Pharmacogenomics Perils and Pearls

A Case for Pharmacist-Driven Pharmacogenomic Testing as a Tool to Improve Medication Therapy Management Outcomes Within Patient-Centered Precision Pharmacy Practice

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Pharmacogenomics Program Consultant
inGENEious RX Precision Medicine Consultants

Disclosures

- Owner, inGENEious RX Precision Medicine Consultants
- Registered Pharmacogenomics Certification Provider, National Association of Chain Drug Stores
- Independent Consultative Representative, Translational Software
- Pharmacogenomics Consultant, My1Lab

Learning Objectives

1. Defend pharmacogenomics as an essential aspect in improving medication therapy management outcomes

2. Identify key industry players who have a stake in pharmacogenomics policy

3. Describe five of the 11 policy committee statements regarding the use of genomic and pharmacogenomic data within pharmacy practice that were adopted by the American Pharmacists Association in March 2018

Learning Objectives

4. Construct a pharmacist-driven, patient-centric pharmacogenomics practice model utilizing the Joint Commission of Pharmacy Practitioners Pharmacists' Patient Care Process as a template

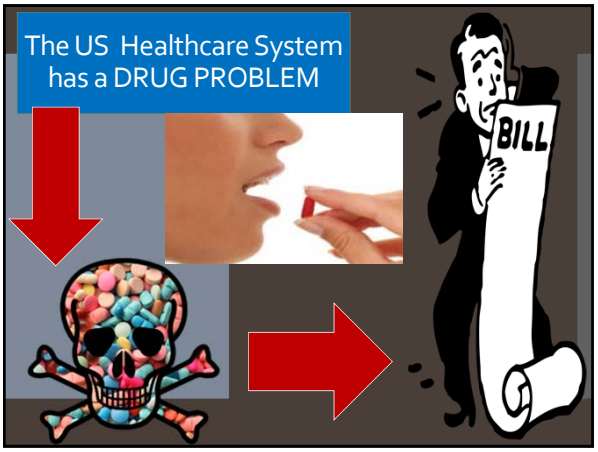
5. Compare and contrast the preemptive, partially preemptive, and reactive pharmacogenomics testing clinical workflow models

6. Describe important considerations when choosing a molecular laboratory to provide pharmacogenomics testing for pharmacogenomics programs

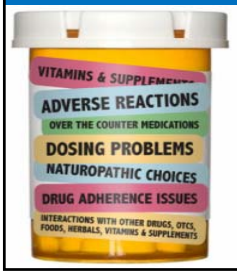
Learning Objectives

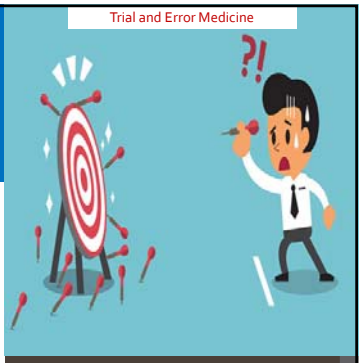
7. Choose trusted evidence-based resources to develop pharmacogenomics practice guidelines and to develop pharmacogenomics clinical support tools and resources

The US Healthcare System has a DRUG PROBLEM

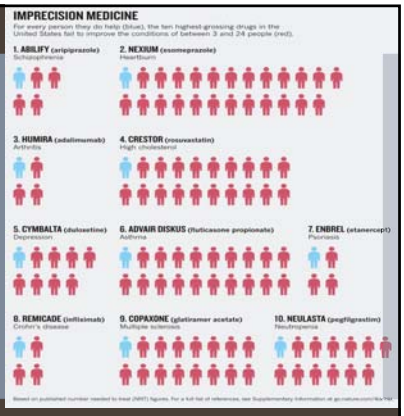


The Drug Problem





Nontherapeutic Medications
Adverse Drug Events

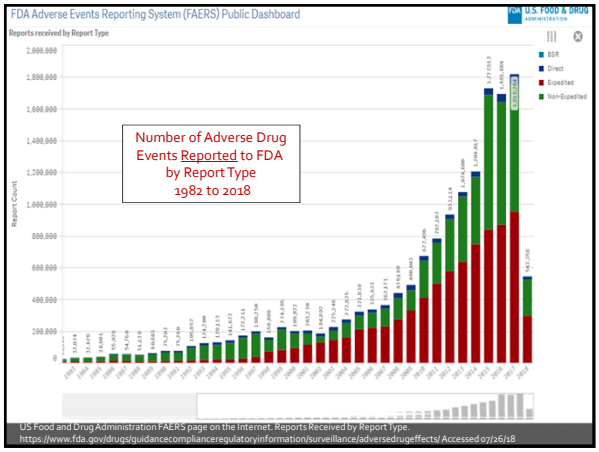


Nontherapeutic Medications

90% of conventional and top-selling blockbuster medicines only work for 30 to 50% of patients

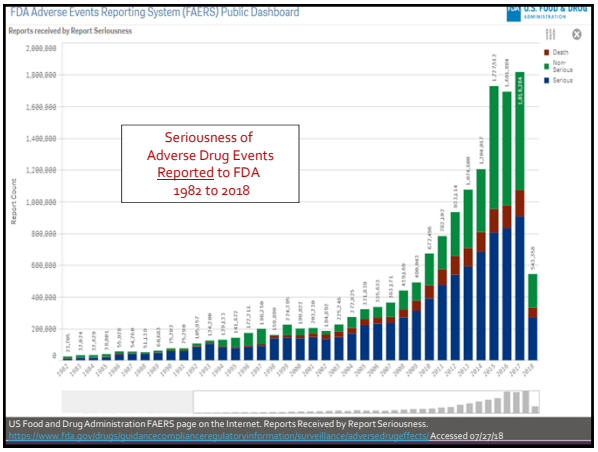
Account for 30% of acute hospital admissions every year

Schork NJ. Personalized medicine: Time for one-person trials. Nature. 2015-04-30; 520.7549: 609-11.doi: 10.1038/520609a.



Number of Adverse Drug Events Reported to FDA by Report Type 1982 to 2018

US Food and Drug Administration FAERS page on the Internet. Reports Received by Report Type. https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ Accessed 07/26/18



Seriousness of Adverse Drug Events Reported to FDA 1982 to 2018

US Food and Drug Administration FAERS page on the Internet. Reports Received by Report Seriousness. https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ Accessed 07/27/18

Costs Associated with Adverse Drug Reactions

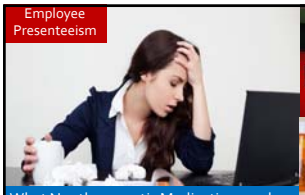
Centers for Education & Research on Therapeutics™

Costs Associated with ADRs

- $136 BILLION yearly
- Greater than total costs of cardiovascular or diabetic care
- ADRs cause 1 out of 5 injuries or deaths per year to hospitalized patients
- Mean length of stay, cost and mortality for ADR patients are DOUBLE that for control patients

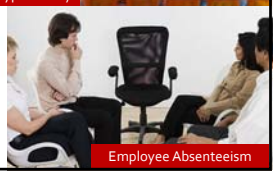
Johnson JA et al. *Arch Intern Med* 1995;155(18):1949–1956
Leape LL et al. *N Engl J Med* 1991;324(6):377–384
Classen DC et al. *JAMA* 1997;277(4):301–306

US Food and Drug Administration Homepage on the Internet. Preventable adverse drug reactions. https://tinyurl.com/FDAUCM310632 Accessed 06/28/18

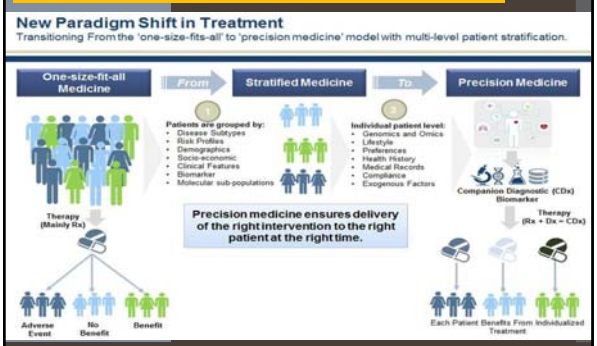


What Nontherapeutic Medications and Adverse Drug Reactions Look Like in Everyday Life

Hospital Readmissions



PRECISION MEDICINE



Forbes Magazine Online. Frost & Sullivan -Figure 1: New Paradigm Shift in Treatment. "Drug Industry Bets Big on Precision Medicine: Five Trends Shaping Care Delivery." https://www.forbes.com/sites/reenitadas/2017/03/08/drug-development-industry-bets-big-on-precision-medicine-5-top-trends-shaping-future-care-delivery/#224c5465d3a2 Accessed 06/28/18.

Pharmacogenomics

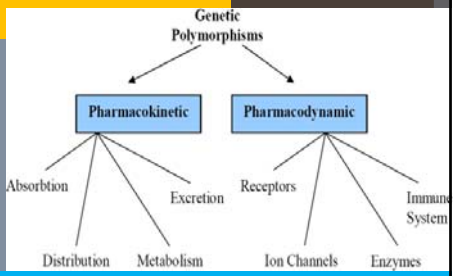
The study of drug responses in relation to specific genetic polymorphisms.

A Tool in the Precision Medicine Toolbox

More than 150 FDA-approved medications contain pharmacogenomics information in their labeling.

