Mrs. Cobb, Vice-Chairman		✓			
Mrs. Carter, Chairman		✓			
		5	0	0	1

Sandy Kelly
COMMITTEE SECRETARY

APPROVED:
[Signature]
HEATHER CARTER, Chairman
REGINA COBB, Vice-Chairman

ATTACHMENT _____

Please Support HB 2310 **Biosimilar Substitution Legislation**

Remove barriers to lower cost drugs and ensure patient safety.

What the bill does:

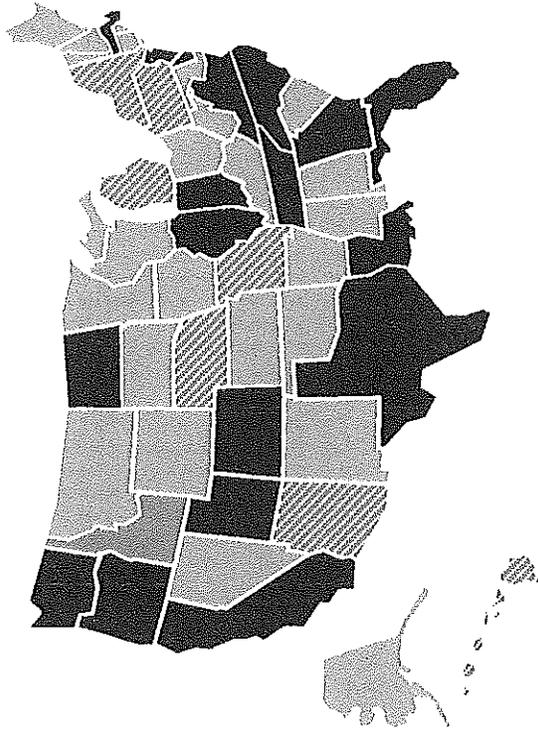
- HB 2310 will update the Arizona Pharmacy Practice Act.
- Allows Arizona pharmacists the ability to dispense safe and less expensive biologic medications to patients, by allowing substitution of an interchangeable biologic for a prescribed brand name biologic.
- Current Arizona law has no clear pathway for substitution of biologic drug products. Therefore, pharmacists will be required to obtain advanced approval from the prescriber before they are allowed to substitute an interchangeable biologic for a brand name biologic. **HB 2310 will remove this requirement.**
- Physicians will retain the authority to use Dispense as Written or DAW. This is identical to the authority they have with generic substitution.
- The current pharmacy practice act has specific rules that must be followed to ensure safe generic substitution. Passing legislation would update these laws to include a similar process to ensure safe biologic substitution. The first biosimilar has been approved and is on the market.
- Assures only FDA approved "interchangeable" biologic products may be substituted without prior prescriber consent. This is similar to substitution requirements of generic substitution.
- Ensures patients will be notified of the substitution, in the same way they are notified with a generic substitution.
- Because biologic products differ from generics in complexity and are not identical chemical products, the legislation ensures there will be **communication** between pharmacists and prescribers to ensure medical records reflect which specific product has been dispensed to the patient. Pharmacists will have up to 5 days to relay information on which prescription is dispensed, for a complete patient medical record.
- Current AZ statute requires the pharmacists to notify the primary care physician within 48 hours after administering a vaccine/immunization. A bill this session supported by the pharmacists expands their authority to include administration to minors, and includes the 48 hour notification requirement.

Why support HB 2310:

- HB 2310 recognizes the growing use of interoperable electronic health records and electronic prescribing records, allowing such systems to be used by a patient's health care team to communicate regarding a patient's medication history.
- **HB 2310 will establish a clear substitution process** by allowing pharmacists to dispense an FDA approved interchangeable biologic without first seeking approval.
- HB 2310 will increase access to lower cost drugs for patients.
- A large coalition (of branded & generic manufacturers and associations, many provider & patient groups, along with pharmacy benefit managers and some health insurers) Support or are Neutral on the language in this legislation.

Legislation to allow pharmacist substitution of interchangeable biologic drugs
has now passed in 20 states. Please vote YES on HB 2310!