US Food and Drug Administration page on the Internet. Table of Pharmacogenomic Biomarkers in Drug Labels. https://www.fda.gov/drugs/scienceresearch/ucm572698.htm Accessed 06/28/18.

Pharmacogenomics Impacts



Pharmacokinetics
Pharmacodynamics

J. Adams, Pharmacogenomics and personalized medicine. *Nature Education* 1(1):194 (2008)

Evidence Based Medicine Includes Pharmacogenomics

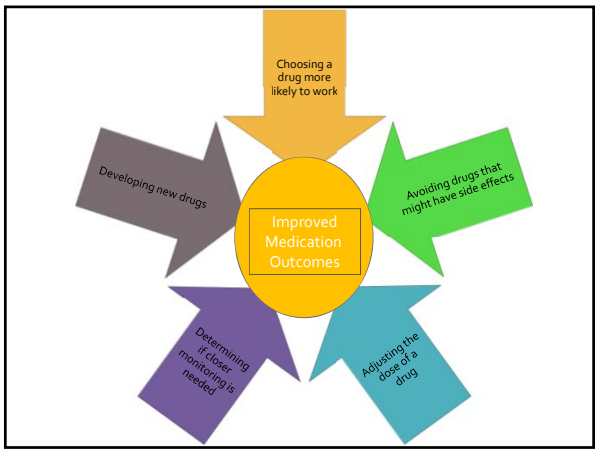
Over 20,000 Articles Exist in PubMed which Discuss Pharmacogenomics

R.M. Weinshilboum and L. Wang, Pharmacogenomics: Precision Medicine and Drug Response. Mayo Clin Proc 92(11):1711-1722. (2017)

HOW DOES PHARMACOGENOMICS IMPROVE MEDICATION THERAPY OUTCOMES?

Therapeutic Relevance

Economic Relevance



Factors Affecting Pharmacogenomics' Therapeutic and Economic Relevance

Therapeutic Relevance

- Genomic variation affects the expression level and/or function of the final gene product.
- There is an established relationship between the genomic variation in the therapeutic response and/or outcome.
- The genomic variation affecting therapeutic responses and/or outcomes are
  - of clinical importance; and
  - their effects cannot be more easily assessed by some direct clinical or para-clinical measurement

Peter Wedlund & Jose de Leon, Pharmacogenomic testing: The cost factor. The Pharmacogenomics Journal. 1. 171-4.10.1038/sj.tpj.6500033. (2001)

Factors Affecting Pharmacogenomics' Therapeutic and Economic Relevance

Economic Relevance

- Affects the length of in-patient stay or likelihood of hospital admission
- Affects the number of clinical visits
- Affects clinical lab services
- Affects use of ancillary health care services
- Affects the cost of drug therapy by its effect on the use or effectiveness of drug therapy and/or treatment outcomes.

Peter Wedlund & Jose de Leon, Pharmacogenomic testing: The cost factor. The Pharmacogenomics Journal. 1. 171-4.10.1038/sj.tpj.6500033. (2001)

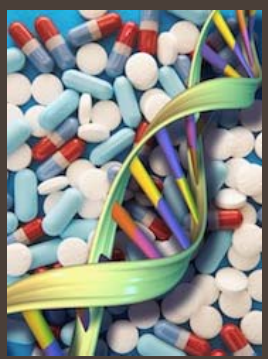
Therapeutic

A retrospective report studied individuals (n=1143) who received a 3-gene pharmacogenetic panel and found that 34% of all potential major adverse drug interactions were caused by the patient's genetics rather than drug-drug interactions

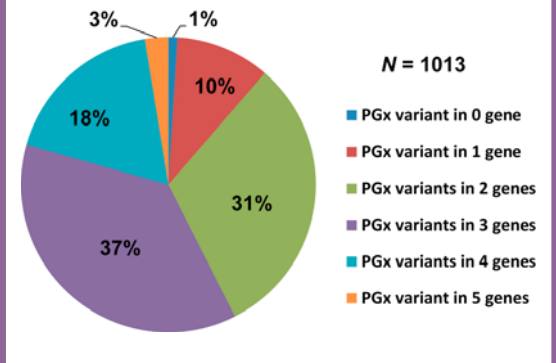
P. Verbeurgt, T. Mamiya and J. Oesterheld, How common are drug and gene interactions? Prevalence in a sample of 1143 patients with CYP2C9, CYP2C19, CYP2D6 genotyping." Pharmacogenomics 15(5):655-665. (2014) .

Therapeutic

In a comprehensive analysis of five actionable pharmacogenomic genes using next-generation DNA sequencing and a customized CYP2D6 genotyping cascade, when all five genes were considered together, 99% of the subjects carried an actionable PGx variant(s) in at least one gene.



Ji Yuan, J.M.Blommel, J.H. Moore, et al. Preemptive pharmacogenomic testing for precision medicine: A comprehensive analysis of five actionable pharmacogenomics genes using next-generation DNA sequencing and a customized CYP2D6 genotyping cascade. The Journal of Molecular Diagnostics : JMD, 18(3), 438-445 (2016).



Therapeutic

The world's largest randomized, controlled study (n=500) of the impact of pharmacogenetics on psychiatric patient treatment to date found that clinical response increased 35% for severely depressed patients when pharmacogenetics was implemented

P. Bradley, M. Shiekh, V. Mehra, et al. Improved efficacy with targeted pharmacogenetic-guided treatment of patients with depression and anxiety: A randomized clinical trial demonstrating clinical utility. J Psychiatr Res 96: 100-107. (2018).

Economic

Highest cost savings are achieved in chronic care patients who consume excessive payer resources.

A systematic review found that pharmacogenetic testing is rapidly becoming more cost effective, and more often cost-saving, as the direct cost of testing falls below $100 per patient.

M. Verbelan, M.E. Weale & C.M. Lewis, Cost-effectiveness of pharmacogenetic-guided treatment: are we there yet? Pharmacogenomics 15(5):655-665. (2017).

Economic Cardiovascular

When a patient's genomic profile was taken into account, cost savings of approximately $6,700 per cardiovascular event avoided (when compared to uninformed clopidogrel treatment) or approximately $11,700 per cardiovascular event avoided (when compared to uninformed prasugrel treatment) were achieved.

E. S. Reese, C. Daniel Mullins, A L. Beitelshees, et al. Cost-effectiveness of cytochrome P450 2C19 genotype screening for selection of antiplatelet therapy with clopidogrel or prasurgel. Pharmacotherapy 32(4):323-332. (2012).

Economic Psychiatry

A recent meta-analysis study looking at the treatment of psychiatric patients forecasted savings of approximately $4,000 per patient per year when pharmacogenetics was used (Brown et al. 2017).

A retrospective study found savings of $562 per patient over just a four-month period with pharmacogenetic testing after taking into account the drug costs represented by increased patient adherence to their prescriptions (Fagerness et al. 2014).

L.C. Brown, R.A. Lorenz, & B.M. Dechairo, Economic Utility: Combinatorial Pharmacogenomics and Medication Cost Savings for Mental Health Care in the primary care setting. Clin Ther 39(3): 592-602.e592. (2017).
J. Fagerness, E. Fonseca, G.P. Hess, et al. Pharmcogenetic-guided psychiatric intervention associated with increased adherence and cost savings. Am J Manag Care 20(1): e146-156. (2014).

Economic Long-Term Care

In a long-term care study of patients taking five or more medications, when poorly suited medications were replaced, patients were taken off incompatible or ineffective medications, and two medications or more medications were consolidated into one prescription, the cost savings over one year was $621 per patient per year.

This correlates to approximately $1,900 per patient over a three-year period.

J. S. Salvidar, D. Taylor, E.A. Sugarman, Initial assessment of the benefits of implementing pharmacogenetics in to the medical management of patients in a long-term care facility. Pharmacogenomics Pers Med 9:1-6. (2016).

Economic Home Health

For patients receiving a 6-gene pharmacogenetic panel in primary care preemptive to prescribing, the estimated cost savings gained per patient by reducing additional treatments needed 60 days post hospital release was $4,382.

Furthermore, rehospitalizations were halved and emergency room visits were nearly halved.

L.S. Elliott, J.C. Henderson, M.B. Neradilek, Clinical impact of pharmacogenetic profiling with a clinical decision support tool in polypharmacy home health patients : A prospective pilot randomized controlled trial. PLoS One 12(2): e0170905

PHARMACEUTICAL INDUSTRY	REGULATORY AGENCIES	PAYORS	ACADEMIC MEDICAL CENTERS
FUNDING AGENCIES	PRESCRIBERS	PHARMACISTS	PATIENTS

KEY Stakeholders in Making Pharmacogenomics a Standard of Care

Key Stakeholders

Perspectives on Policy-Relevant Concerns Surrounding Pharmacogenomics

Pharmacogenomics Education is the KEY to Influencing Perspectives

Earl B. Ettienne, Edwin Chapman, Mary Maneno, et al., Pharmacogenomics-guided policy in opioid use disorder (OUD) management: An ethnically-diverse case-based approach. Addictive Behaviors Reports, Volume 6, pages 8-14. (2017).

PHARMACISTS,

as key stakeholders, are uniquely positioned to ADVOCATE for pharmacogenomics

But first, pharmacists must be INFLUENCED to be INFLUENCERS…

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

The 2017-2018 American Pharmacists Association House of Delegates Policy Committee Report supports PHARMACISTS as the KEY Stakeholders in Advocating for Pharmacogenomics as a Standard of Care

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

1

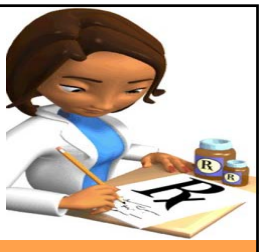
Patient Safety

APhA emphasizes genomics as an essential aspect of pharmacy practice.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

2

Pharmacogenomics Consultant



APhA recognizes pharmacists as the health care professional best suited to provide medication-related consults and services based on a patient's genomic information. All pharmacists involved in the care of the patient should have access to relevant genomic information.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

3

Privacy

GINA GENETIC INFORMATION NONDISCRIMINATION ACT

HIPAA Health Insurance Portability and Accountability Act

General Data Protection Regulation

APhA supports processes to protect patient data confidentiality and opposes unethical utilization of genomic data.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

4

Provider Status

aetna Cigna BlueCross BlueShield CMS CENTERS FOR MEDICARE & MEDICAID SERVICES UnitedHealthcare

APhA demands payers include pharmacists as eligible providers for covered genomic interpretation and related services to support sustainable models that optimize patient care and outcomes.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

5

Genomics Goes Here

APhA urges pharmacy management system vendors to include functionality that uses established and adopted electronic health record standards for the exchange, storage, utilization, and documentation of clinically actionable genetic variations and actions taken by the pharmacist in the provision of patient care.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

6

Evidence Based Practice Guidelines

Alzghari S K, Blakeney L., Rambaran K (May 30, 2017) Proposal for a Pharmacogenetic Decision Algorithm. Cureus 9(5): e1289. DOI 10.7759/cureus.1289

APhA recommends pharmacists lead the development of evidence-based practice guidelines for pharmacogenomic and related services.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

7

Patient Data

Medical Knowledge

Inference Engine

Case Specific Advice

Clinical Decision Support

APhA advocates for the involvement of pharmacists in the development of pharmacogenomic clinical support tools and resources.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

8

Medical Grade Labs

Clinical Laboratory Improvement Amendments

CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS

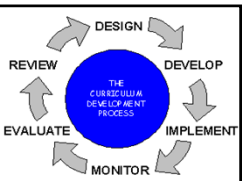
JUST SAY NO

APhA encourages pharmacists to use their professional judgement and published guidelines when providing access to testing or utilizing direct to consumer genomic test results in their patient care services.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

9

Clinical Genomics Curriculum



APhA urges schools and colleges of pharmacy to include clinical application of genomics as a required element of the Doctor of Pharmacy curriculum.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

10

Professional Development

UC San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

Manchester University

APhA encourages the creation of continuing professional development and post-graduate education and training programs for pharmacists in genomics and its clinical application to meet varying practice needs.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

11

Cost Effectiveness Research

$$\text{Healthcare Value} = \frac{\text{Quality of Care}}{\text{Cost of Care}}$$

APhA encourages the funding of pharmacist-led research examining the cost effectiveness of care models that utilize pharmacists providing genomic services.

American Pharmacists Association page on the Internet. Use of Pharmacogenomics Data within Pharmacy Practice. https://pharmacist.com/sites/default/files/2017-18_Policy_Committee_Report_FINAL.pdf Accessed 06/28/18.

Pharmacist-Driven Clinical Pharmacogenomics

How Can Pharmacists Influence Key Stakeholders' Perspectives Regarding Pharmacogenomics as a Standard of Care ?

Construct a Pharmacist-Driven, Patient-Centric Pharmacogenomics Model

Where to Start? How to Get There?

NO "GOLD STANDARD" PHARMACOGENOMICS MODEL CURRENTLY EXISTS

The Pharmacists' Patient-Centered Care Process

Joint Commission of Pharmacy Practitioners. Internet page. Pharmacists' patient care process. May 2014. http://www.accp.com/docs/positions/misc/JCPP_Pharmacists_Patient_Care_Process.pdf Accessed 06/28/18

COLLECTION

Consider the entire patient picture in addition to the pharmacogenomics

<u>Subjective</u>

Past medical history
- adverse drug reactions
- nontherapeutic medications
- polypharmacy

<u>Objective</u>
- Additional clinical lab values

SPECIAL CONSIDERATIONS FOR COLLECTION

Who are the payers?
- Do they pay for pharmacogenomic testing?
- Which drug-genes do they pay for?
- Do they pay for genetic counseling?
- How much do they pay?

Which molecular laboratory will provide the testing?
- In-house lab
- Outsourced lab
- Medical laboratory versus entertainment laboratory

Test to be used?
- Single-gene
- Gene panels
- Sequencing

Unclear regulatory landscape
- Clinician-ordered
- Direct to consumer

SPECIAL CONSIDERATIONS FOR COLLECTION

Who will physically collect the patient's DNA sample?
- Pharmacist?
- Technician?
- Lab representative?

Safety procedures for handling biological specimens including
- Cheek swab?
- Saliva?
- Mailing restrictions?

Considerations When Choosing a Molecular Laboratory

Clinical Laboratory Improvement Amendments

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

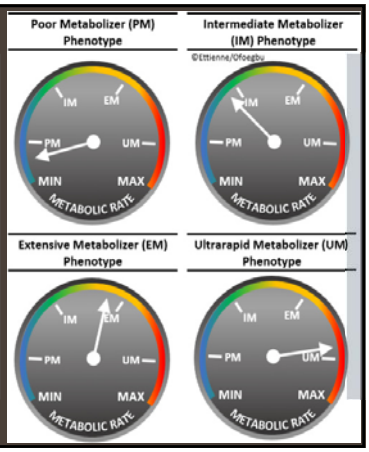
Testing Quality	Testing Capability/ Capacity	Software Capabilities	Testing Costs
CLIA CERTIFICATION COLA CERTIFICATION CAP Certification	DRUG GENE TESTS AVAILABLE Results turnaround time	Paper results Electronic results Quality of reports	PGX TEST COST – Wholesale cost – INSURANCE BILLING – SELF-PAY CASH OPTION
Analytes Correct analytes? How many analytes tested? Diagnosis of inclusion not exclusion	How many specimens can lab process per day? Capacity to increase testing?	Ability to integrate into EMR	Does testing cost include test kits, return postage? Does cost include software capabilities such as patient stratification?
Clinical staff on hand to facilitate clinical inquiries Physician on staff to order tests	Contingency plans for testing reagents, etc.	CLINICAL DECISION SUPPORT SOFTWARE OFFERED BY LAB? Software capabilities such as patient stratification?	Will clinic be "charged back" for insurance denials/reversals?
No association with fraudulent billing practices	Provides collectors for high volume accounts	Evidence-based genotype to phenotype translation ----CPIC ----Pharm GKB ----FDA How often is database updated?	Is there a minimum testing quantity required to secure contract?
LICENSED WITHIN THE STATE for which the samples will be collected	Cheek swabs, saliva, blood specimens Shipping considerations, how long are specimens stabile?	Will the test be a static result or will the test data be available over the patients' lifetimes?	**SECURITY OF DATA**

Considerations When Choosing a Molecular Laboratory. Copyright 2018 inGENious RX

ASSESSMENT

PGX Test Results

- Poor metabolizer
- Intermediate metabolizer
- Rapid metabolizer
- Ultra-rapid metabolizer



ASSESSMENT

Medication Therapy Management

- Discontinue medication?
- Increase/decrease dose?

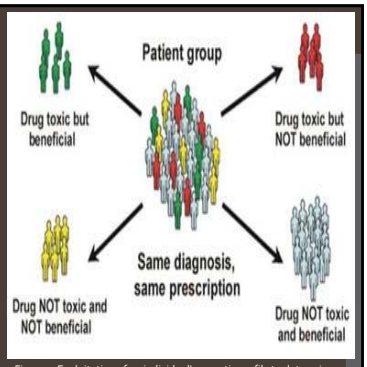


Figure 1: Exploitation of an individual's genetic profile to determine his/her response to a certain drug , in terms of both efficacy and toxicity, towards achieving individualized (personalized) therapy.

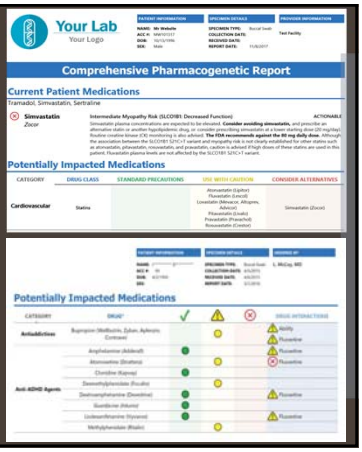
George Patrinos "Next Generation Pharmacogenomics" Slide 3. https://slideplayer.com/slide/12661463/ Accessed 7/26/18.

ASSESSMENT

Clinical Decision Support Tools

What other interactions may result and POSSIBLY be worse than the original interaction?

- drug-gene
- drug-drug
- Drug-food



SPECIAL CONSIDERATIONS FOR ASSESSMENT

What additional training and education will the team need?