State Pharmacy Practice Act Update – January 2016 Status



-  Legislation enacted (19 + Puerto Rico)
-  Board of Pharmacy regulation (1)
-  Legislation is active and progressing (8)

January 2016 Status

- In 2015, 12 states and Puerto Rico enacted legislation updating pharmacy practice acts to address biologics and biosimilars.
- Since 2013, 19 states and Puerto Rico have enacted state pharmacy practice acts to address biologics and biosimilars.
- Legislation is currently progressing in eight states, with additional states expected to consider.
- Thirty-one states and the District of Columbia have yet to update their state pharmacy practice acts.
- The FDA approved the first US biosimilar in early 2015.

Legislation Passed 2013-14

- ✓ Indiana
- ✓ Delaware
- ✓ Massachusetts
- ✓ North Dakota
- ✓ Florida
- ✓ Virginia
- ✓ Oregon

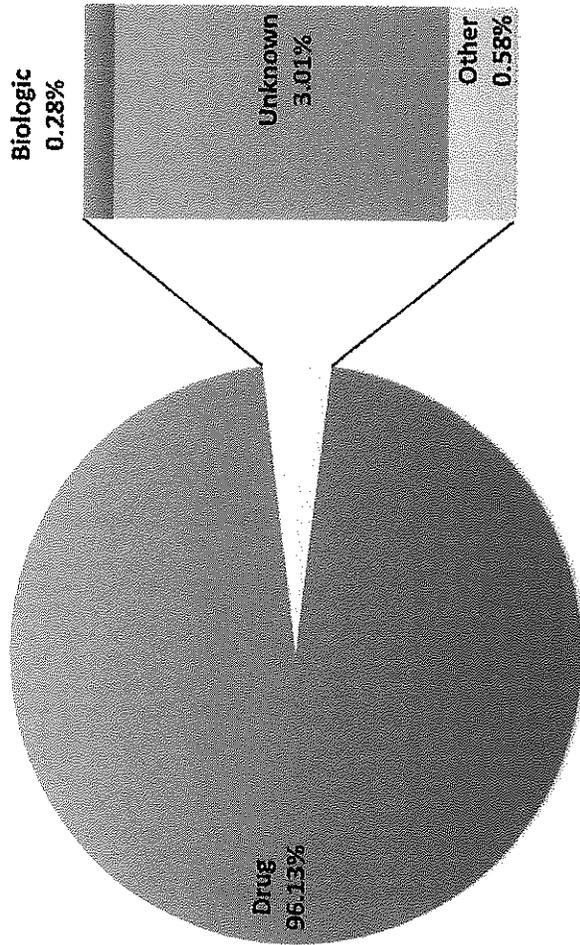
Legislation Passed 2015

- ✓ California
- ✓ Colorado
- ✓ Georgia
- ✓ Illinois
- ✓ Idaho (*BoP regulation*)
- ✓ Louisiana
- ✓ New Jersey
- ✓ North Carolina
- ✓ Tennessee
- ✓ Texas
- ✓ Utah
- ✓ Washington
- ✓ Puerto Rico

Legislation Currently Progressing 2016

- ✓ Arizona
- ✓ Hawaii
- ✓ Michigan
- ✓ Missouri
- ✓ Nebraska
- ✓ New York
- ✓ Oregon
- ✓ Pennsylvania

Arizona: Biologics Represented 0.28% of Prescriptions Dispensed by Retail Pharmacies in 2013



Rxs Filled	In 2013	Per month (average)	Per week (average)
Drugs	74,105,167	6,175,431	1,425,099
Biologics	214,298	17,858	4,121

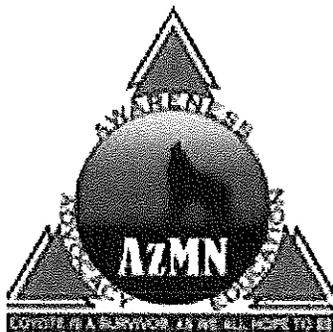
There are 1,082 retail pharmacies in Arizona. On average a retail pharmacy dispenses 3.81 biologic prescriptions per week.