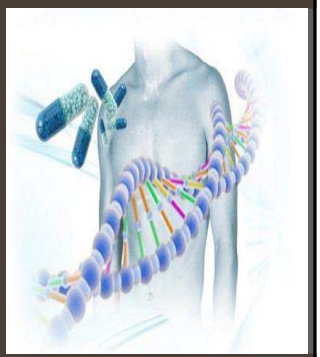
- Pharmacogenomics science/ clinical application education
- Clinical workflow training
- Billing training

When to Pursue Pharmacogenomic Testing

Preemptive Testing

Semi-Preemptive Testing

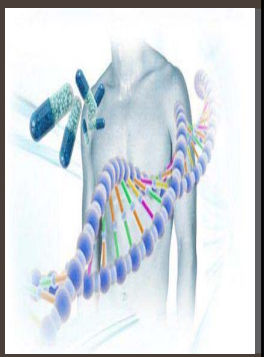
Reactive Testing



PREEMPTIVE TESTING

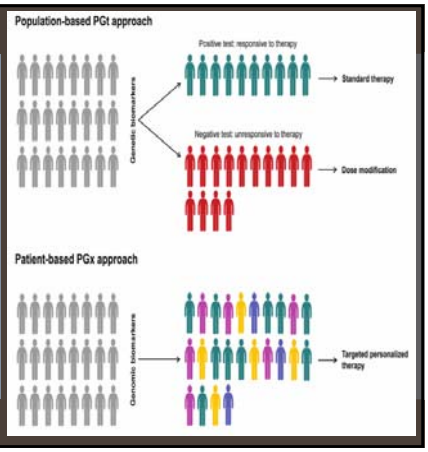
Aims to optimize medication use by having genetic information at the point of prescribing, available before any medication is ever prescribed.

"Pharmacogenomic UTOPIA"



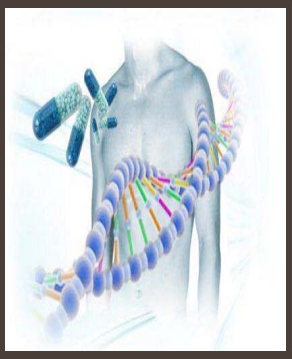
SEMI-PREEMPTIVE TESTING

Aims to optimize medication use by having genetic information at the point of prescribing for specially defined "at-risk" populations.



REACTIVE TESTING

Aims to identify a genetic polymorphism cause for an adverse drug event that has already occurred and prevent further adverse drug events



SPECIAL CONSIDERATIONS FOR ASSESSMENT

What additional infrastructure will be needed to facilitate the safe and ethical provision of pharmacogenomics testing?

- Funding
- Staff
- Information Technology
- Security

Identify pharmacy/collaborative team and predicted responsibilities

- Pharmacist PGx Champion
- Physicians
- Information Technology
- Billing Department

SPECIAL CONSIDERATIONS FOR ASSESSMENT

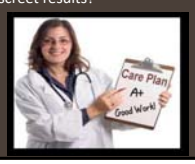
- EHR systems designed for genomic data?
- Results persistently accessible?
  - Updated as new pharmacogenomic guidelines emerge?
- Managing new knowledge or changes in interpretations?
  - Discovering patient has been taking medication not pharmacogenomically suited for the patient
- Standardization of terms

PLAN

Develop an individualized patient-centered care plan
- Evidence-based
- Cost-effective

Collaborate
- Other health care professionals
- Patient or caregiver
- Prevent information silos

How will you communicate results to the patient and other providers?
- Paper reports versus discreet results?



Special Considerations for Planning

Develop standardized
- Education
- Protocols
- Policies
- Procedures

How will identified drug therapy problems be addressed?

When will patients be referred to other providers?

Special Considerations for Planning

Where will the results be documented and stored safely according to:

- HIPAA
- GINA
- GDPR

What will your quality control measures be?

Implement

The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

Considerations:

- Project timeline
- Progress NOT perfection

MONITOR AND EVALUATE

The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

- Record pharmacist interventions
- Record prescriber acceptance of recommendations
- Record patient acceptance
- Record clinical results
- Record financial results
- Evaluate and Report

Pharmacist-Driven Clinical Pharmacogenomics

How can Pharmacists Influence Key Stakeholders' Perceptions on Pharmacogenomics as a Standard of Care?

Know Evidence-Based Resources for PGx information

FDA
https://www.fda.gov/Drugs/ScienceResearch/ucm572698.htm

Pharm GKB
https://www.pharmgkb.org/page/pgxImplementationResources

CPIC
https://cpicpgx.org

Know Evidence-Based Resources for PGx Information

National Institutes of Health
https://ghr.nlm.nih.gov/primer/genomicresearch/pharmacogenomics

https://clinicaltrials.gov/ct2/results?cond=&term=pharmacogenomics&cntry=&state=&city=&dist=

Genetics Home Reference

NIH National Institutes of Health

Know Evidence-Based Resources for PGx Information

National Institutes of Health

PGRN

http://www.pgrn.org

PGRN

NIH National Institutes of Health

Summary

Pharmacogenomics is a powerful medication management tool that improves medication therapy management outcomes both therapeutically and economically.

Pharmacists, as medication experts, with the proper pharmacogenomics education, are uniquely positioned to leverage pharmacogenomics as a medication therapy management tool in collaboration with other health care professionals.

Contact Information

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website: www.ingeneiousrx.com

Join my LinkedIn network:

www.linkedin.com/in/becky-winslow-ingeneiousrx

Schedule a consultation on my calendar:

https://calendly.com/ingeneiousrx

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2. https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ FDA Adverse Event Reporting System (FAERS) Public Dashboard. Accessed 07/24/18.
3. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm110632.htm#ADRs:%20Prevalence%20and%20Incidence FDA (2018). "Preventable adverse drug reactions." Accessed 06/28/18.
4. https://www.forbes.com/sites/reenitadas/2017/03/08/drug-development-industry-bets-big-on-precision-medicine-5-top-trends-shaping-future-care-delivery/#224c5465d3a2. Frost & Sullivan -Figure 1: New Paradigm Shift in Treatment. "Drug Industry Bets Big on Precision Medicine: Five Trends Shaping Care Delivery."

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Pharmacist Driven Clinical Pharmacogenomics

How can Pharmacists influence Key Stakeholders' Perspectives on Pharmacogenomics as a Standard of Care ?

Patient Education

- How can PGx help me?
- Who performs the test?
- Are PGx results 100% accurate?
- Where are my PGx results stored?
- What happens if my results are mistaken or miscommunicated?
- Can my PGx results change over my lifetime?
- Will my PGx results affect my insurability?

Provider Education

Drug therapy problems are the clinical domain of pharmacists

- Major responsibility of the pharmacist practitioner
- The description of a drug therapy problem directly influences the patient's pharmacotherapy
  - 1. Description of medical condition
  - 2. Drug therapy involved
  - 3. Association between drug therapy and medical condition

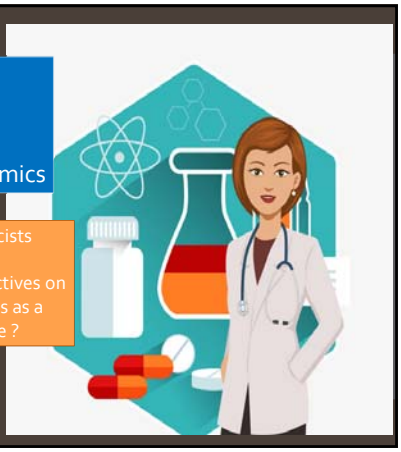
Cipolle RJ, Strand LM, Morley PC. Components of a Drug Therapy Problem. In: Pharmaceutical care practice: the patient centered approach to medication management. 3rd ed. New York: McGraw-Hill; 2012.

Payer Education

- What does pharmacogenomics testing cost?
  - Test acquisition cost?
  - Ancillary service costs?
  - Downline costs?
- What financial savings does pharmacogenomics produce?
  - Decreased medication expenses?
  - Decreased adverse drug reaction expenses?
  - Are the savings short term or long term?
  - How long before savings will outweigh the cost for implementation?
- Which randomized, controlled trials show the financial return on investment for the population I serve?
- What is the clinical utility in the patient population I serve?
- What are the guidelines for implementing the testing?
  - Who do we test?
  - When do we test?
- What impact does this testing make on clinical decision making?
- What are the legal risks associated with implementing testing versus not implementing testing?

Pharmacist Driven Clinical Pharmacogenomics

How can Pharmacists influence Key Stakeholders' Perspectives on Pharmacogenomics as a Standard of Care ?



Advocate For:

Reimbursement policies for pharmacogenomics testing

Federal and state law compensating pharmacists who provide direct patient-care services

Reduction in Interstate licensing burden to address shortage of pharmacogenomics trained pharmacists to provide consulting for patients

Reduce restrictive laws and regulations governing CPAs

Reduce limitations on pharmacists' ability to access health information system.

Summary Table
IMPORTANT CONSIDERATIONS

PATIENT CENTERED CARE PROCESSES	COLLABORATE	COMMUNICATE	DOCUMENT
COLLECT	Which molecular laboratory will provide the pharmacogenomics testing? Who will physically collect the samples? Lab, RPh, Tech, Patient Who are the payers? Do they pay for PGx testing? Single gene tests? Multi-gene, multi-drug panels?		
ASSESS	Which testing approach will best fit your clinical setting? Preemptive? Reactive? What additional infrastructure will be needed to facilitate the safe and ethical provision of pharmacogenomics testing? Funding, Staff, IT, etc. Identify pharmacy/collaborative team and predicted responsibilities.		
PLAN	Develop standardized education, protocols, policies, procedures How will identified drug therapy problems be addressed? When will patients be referred to other providers? How will results be communicated to prescribers and patients? Where will the results be documented and stored safely according to HIPAA, GINA, G6DP?		
IMPLEMENT	Project Timeline. Progress not Perfection		
MONITOR & EVALUATE	Record pharmacist interventions and patient/prescriber acceptance of recommendations. Record clinical and financial results. Evaluate and Report		

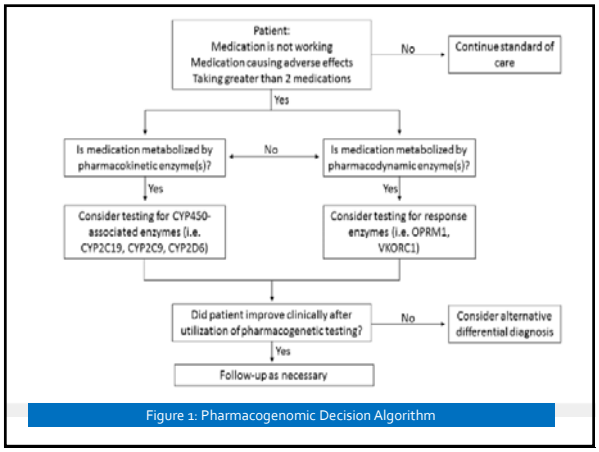


Figure 1: Pharmacogenomic Decision Algorithm

ADR Facts From the FDA

Centers for Education & Research on Therapeutics™

Why Learn about Adverse Drug Reactions (ADR)?

- Over 2 MILLION serious ADRs yearly
- 100,000 DEATHS yearly
- ADRs 4th leading cause of death ahead of pulmonary disease, diabetes, AIDS, pneumonia, accidents and automobile deaths
- Ambulatory patients ADR rate—unknown
- Nursing home patients ADR rate—350,000 yearly

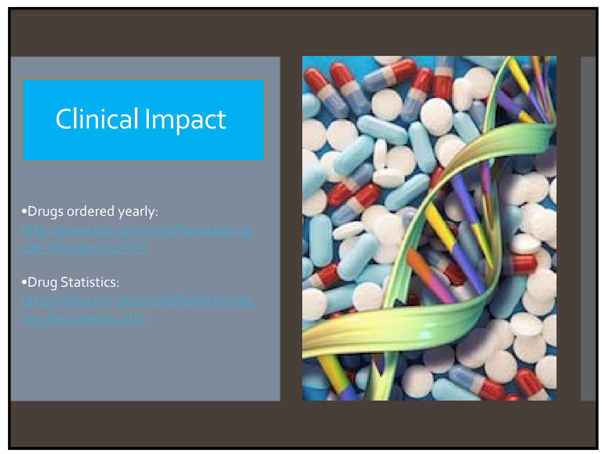
Institute of Medicine, National Academy Press, 2000
Lazarou J et al. JAMA 1998;279(15):1200–1205
Gurwitz JH et al. Am J Med 2000;109(2):87–94

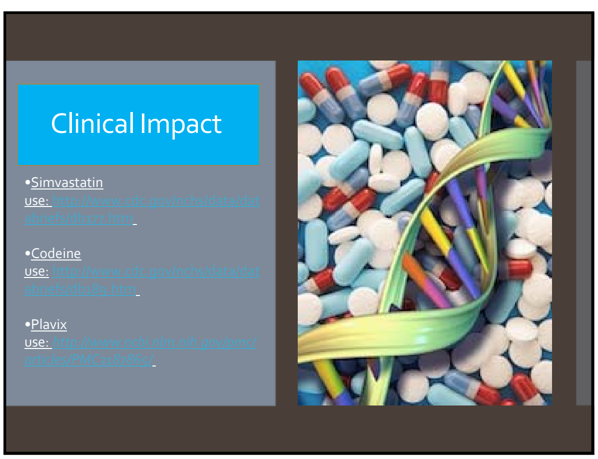
FDA (2018). "Preventable adverse drug reactions." https://tinyurl.com/FDAUCM110632 Accessed 06/28/18

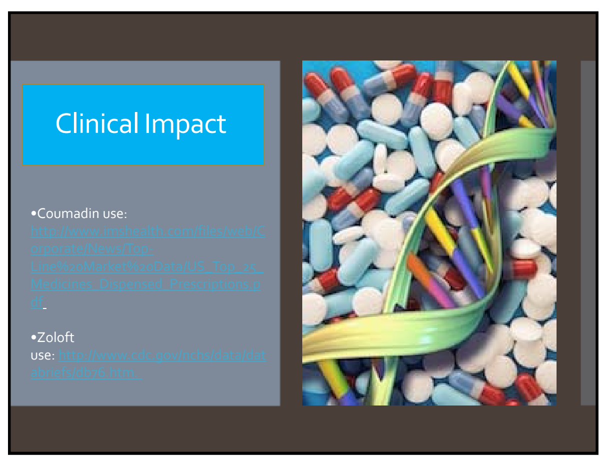

Pharmacist
Driven
Clinical
Pharmacogenomics
How can Pharmacists influence Key Stakeholders' Perspectives on PGx as a Standard of Care ?


Among adults, ADRs are estimated to exceed $3.5 billion in costs annually
Account for increasing length of stay in hospitals from 1.7 to 4.6 days
Account for over 3.5 million physician office visits
Account for an estimated 1 million emergency department visits
Account for approximately 125,000 hospital admissions
Accounted for over 100,000 deaths in 2000
ADVERSE DRUG EVENTS


What do ADEs COST the US Workforce?
Improperly managed CHRONIC PAIN costs more than $600 billion a year in both medical costs and lost productivity ($261 – $300 billion for health care alone)
Low Workplace Morale
Longer More Expensive Disability Claims
In a classic study of Dow Chemical workers, employees who were present but sick actually cost the company more than employees who were out sick. Dow Chemical employees with common illnesses like depression, anxiety, migraines, respiratory illnesses, arthritis, diabetes and back and neck pain had performance levels 10 to 20 percent lower than healthy counterparts.
Recent research shows that the sudden death of a top executive affects not only productivity but also reduces sales and the value of company assets by 50 percent, regardless of the size and age of the company—the more important the employee is the greater the potential loss.
When your employees are absent from work due to sickness, lost productivity costs companies 2.3 times more than the medical and pharmacy bills do


Clinical Impact
•Drugs ordered yearly: http://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm
•Drug Statistics: http://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm


Clinical Impact
•Simvastatin use: http://www.cdc.gov/nchs/data/databriefs/db177.htm
•Codeine use: http://www.cdc.gov/nchs/data/databriefs/db189.htm
•Plavix use: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3187865/


Clinical Impact
•Coumadin use: http://www.imshealth.com/files/web/Corporate/News/Top-Line%20Market%20Data/US_Top_25_Medicines_Dispensed_Prescriptions.pdf
•Zoloft use: http://www.cdc.gov/nchs/data/databriefs/db76.htm.

Clinical Impact

The promise of biological markers for treatment response in first-episode psychosis: a systematic review. Fond G, d'Albis MA, Jamain S, Tamouza R, Arango C, Fleischhacker WW, Glenthøj B, Leweke M, Lewis S, McGuire P, Meyer-Lindenberg A, Sommer IE, Winter-van Rossum I, Kapur S, Kahn RS, Rujescu D, Leboyer M. Schizophr Bull. 2015 May;41(3):559-73. doi: 10.1093/schbul/sbv002. Epub 2015 Mar 10.

Clinical Impact

• Cardiovascular drugs and the genetic response. Dandona S. Methodist Debakey Cardiovasc J. 2014 Jan-Mar;10(1):13-7.

Clinical Impact

Screening of Genetic Polymorphisms of CYP2C9 and CYP2C19 in Korean. Lee JS, Cheong HS, Kim LH, Kim JO, Seo DW, Kim YH, Chung MW, Han SY, Shin HD. Korean J Physiol Pharmacol. 2013 Dec;17(6):479-84. doi: 10.4196/kjpp.2013.17.6.479. Epub 2013 Dec 16.

Clinical Impact

Impact of CYP2C19 genetic testing on guiding prescribing pattern for antiplatelet therapy after acute coronary syndromes and percutaneous coronary intervention. Desai NR, Canestaro WJ, Kyrychenko P, Chaplin D, Martell LA, Brennan T, Matlin OS, Choudhry NK. Circ Cardiovasc Qual Outcomes. 2013 Nov;6(6):694-9. doi: 10.1161/CIRCOUTCOMES.113.000321. Epub 2013 Nov 5.

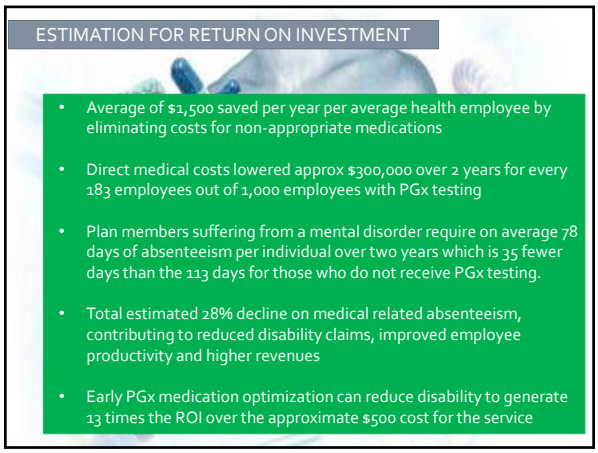
Financial Impact Cardiovascular

Another study modeling the use of the cardiovascular drugs clopidogrel, ticagrelor, and prasugrel, pharmacogenetics was found to lead to cost savings of $445 per patient annually (Johnson et al. 2015).