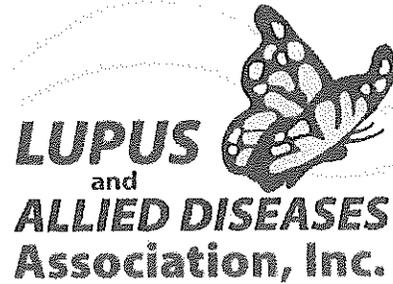
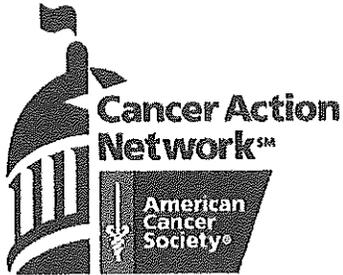
Sources: MarketScan, July 2014; Data for Jan 2013-Dec 2013 Other includes "Unapproved (Not Included)" "Others", "OTC, and vaccines; insulin is categorized as a drug. Vaccines are excluded from the biologics category. Data extrapolated to map to full universe using Kaiser State Health Facts. Retail may include specialty pharmacy data. Retail pharmacy count is from NPMS 2014, SK&A, A Cegedim Company

We are **UNITED** in our Support for House Bill 2310



Southwest Chapter





Kidney Cancer Association

Contact:
Mark Guimond, Director of State Legislative Affairs
Arthritis Foundation
202 887-2912
MGuimond@Arthritis.org



ARTHRITIS FOUNDATION, PACIFIC REGION
c/o 5009 E. Washington St., Suite 125
Phoenix, AZ 85034
www.arthritis.org

January 25, 2016

The Honorable Heather Carter, Chair
House Health Committee
Arizona State Capitol
1700 West Washington Street
Phoenix, AZ 85007

RE: House Bill 2310 (Cobb) - Support

Dear Representative Carter,

The Arthritis Foundation urges the members of the House Health Committee to support this important bill. House Bill 2310 will update current law and allow the substitution of biologic medicines with interchangeable biological products. This bill would also require a pharmacist, when dispensing an interchangeable biological product, to notify both the patient and the prescriber of the switch thus ensuring a complete medical record.

Arthritis is an umbrella term for more than 100 different conditions such as rheumatoid arthritis, lupus, ankylosing spondylitis that affects the spine, and uveitis that affects the eye and can lead to permanent vision loss. For more than 1.1 million adults and 6,000 children in Arizona suffering from this debilitating disease, ensuring they have access to life-changing medications is vital. In many cases that means the difference between a lifetime of disability and full participation in work and civic life. In addition to the ongoing management of a patient's arthritis, of which there is no cure, the vast majority of patients with arthritis also have multiple other chronic conditions. Because of the complexity to not only treat rheumatic conditions, but also the patient's comorbidities, it is imperative the patient and their physician are able to discuss their treatment options, switches in medications, as well as options available to them. Additionally notification and communication of these switches will ensure the patients have a complete medical record of all medications dispensed. This information can be especially important for children with juvenile arthritis who, when they become an adult, will transition away from pediatric rheumatology and into their adult care team.

When therapeutic innovations come to market, patient safety must remain the number one priority in any discussion; even if a drug is less expensive, these advantages mean nothing if the drug does not successfully treat the patient. It is important to remember that these are complex medications, and that interchangeable biological products are not the same as generics. Because of this, the Arthritis Foundation is committed to ensuring that the concerns of people who take these medications, and the specialist physicians who treat them, are kept at the forefront. By doing so, the patient and physician can continue a dialogue ensuring they receive the optimal care with these game-changing medicines. House Bill 2310 takes a step in the right direction to ensure that both the patient and the physician are notified and will encourage a high level of communication between all players on the healthcare team.

On behalf of the Arthritis Foundation, I thank you for your consideration and urge your support of HB 2310, which will keep patients and providers informed when medications are substituted.

Sincerely,

A handwritten signature in black ink, appearing to read "Krystin Herr".

Krystin Herr
Vice President, Government Affairs & Advocacy
Cell (916) 502-2979
kherr@arthritis.org

cc: Representative Regina Cobb, Vice Chair
Members, House Health Committee
Ingrid Garvey

January 26, 2016

The Honorable Heather Carter
Chair, Health Committee
Arizona House of Representatives
1700 W. Washington Street
Phoenix, AZ 85007

RE: Support for HB 2310 - biological products; prescription orders

Dear Chairman Carter,

On behalf of the Arizona Bioindustry Association (AZBio), we would like to convey our full support for House Bill 2310, which establishes the process to provide Arizona pharmacists with the ability to substitute an U.S. Food and Drug Administration (FDA) approved "interchangeable biosimilar" for the corresponding biologic prescribed by the patient's physician and provides a process for communication with both the patient and the prescriber.

As Arizona's statewide bioscience association, AZBio works closely across the care continuum with patient groups, healthcare providers, biotechnology manufacturers, biotechnology centers and research centers here in Arizona to ensure that people in Arizona benefit from the lifesaving and life changing innovations our industry discovers, develops, and delivers.

Biologic medicines are making life better for patients with life threatening diseases and conditions such as cancer, rheumatoid arthritis, Crohn's Disease and diabetes. They are also very different from traditional chemically derived medicines (drugs) because biologics are made from living organisms. While a chemically manufactured drug can be identically reproduced to formulate a generic drug, the unique qualities of all living organisms makes this impossible for biologics. That is why the new classes of biosimilars and interchangeable Biosimilars were created by the FDA. These new products will be close to the original biologic medicine or in the case of interchangeable biosimilars, very close, but they will never be exactly the same.

HB 2310 contains important provisions that take into account the special and complex characteristics of biologic medicines. Pharmacy substitution with these special medicines should therefore ensure patient safety by limiting substitution to biologics designated as interchangeable by the U.S. Food and Drug Administration and by establishing open communications between the pharmacy and prescriber as a way to ensure all those involved in a patient's care know exactly the course of treatment for that patient.

Over the last 5 years, I have had the opportunity to meet with both patients and their physicians and to see first-hand the impact that biologics have made in improving the quality of care and the quality of life for patients. With the advent of biosimilars and the expected approval of interchangeable biosimilars in the future, patients and their physicians will have even more options. This is great news both for patient care and for the competitive process that will help to further reduce healthcare costs.

Thank you to you and your committee for giving full consideration to HB 2310.

Please do not hesitate contacting me if you have questions or require any additional information.

Regards,

If you have any questions, please feel free to contact me directly at 480.332.9636.

Sincerely,



Joan Koerber-Walker

President & CEO

Arizona Bioindustry Association, Inc. (AZBio)

107 S. Southgate Drive, Chandler, AZ 85226

Mobile phone: 480-332-9636

Email: jkw@azbio.org

CC: Health Committee



January 25, 2016

The Honorable Heather Carter
Chair, Health Committee
Arizona House of Representatives
1700 W. Washington Street
Phoenix, AZ 85007

Dear Chairman Carter,

On behalf of the Biotechnology Innovation Organization (BIO), we would like to convey our full support for House Bill 2310, which permits substitution of biologic medicines by Arizona pharmacists. BIO represents over 1,000 biotechnology manufacturers, biotechnology centers and research centers across the United States and around the world.

Our organization supports HB 2310 because it contains important provisions that take into account the special and complex characteristics of biologic medicines. Unlike traditional chemically derived medicines, biologics are made from living organisms making them effective in treating life threatening diseases and conditions such as cancer, rheumatoid arthritis and diabetes. Pharmacy substitution with these special medicines should therefore ensure patient safety by limiting substitution to biologics designated as interchangeable by the U.S. Food and Drug Administration and by establishing open communications between the pharmacy and prescriber as a way to ensure all those involved in a patient's care know exactly the course of treatment for that patient. HB 2310 by Representative Cobb contains those important provisions, which is why we encourage you and your colleagues on the Health Committee to support HB 2310.

We are encouraged that your committee is giving full consideration to HB 2310. Please do not hesitate contacting me if you have questions or require any additional information.

Regards,

A handwritten signature in black ink, appearing to read "Patrick Plues", is written in a cursive style.

Patrick Plues
Senior Director, State Government Affairs
BIO

CC: Health Committee

The Biotechnology Innovation Organization - 1200 Maryland Avenue, SW - Washington, DC 20024
(202) 962-9200

27 West Morten Avenue
Phoenix, AZ 85021-7246
phone (602) 618-0183 - fax (602) 926-8109
programs@askican.org - www.askican.org

3944 Pine Avenue
Long Beach, CA 90807
phone (562) 427-5561

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Qingmei Xie, MD



January 22, 2016

Chairman Heather Carter
House of Representatives
1700 W. Washington
Room 303
Phoenix, AZ 85007

Re: HB 2310—Biological Products/Prescription Orders, to be considered by the Committee on Health on Tuesday, January 26, 2016.

Dear Chairman Carter,

All over the country, state legislatures are considering legislation, and many have already passed bills, to ensure that their residents have access to interchangeable biological products, or “biosimilars.” We are at the beginning of a new age of biological therapies, and laws and regulations must reflect this new reality. HB 2310, to be considered by the Committee on Health on Tuesday, January 26, 2016, is an excellent example of legislation that does just that.