Financial Impact

Combinatorial pharmacogenomic guidance for psychiatric medications reduces overall pharmacy costs in a 1 year prospective evaluation.
Current Medical Research and Opinion. Vol 31, Issue 9, 2015
In this recently published study, evaluating data from more than 13,000 patients being treated for behavioral health issues found:

- Patients receiving a PGx test saved $1,036 per year on average in pharmacy costs alone compared to traditional prescribing methods.
- Pharmacogenomic testing improved patients' adherence to the prescribed treatment by 17%.
- Polypharmacy was reduced with 1 out of 5 patients being prescribed fewer medications after receiving PGx testing.


ESTIMATION FOR RETURN ON INVESTMENT
• Average of $1,500 saved per year per average health employee by eliminating costs for non-appropriate medications
• Direct medical costs lowered approx $300,000 over 2 years for every 183 employees out of 1,000 employees with PGx testing
• Plan members suffering from a mental disorder require on average 78 days of absenteeism per individual over two years which is 35 fewer days than the 113 days for those who do not receive PGx testing.
• Total estimated 28% decline on medical related absenteeism, contributing to reduced disability claims, improved employee productivity and higher revenues
• Early PGx medication optimization can reduce disability to generate 13 times the ROI over the approximate $500 cost for the service

USP Standard Setting Process and Compounding Standards

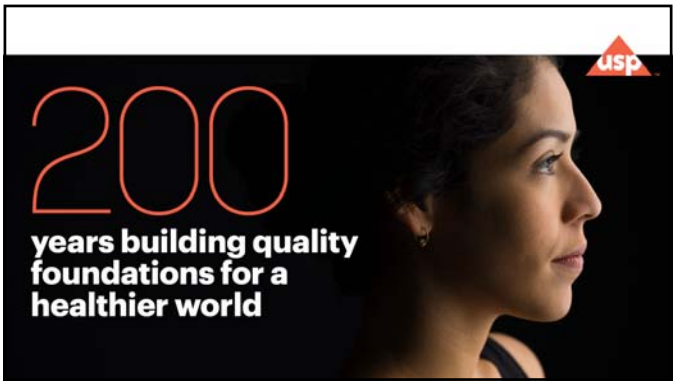
Jeanne Sun, PharmD
NABP District III Meeting – August 2018

Learning Objectives

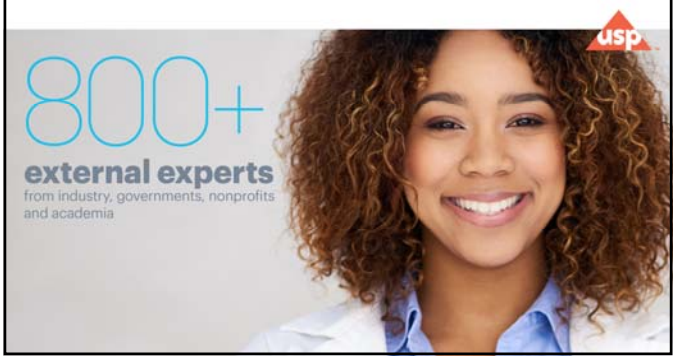
- Describe the role of USP in setting standards for patient and provider safety
- Understand the standard setting process and opportunities for stakeholder engagement
- Identify practitioner-specific standards for sterile and nonsterile compounding and safe handling of hazardous drugs:
  - <795> *Pharmaceutical Compounding – Nonsterile Preparations*
  - <797> *Pharmaceutical Compounding – Sterile Preparations*
  - <800> *Hazardous Drugs – Handling in Healthcare Settings*
- Describe the timeline and next steps of the revisions to General Chapters <795> and <797>
- Describe the timeline and official date of General Chapter <800>

Mission

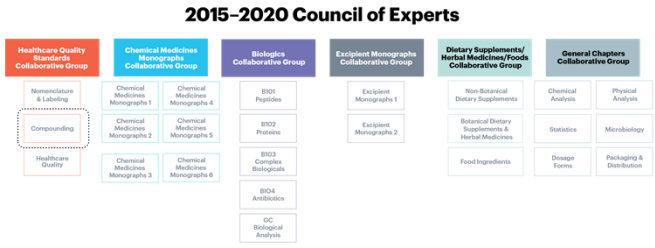
To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods



Advocating for quality



The experts behind our standards



2015 – 2020 Compounding Expert Committee

Chair: Gigi Davidson, B.S. Pharm, DICVP, NC State College of Veterinary Medicine
Vice Chair: Connie Rae Sullivan, B.S. Pharm, National Home Infusion Association

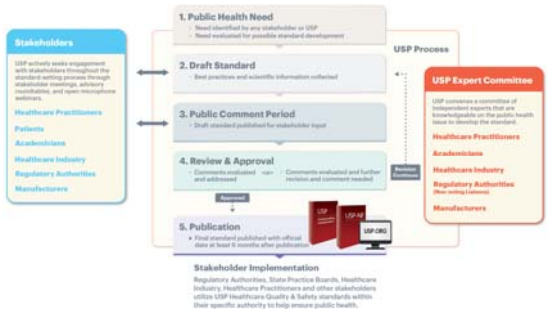
Member	Affiliation
Lisa Ashworth, B.S. Pharm	Children's Health System of Texas
Gus Bassani, Pharm.D.	PCCA
Edmund Elder, Ph.D. , B.S. Pharm	University of Wisconsin-Madison
Ryan Forrey, Pharm.D., M.S.	Beckon Dickinson
Deborah Houston, Pharm.D.	Novant Health - Kernersville Medical Center
Brenda Jensen, M.A.	Compounding Consultants, LLC.
Patricia Kienle, MPA, B.S. Pharm	Cardinal Health

2015 – 2020 Compounding Expert Committee

Chair: Gigi Davidson, B.S. Pharm, DICVP, NC State College of Veterinary Medicine
Vice Chair: Connie Rae Sullivan, B.S. Pharm, National Home Infusion Association

Member	Affiliation
William Mixon, B.S. Pharm	The Compounding Pharmacy
John Musil, Pharm.D.	Avella, Inc
David Newton, Ph.D.	Shenandoah University (retired)
Alan Parr, Pharm.D., Ph.D.	BioCeutics, LLC
Abby Roth, B.Sc.	ClinicalIQ
Robert Shrewsbury, Ph.D.	UNC Eshelman School of Pharmacy
James Wagner	Controlled Environment Consulting
Brenda Yuzdepski, B.S. Pharm	Saskatoon Medical Arts Pharmacy

How we work



USP Timeline for General Chapter Revisions

USP Compounding General Chapters

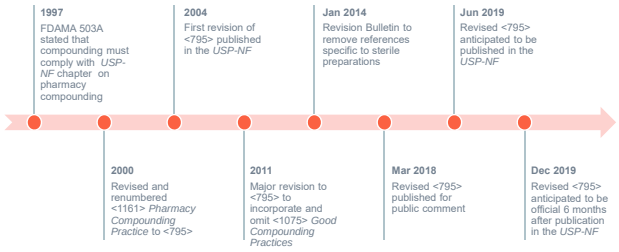
- **Quality Standards**
  - <795> *Pharmaceutical Compounding – Nonsterile Preparations*
  - <797> *Pharmaceutical Compounding – Sterile Preparations*
  - <800> *Hazardous Drugs – Handling in Healthcare Settings*
  - <1163> *Quality Assurance in Pharmaceutical Compounding*
  - <1160> *Pharmaceutical Calculations in Prescription Compounding*
  - <1168> *Compounding for Phase I Investigational Studies*
  - <1176> *Prescription Balances & Volumetric Apparatus*
- **Proposed Standard**
  - <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*

General Chapter <795>

Pharmaceutical Compounding – Nonsterile Preparations

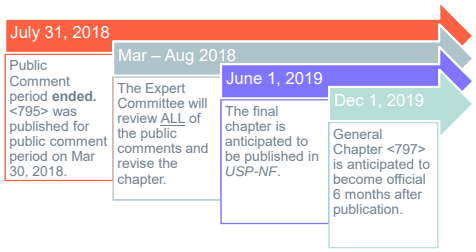
- Provides standards for compounding nonsterile drugs to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing.
- The chapter describes requirements for the compounding process, facilities, equipment, components, documentation, quality controls and training.
  - General Chapter <795> also provides general guidelines for assigning beyond-use dates to nonsterile preparations.