ICAN, the International Cancer Advocacy Network, is in strong support of HB 2310 because of its patient safety protections for dispensing biosimilars. We appreciate your co-sponsorship of the bill and are confident it will receive favorable consideration during the hearing.

ICAN is a Phoenix-based, five-star rated 501(c)(3) charitable cancer patient advocacy organization. We work with the direct navigation of Stage IV cancer patients throughout Arizona and throughout the country. We deal daily with biologic therapies for our U.S. patients, and for our patients in 53 countries. Biologic therapies, and thus biosimilars, will become a growing area for metastatic cancer patients.

This is a particularly timely issue given the first approval of a biosimilar in the United States just last year and the expected approval of more in the future. HB 2310 ensures that when an FDA-approved, lower-cost, interchangeable biosimilar is substituted by a pharmacist for a brand-name biologic, records will be kept, and the prescribing physician will be notified, thus ensuring patient safety.

Notification of the physician is essential because, unlike generic drugs that are an exact copy, the biosimilar can be slightly different due to manufacture, transportation, or handling. If a patient experiences any adverse reactions, a physician needs to know all possible causes, including and especially, that the patient received a biosimilar. Failing to notify a physician when a substitution is made is an unnecessary risk to patient safety.

While we acknowledge (and welcome) the economic impact on healthcare of biosimilars, they do not require the same stringent approval process as is required by their reference biologic drugs. Certain biosimilars have caused life-threatening complications in patients due to structural changes in their protein coding sequences, their differential processing, and their unintended induction of potent, immunologic reactions. Each and every patient may respond differently to any biologic, depending on their individual genetics and immunologic status.

Your support for HB 2310 in the hearing on January 26, and throughout the legislative process, is a powerful voice for patient safety for ICAN's Arizona patients, and for all Arizona patients. It is also supporting well-crafted legislation that can serve as a model for other states.

Please do not hesitate to contact me at marcia@askican.org if you need additional information.

Thank you for your consideration, and for your support.

Respectfully submitted,

Marcia K. Horn

Marcia K. Horn, J.D.
President and CEO
International Cancer Advocacy Network (ICAN)
27 West Morten Avenue
Phoenix, AZ 85021-7246
602-618-0183 (phone)
602-926-8109 (fax)
www.askican.org
marcia@askican.org

Cathy Dalzell

Cathy Dalzell
Chairman
ICAN Advisory Council

Organizations in SUPPORT of HB 2310
Biological Products; Prescription Orders

Pharmacists Substitute Interchangeable Biologics
and Communicate Substitution to Prescriber

AbbVie
Allergan
American Cancer Society Cancer Action Network
Amgen
Arizona Medical Association
Arizona Myeloma Network
Arizona Osteopathic Medical Association
Arthritis Foundation
Astellas
AZ BIO
BIO
Biogen
Boehringer Ingelheim
Bristol Myers Squibb
Coherus
EMD Serono
Express Scripts
Genentech
GlaxoSmithKline
GPhA
Horizon Pharma
ICAN, International Cancer Advocacy Network
Johnson & Johnson
Lilly
Merck
Novo Nordisk
Pfizer
PhRMA
Sandoz/Novartis
Sanofi
Southwest Chapter, Crohn's & Colitis Foundation
Takeda
Teva
UCB

Patient Name:			
Birthdate:	Age:	Years	Sex: MRN:
Allergies: No known allergies			
Pharmacist please note--Allergy list may be incomplete.			
Patient Address:		Home Phone:	
		Work Phone:	

New Prescription:	Date Issued: 01/25/2016
--------------------------	--------------------------------

Rx: Keflex 500 mg oral capsule	Date Written: 01/25/2016
SIG: 1 cap PO QID for 3 day(s)	
Dispense/Supply: <12 cap>	
Refill: None	

DISPENSE AS WRITTEN

SUBSTITUTION PERMITTED

Prescribed by:

Electronically Signed On: 01/25/16 13:21:00 MS
NPI #:

This prescription should only be accepted if it is printed on security paper.
 This prescription is valid when signed electronically (E-Sig.) or signed by hand by the prescriber.
 If you feel for any reason, this prescription is not valid, please contact the prescriber immediately.

lbrxregen; 8/03/2015

PRINTED PRESCRIPTION

Date: 01/25/2016

40

3

Pharmacy

Rx

azithromycin tablet 250 mg orally

Disp: ***6*** (SIX)

Sig: 2 tabs today, then 1 tab each days x 4 days once a day 5 days

Diagnosis: (J20.9) Acute bronchitis, unspecified

Refills: ***0*** (ZERO)

Auth No:

DEA #:

NPI #:

LIC.#:



To ensure brand name dispensing, prescriber must write "Dispense as Written" or "D.A.W" on the prescription.



AZ Biosimilar Substitution Legislation Talking Points

ASBM supports this bill because it removes barriers to lower cost medicines and increasing treatment options, while recognizing the need for transparency and communication between healthcare providers to ensure patient safety.

Intro:

- Philip J. Schneider, M.S. F.A.S.H.P. is a Clinical Professor and Director of Administrative and Professional Affairs at the University of Arizona, College of Pharmacy – Phoenix campus.
- Former President of American Society of Health-system Pharmacists (ASHP)
- Also serves Advisory Board Chair for the Alliance for Safe Biologic Medicines
- ASBM has been working on biosimilar issues at the state, federal and international level for 5 years
- Dr. Schneider has worked to foster a more collaborative approach between healthcare providers regarding biosimilars, and participated in the development of the World Health Organization's distinguishable naming standard for biologic medicines, recently embraced by the FDA.

What the bill does:

- Legislation will update the Arizona Pharmacy Practice Act.
- Allows Arizona pharmacists the ability to dispense safe and less expensive biologic medications to patients, by allowing substitution of an interchangeable biologic for a prescribed brand name biologic.
- Current Arizona law has no clear pathway for substitution of biologic drug products. Therefore, pharmacists will be required to obtain advanced approval from the prescriber before they are allowed to substitute an interchangeable biologic for a brand name biologic.
This legislation will remove this requirement.
- The current pharmacy practice act has specific rules that must be followed to ensure safe generic substitution. Passing legislation would update these laws to include a similar process to ensure safe biologic substitution. The first biosimilar has been approved and is on the market.



- Assures only FDA approved “interchangeable” biologic products may be substituted without prior prescriber consent. This is similar to substitution requirements of generic substitution.
- Physicians will retain the authority to use Dispense as Written or DAW. This is identical to the authority they have with generic substitution.
- Ensures patients will be notified of the substitution, in the same way they are notified with a generic substitution.
- Because biologic products differ from generics in complexity and are not identical chemical products, the legislation ensures there will be **communication** between pharmacists and prescribers to ensure medical records reflect which specific product has been dispensed to the patient. Pharmacists will have up to 5 days to relay information on what prescription is dispensed, for a complete patient medical record.

Why support this legislation:

- It recognizes the growing use of interoperable electronic health records and electronic prescribing records, allowing such systems to be used by a patient’s health care team to communicate regarding a patient’s medication history.
- **It will establish a clear substitution process** by allowing pharmacists to dispense an FDA approved interchangeable biologic without first seeking approval.
- It will increase access to lower cost drugs for patients.
- A large coalition (of branded & generic manufacturers and associations, many provider & patient groups, along with the largest pharmacy benefit manager and some health insurers) agree on the language in this legislation.
- **Legislation to allow pharmacist substitution of biologic drugs has now passed in 19 states, including Puerto Rico and by rule in ID.**



HOUSE OF REPRESENTATIVES

HB 2265

epinephrine auto-injectors

Prime Sponsor: Representative Cobb, et al., LD 5

X Committee on Health

Caucus and COW

House Engrossed

OVERVIEW

HB 2265 permits an authorized entity to acquire and stock a supply of epinephrine auto-injectors that have been prescribed by a medical practitioner.