<795> Background and Development



<795> Next Steps

http://www.usp.org/compounding/general-chapter-795

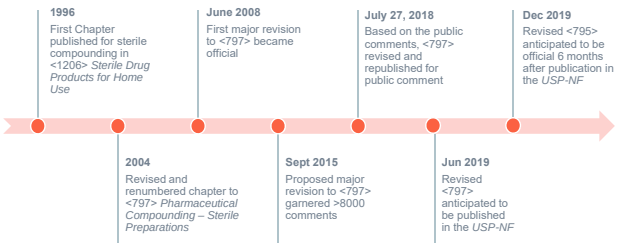


General Chapter <797>

Pharmaceutical Compounding – Sterile Preparations

- Provides standards for compounding sterile drugs to help ensure patient benefit and reduce risks such as contamination, infection or incorrect dosing
- The chapter describes a number of requirements, including responsibilities of compounding personnel, training, facilities, environmental monitoring, and storage and testing of finished preparations

<797> Background and Development



<797> Next Steps

http://www.usp.org/compounding/general-chapter-797

General Chapter <800>

Hazardous Drugs – Handling in Healthcare Settings

- Describes requirements including responsibilities of personnel handling hazardous drugs; facility and engineering controls; procedures for deactivating, decontaminating and cleaning; spill control; and documentation.
- These standards apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs and all the environments in which they are handled.

<800> Background and Development

2000
NOISH published Alert on Preventing Occupational Exposure to HDs

2010-2011
USP formed subcommittee and Expert Panel to begin work on hazardous drugs

Mar 2014
USP published 1st version of <800> for public comment

Dec 2014
Based on the public comments, USP revised and republished <800> for public comments

Feb 2016
Final version of <800> published in the *USP-NF*

Nov 1, 2017
Revision bulletin published to postpone the official date of <800>

Dec 2019
<800> anticipated to be official pending revisions to <795> and <797>

<800> Next Steps

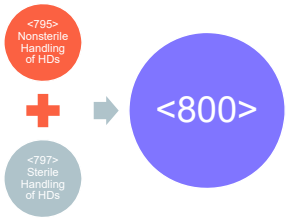
http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

Feb 1, 2018
Final version of <800> published in the *USP-NF*

Dec 1, 2019
General Chapter <800> is anticipated to become official 6 months after publication

Alignment of Compounding Chapters

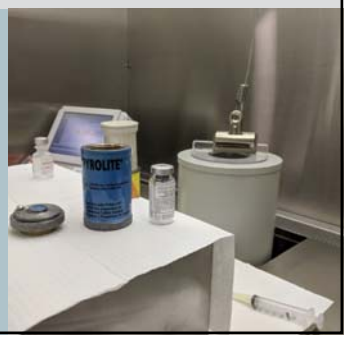
- Proposals of <795> and <797> eliminates provisions for handling of hazardous drugs
  - Compounding of hazardous drugs must additionally comply with <800> *Hazardous Drugs – Handling in Healthcare Settings*
- All 3 chapters, revised <795>, revised <797>, and existing <800> are anticipated to become official on Dec 1, 2019



General Chapter <825>

Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

- Describes radiopharmaceuticals, a unique class of drug products where compounding and other handling activities include:
  - the use of radionuclide generators,
  - the preparation of commercially-manufactured radiopharmaceutical kits,
  - the dilution of FDA-approved multi-dose vials,
  - the labeling of human blood products with radionuclides,
  - the preparation of patient-specific radiopharmaceutical doses,
  - and other activities.



<825> Next Steps

http://www.usp.org/chemical-medicines/general-chapter-825

Jul 27 – Nov 30, 2018
Provide public comments on the revisions to <825>

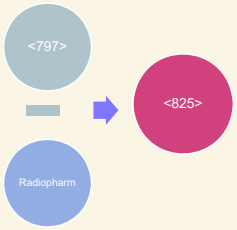
Oct 10, 2018
Attend the **Open Microphone** session with Expert Committee members

June 1, 2019
The final chapter is anticipated to be published in *USP-NF*

Dec 1, 2019
General Chapter <795> is anticipated to become official 6 months after publication

Alignment of Compounding Chapters

- <797> revision proposal eliminates section of *Radiopharmaceuticals as Compounded Sterile Preparations*
  - Compounding of radiopharmaceuticals is subject to the requirements in ⟨825⟩ *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*
  - <825> published for public comment on July 27, 2018
- Both revised <797> and <825> anticipated to become official on Dec 1, 2019

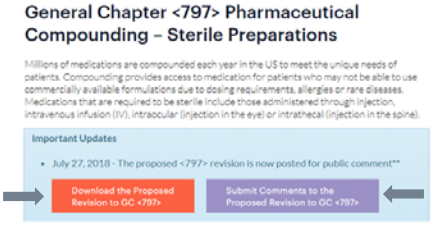


USP Timeline for General Chapter Revisions

Note: The current version of General Chapters <795> and <797> published in USP-NF are official.

Submit Comments on <797> and <825>

- <797> http://www.usp.org/compounding/general-chapter-797
- <825> http://www.usp.org/chemical-medicines/general-chapter-825



USP Resources

General
- USP Web Page: Healthcare Quality & Safety
- Compounding Compendium
- USP Education

Compounding
- <795> Pharmaceutical Compounding – Nonsterile Preparations
- <797> Pharmaceutical Compounding – Sterile Preparations

<800>
- Complimentary download <800>
- Updated <800> FAQs
- HazRx™ Mobile App
- Infographic





Stay informed signup for updates: http://www.usp.org/hqs-signup-form

Signup to Receive Alerts

- Sign up for the Healthcare Quality and Safety Alerts to receive updates on USP activities
  - http://www.usp.org/hqs-signup-form

Questions

Empowering a healthy tomorrow

Thank You

Empowering a healthy tomorrow

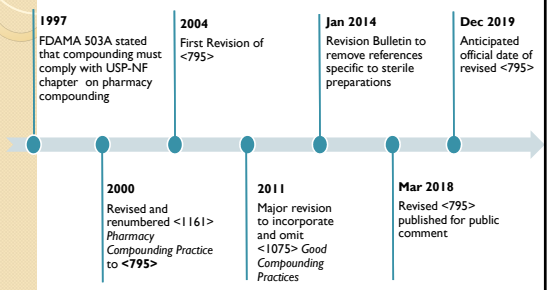
Update on USP <795> Revisions

Bob Shrewsbury, Ph.D.
UNC Eshelman School of Pharmacy

Learning Objectives

- Review the major differences between the current <795> chapter and the proposed revised chapter.
- Enhance audience understanding of the comment process utilized by USP.
- Summarize the most significant comments received by the close of the comment period.

Background



Overview of Major Changes

- **Purpose of Current Revision**
  - To reflect new science and evidence based on updated guidance documents, best practices, and new learnings from investigations
  - To respond to stakeholder input received throughout the cycle
  - To clarify topics that are frequently queried and misconstrued
  - To align with published <800> and revision efforts for <797>
- **Current <795> Served as an Template for Revision**
  - Many sections were "summary" statements and were expanded to add clarity and additional information
  - Revision proposal was modeled after current revision efforts for <797>

<795> Proposal

Sections in the currently official <795> that have been omitted in the revision proposal

- Categories of Compounding
  - Criteria for Simple, Moderate, and Complex eliminated
- Patient Counseling
- Compounding for Animal Patients

Content in currently official <795> that have been developed into new sections

- Component Selection, Handling, and Storage
- Packaging and Drug Preparation Containers
- Compounding Documentation
- Compounding Controls
- Quality Control

<795> Overview

1. INTRODUCTION AND SCOPE
2. PERSONNEL QUALIFICATIONS—TRAINING, EVALUATION, AND REQUALIFICATION
3. PERSONAL HYGIENE AND GARBING
4. BUILDINGS AND FACILITIES
5. CLEANING AND SANITIZING
6. EQUIPMENT AND COMPONENTS
7. SOPs AND MASTER FORMULATION AND COMPOUNDING RECORDS
8. RELEASE TESTING
9. LABELING
10. ESTABLISHING BEYOND-USE DATES
11. QUALITY ASSURANCE AND QUALITY CONTROL
12. CNSP HANDLING, PACKAGING, STORAGE, AND TRANSPORT
13. COMPLAINT HANDLING AND ADVERSE EVENT REPORTING
14. DOCUMENTATION

GLOSSARY

APPENDIX

<795> Proposal

Section 1. Introduction And Scope

- Scope
  - Added information on types of Compounded Nonsterile Preparations (CNSP)
- Hazardous Drugs
  - Removed all information on handling of hazardous drugs
  - Added references to General Chapter <800> *Hazardous Drugs — Handling in Healthcare Settings*
- Affected Personnel and Settings
  - Added roles and responsibility of the designated person
    - Designated person = one or more individual responsible and accountable for the performance and operation of the facility and personnel

<795> Proposal

Section 2. Personnel Qualifications—Training, Evaluation, And Requalification

- Added guidance on training and core competencies
- Included steps in training procedures

Section 3. Personal Hygiene And Garbing

- Added Box on Hand Hygiene Procedures
- Included description of garb and glove requirements
  - Gloves are required for all compounding activities
  - Other garb must be used as appropriate for the type of compounding

<795> Proposal

- **Section 4. Buildings And Facilities**
  - Added requirement for a designated space for nonsterile compounding
  - Area must be designed and controlled to provide well-lighted comfortable conditions for garbed personnel
  - Surfaces in a compounding area must be cleanable and clean
  - Easily accessible sink must be available
- **Section 5. Cleaning and Sanitizing**
  - New table on minimum frequencies of cleaning and sanitizing surfaces in the nonsterile compounding areas, including
    - Floors
    - Walls
    - Ceilings
    - Storage Shelving