PROVISIONS

1. Allows medical practitioners to prescribe epinephrine auto-injectors in the name of an authorized entity and allows pharmacists and practitioners to dispense epinephrine auto-injectors.
2. Makes prescriptions valid for two years.
3. Permits an authorized entity to acquire, stock and store a supply of epinephrine auto-injectors in a location that is readily accessible in case of an emergency.
4. Designates employees or agents of an authorized entity who have completed required training to be responsible for the storage, maintenance, control and general oversight of epinephrine auto-injectors acquired by the authorized entity.
5. Specifies that an employee or agent of an authorized entity who has completed the required training may provide and administer an epinephrine auto-injector to any person whom they believe in good faith is experiencing anaphylaxis regardless of whether the person has a prescription or has been previously diagnosed with an allergy.
6. Requires any person providing or administering an epinephrine auto-injector complete initial anaphylaxis training and a training every two years thereafter.
7. Requires an epinephrine auto-injection training program to be conducted by a nationally recognized organization that is experienced in training laypersons in emergency health treatment or by any person approved by the Arizona Department of Health Services (ADHS).
8. Allows for training to be conducted online or in person and must cover the following:
 - a. Recognizing signs and symptoms of severe allergic reaction, including anaphylaxis;
 - b. Standards and procedures for the storage and administration of an epinephrine auto-injector; and
 - c. Emergency follow-up procedures.
9. Specifies that the entity conducting the required training must issue an approved certificate to each person who successfully completes the program.
10. Clarifies that the administration of epinephrine auto-injectors is not the practice of medicine or any other profession that requires a license.

HB 2265

11. States that a Practitioner prescribing epinephrine auto-injectors in the name of an authorized entity are immune from civil liability with respect to all actions or omissions taken based on good faith, except in cases of gross negligence, willful misconduct or intentional wrongdoing.
12. Clarifies that the immunity from civil liability does not affect a manufacturer's product liability regarding the design, manufacturing or instructions for use of an epinephrine auto-injector.
13. Requires that an authorized entity who possesses and makes available epinephrine auto-injectors must submit a report of each incident that occurs on the premise to ADHS.
14. Defines *administer*, *authorized entity*, *epinephrine auto-injector* and *practitioner*.
15. Makes technical and conforming changes.

CURRENT LAW

A.R.S. § 15-341 requires school district governing boards to prescribe and enforce policies and procedures that allow students diagnosed with anaphylaxis to carry and self-administer emergency medications, including auto-injectable epinephrine, while at school and school-sponsored activities. Policies must require that the student notify the nurse or designated staff of the use of the medication as soon as possible.

A.R.S. § 15-157 allows a trained school employee to administer, or assist in the administration of auto-injectable epinephrine if they are acting in good faith. Statute also provides immunity from civil liability to medical professionals that prescribe auto-injector epinephrine to a school or a charter school.

ARIZONA HOUSE OF REPRESENTATIVES
Fifty-second Legislature - Second Regular Session

ROLL CALL VOTE

COMMITTEE ON _____ HEALTH _____ BILL NO. HB 2265

DATE January 26, 2016 MOTION: dp

	PASS	AYE	NAY	PRESENT	ABSENT
Mr. Boyer		✓			
Mr. Friese		✓			
Mr. Lawrence		✓			
Mr. Meyer		✓			
Mrs. Cobb, Vice-Chairman		✓			
Mrs. Carter, Chairman		✓			
		6	0	0	0

Sandy Kelley
 COMMITTEE SECRETARY

APPROVED:
[Signature]
 HEATHER CARTER, Chairman
 REGINA COBB, Vice-Chairman

ATTACHMENT _____



HOUSE OF REPRESENTATIVES

HB 2225

radiologic technology; out-of-state licensed practitioners
Prime Sponsor: Representative Lawrence, LD 23

X Committee on Health
Caucus and COW
House Engrossed

OVERVIEW

HB 2225 clarifies that a person who holds a certificate to use ionizing radiation may do so under the direction of a licensed practitioner who is licensed in this state or any state, territory or district of the United States.

PROVISIONS

1. Clarifies that a person who holds a certificate to use ionizing radiation may do so under the direction of a licensed practitioner who is licensed in this state or any state, territory or district of the United States.

CURRENT LAW

A.R.S. § 32-2811 prohibits any person from using ionizing radiation on a human being unless the person is a licensed practitioner or the holder of a certificate. Ionizing radiation may only be used for diagnostic or therapeutic purposes while operating in each particular case at the direction of a licensed practitioner. The use of ionizing radiation and the direction to apply ionizing radiation are limited to those persons or parts of the human body specified in the laws under which the practitioner is licensed. Further, the provisions of the technologist's certificate govern the extent of application of ionizing radiation.

PROPOSED

HOUSE OF REPRESENTATIVES AMENDMENTS TO H.B. 2225

(Reference to printed bill)

- 1 Page 1, line 10, after "practitioner" insert ". A PERSON HOLDING A CERTIFICATE MAY
2 USE IONIZING RADIATION ON HUMAN BEINGS FOR DIAGNOSTIC PURPOSES ONLY WHILE
3 OPERATING IN EACH PARTICULAR CASE AT THE DIRECTION OF A LICENSED
4 PRACTITIONER"
5 Line 11, strike "THIS STATE OR" after "ANY" insert "OTHER"
6 Amend title to conform

JAY LAWRENCE

2225LAWRENCE
01/25/2016
09:16 AM
H: ig/ajh

Attachment 18

Adopted # of Verbals _____
Failed _____ Withdrawn _____
Not Offered _____ Analysts Initials _____

ARIZONA HOUSE OF REPRESENTATIVES
Fifty-second Legislature - Second Regular Session

ROLL CALL VOTE

COMMITTEE ON HEALTH BILL NO. HB 2225

DATE January 26, 2016 MOTION: d pa

	PASS	AYE	NAY	PRESENT	ABSENT
Mr. Boyer		✓			
Mr. Friese		✓			
Mr. Lawrence		✓			
Mr. Meyer		✓			
Mrs. Cobb, Vice-Chairman		✓			
Mrs. Carter, Chairman		✓			
		6	0	0	0

Sandy Kelley
 COMMITTEE SECRETARY

APPROVED:
[Signature]
 HEATHER CARTER, Chairman
 REGINA COBB, Vice-Chairman

ATTACHMENT _____



HOUSE OF REPRESENTATIVES

HCM 2001

health insurance tax; repeal

Prime Sponsor: Representative Leach, et al., LD 11

X Committee on Health
Caucus and COW
House Engrossed

OVERVIEW

HCM 2001 urges the United States Congress to repeal the health insurance tax.

PROVISIONS

1. Urges the United States Congress to repeal the health insurance tax, sections 9010 and 10905 of the Patient Protection and Affordable Care Act and section 1406 of the Health Care and Education Reconciliation Act of 2010 in order to make health care more affordable to individuals, working families and businesses.
2. Asks the Arizona Secretary of State to transmit copies of this memorial to the following individuals:
 - a. The President of the United States.
 - b. The Speaker of the United States House of Representatives.
 - c. The President of the United States Senate.
 - d. Each member of Congress from the State of Arizona.

CURRENT LAW

Not currently addressed in statute.

ADDITIONAL INFORMATION

Sections 9010 and 10905 of the Patient Protection and Affordable Care Act (P.L. 111-148) encompasses the imposition and modification of the annual fee on health insurance providers and section 1406 of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) focuses on health insurance providers.

ARIZONA HOUSE OF REPRESENTATIVES
Fifty-second Legislature - Second Regular Session

ROLL CALL VOTE

COMMITTEE ON HEALTH BILL NO. HCM 2001

DATE January 26, 2016 MOTION: dp

	PASS	AYE	NAY	PRESENT	ABSENT
Mr. Boyer		✓			
Mr. Friese			✓		
Mr. Lawrence		✓			
Mr. Meyer			✓		
Mrs. Cobb, Vice-Chairman		✓			
Mrs. Carter, Chairman		✓			
		4	2	0	0

APPROVED:



 HEATHER CARTER, Chairman
 REGINA COBB, Vice-Chairman



 COMMITTEE SECRETARY

ATTACHMENT _____

ARIZONA STATE LEGISLATURE
 Fifty-second Legislature - Second Regular Session
COMMITTEE ATTENDANCE RECORD

COMMITTEE ON HEALTH

CHAIRMAN: Heather Carter VICE-CHAIRMAN: Regina Cobb

DATE	1/12/16	1/19/16	1/26/16	1/16	1/16
CONVENED	2:19pm	2:39 m	2:15pm	m	m
RECESSED					
RECONVENED					
ADJOURNED	3:22pm	3:10	5:57pm		
MEMBERS					
Mr. Boyer	✓	✓	✓		
Mr. Friese	✓	✓	✓		
Mr. Lawrence	✓	✓	✓		
Mr. Meyer	✓	✓	✓		
Mrs. Cobb, Vice-Chairman	✓	✓	✓		
Mrs. Carter, Chairman	✓	✓	✓		

✓ Present --- Absent exc Excused