<795> Proposal

Section 6. Equipment and Components

- Includes frequency for cleaning and sanitizing compounding equipment
- Any weighing, measuring, or other manipulation of an API or added substance in powder form that can generate airborne contamination from drug particles must occur inside a containment device
  - CVE must be certified annually
- Components
  - APIs must be manufactured by an FDA-registered facility
    - Each API must be accompanied by a valid COA
  - Ingredients other than APIs should be obtained from an FDA-registered facility
  - Packages of ingredients that lack vendor expiration must not be used after 1 year from the date of receipt

<795> Proposal

Section 7. SOPs and Master Formulation And Compounding Records

- Boxes include required elements of Master Formulation Record and Compounding Record

Section 8. Release Testing

- Confirm CNSP and labeling match Compounding Records
- Visual inspections to determine if physical appearance is as expected
- Other tests to ensure quality (e.g. pH, assays)

Section 9. Labeling

- Requirements for labels (labeling on immediate container)
- Requirements for labeling (all matter on container or in package or wrapper)

<795> Proposal

Section 10. Establishing Beyond-Use Dates

- Terminology
  - Expiration Date = applies to conventionally manufactured drug products
  - BUD = applies to CNSPs calculated in terms of hours, days, or months
- Parameters to consider
  - Chemical and physical stability
  - Compatibility of container-closure system
  - Degradation of container-closure system
  - Potential for microbial proliferation

<795> Proposal

Section 10. Establishing Beyond-Use Dates

- Maximum BUD by Type of Preparation in the Absence of CNSP-Specific Stability Information
  - Day that preparation is compounded is considered day 1

Type of Preparation	BUDs (days)	Storage Temperature
Solid dosage forms	180	Controlled room temperature
Nonaqueous dosage forms Aw ≤ 0.6	90	Controlled room temperature
Preserved aqueous dosage forms	30	Controlled room temperature
Non-preserved aqueous dosage forms Aw > 0.6	14	Refrigerator

<795> Proposal

Section 10. Establishing Beyond-Use Dates

- In the Presence of CNSP-Specific Stability Information
  - BUD may be extended up to maximum of 180 days
  - Stability-indicating assay for the specific API, CNSP, and container–closure that will be used
  - Must first be tested for antimicrobial effectiveness <51> at the end of the proposed BUD
- Shorter BUDs May be Required
  - If ingredients have an earlier expiration date
  - If components have a earlier expiration date or BUD
  - If ingredients are known to be susceptible to decomposition

<795> Proposal

Section 11. Quality Assurance and Quality Control

- Quality Assurance (QA) = set of written processes that, at a minimum, verifies, monitors, and reviews the adequacy of the compounding process
- Quality Control (QC) = observation of techniques and activities that demonstrate that requirements are met
- Facilities must have a formal QA and QC program
  - Must be documented in SOPs
  - Annual assessment

Section 12. CNSP Handling, Packaging, Storage, And Transport

- Program that will provide information and protections needed for safe handling and storage of CNSPs and/or components
- Packaging materials to maintain physical and chemical integrity and stability of the CNSP
- Monitoring and SOPs to detect and prevent temperature excursions

<795> Proposal

Section 13. Complaint Handling And Adverse Event Reporting

- SOPs for complaint receipt, acknowledgement, and handling
- Adverse event reporting
  - FDA MedWatch (human drugs)
  - Form FDA 1932a (animal drugs)

Section 14. Documentation

- Written or electronic documentation
- Required compounding records must be retrievable for ≥ 3 years after preparation or as required by applicable laws and regulations of the regulatory jurisdiction, whichever is longer

<795> Next Steps

July 31, 2018
Public Comment period **ended.** <795> was published for public comment period on March 30, 2018.

Mar – Aug 2018
The Expert Committee will review ALL of the public comments and revise the chapter.

June 1, 2019
The final chapter is anticipated to be published in *USP-NF*.

Dec 1, 2019
General Chapter <795> is anticipated to become official 6 months after publication.

QUESTIONS?

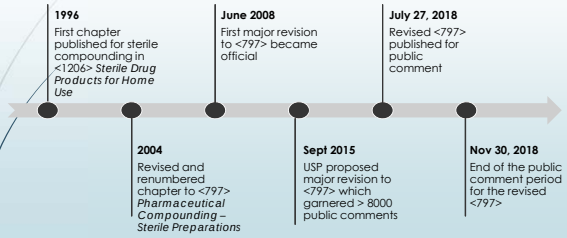
Update on USP <797> Revisions

Bill Mixon, RPh, MS, FACA
NC Board of Pharmacy

Learning Objectives

- Compare proposed changes to USP <797> with the current Chapter.
- Identify at least 3 major changes to USP Chapter 797 that have been proposed by the USP Compounding Expert Committee.
- Review the major benefits of the revision

Background



Purpose of Current Revision

- To address public comments received in the first revision proposal in September 2015
- To clarify topics that are frequently queried and misconstrued
- To align with published <800> and revision efforts for <795>

Overview of Major Changes

- Reorganized to include section and subsection numbers.
- Placement of procedural information in boxes.
- Revised definition of the scope of the chapter to include sterile compounding activities and exclude administration of medication
- Simplified compounded sterile preparation (CSP) microbial risk levels from three (low, medium, and high) to two
  - **Category 1 CSPs** have a shorter BUD and may be prepared in an unclassified segregated compounding area (SCA).
  - **Category 2 CSPs** have a longer BUD and must be prepared in a cleanroom suite (buffer room with ante-room).

Overview of Major Changes

- Added guidance on use and storage of opened or needle-punctured conventionally manufactured products and CSPs.
- Added information on notification and recall of (previously dispensed) CSPs that have out-of-specification results.
- Clarified requirements for compounding allergy extract prescription sets.
- Removed information related to handling of hazardous drugs
- Removed of the section on radiopharmaceuticals as CSPs
  - Added reference to ***Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*** (825)
  - General chapter (825) is also proposed for public comment in PF 44(5)

<797> Proposal

1. Introduction and Scope
2. Personnel Qualifications—Training, Evaluation, and Requalification
3. Personal Hygiene and Garbing
4. Facilities and Engineering Controls
5. Microbiological Air and Surface Monitoring
6. Cleaning and Disinfecting Compounding Areas
7. Equipment, Supplies, and Components
8. Sterilization And Depyrogenation
9. SOPs and Master Formulation and Compounding Records
10. Release Testing
11. Labeling
12. Establishing Beyond-Use Dates
13. Use Of Conventionally Manufactured Products
14. Use of CSPs as Components
15. Quality Assurance And Quality Control
16. CSP Storage, Handling, Packaging, Shipping, And Transport
17. Documentation
18. Compounding Allergenic Extracts

Glossary

Appendices

<797>: Major Elements of Revision


Scope


Removal of Hazardous Drugs


Removal of Radiopharmaceuticals


Personnel Qualifications


Personnel Hygiene and Garbing


Facilities and Engineering Control


Microbiological Monitoring


Cleaning and Disinfecting

<797>: Major Elements of Revision


Equipment, Supplies, and Components


Sterilization and Depyrogenation


SOPs and Documentation


Release Testing


Establishing Beyond-Use Date


Use of Conventionally Manufactured Products


Quality Assurance and Quality Control


Compounding Allergenic Extracts

<797> Categories of CSPs

Category 1 CSPs

- May be prepared in a PEC located in a unclassified segregated compounding area
- Assigned a BUD of ≤ 12 hours at controlled room temperature or ≤ 24 hours when refrigerated

Category 2 CSPs

- Must be prepared in a cleanroom suite
- Assigned a BUD of > 12 hours at controlled room temperature or > 24 hours if refrigerated

<797>: Summary of Minimum Requirements

	Category 1	Category 2
Personnel Qualifications		
Visual observation of hand hygiene and garbing	Every 6 months	Every 6 months
Gloved fingertip and thumb sampling	Every 6 months	Every 6 months
Media fill testing	Every 6 months	Every 6 months
Requalification	Every 12 months	Every 12 months

<797>: Summary of Minimum Requirements

	Category 1	Category 2
Buildings and Facilities		
Placement of the primary engineering control (PEC)	Not required to be placed in a classified area	Required to be placed in a classified area
Recertification	Every 6 months for the PEC	Every 6 months for the PEC and secondary engineering control (SEC)
Nonviable airborne monitoring	Every 6 months	Every 6 months
Microbiological Air and Surface Monitoring		
Viable air sampling	Every 6 months	Every 6 months
Surface sampling	**Monthly**	**Monthly**

<797>: Summary of Minimum Requirements

	Category 1	Category 2
Release Testing		
Visual inspection	Required	Required
Sterility testing	Not required	Based on assigned BUD
Endotoxin testing	Not required	Based on assigned BUD (e.g., if sterility testing is required)

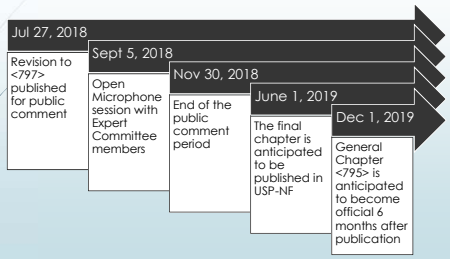
<797>: BUDs for Category 1 CSPs

	Storage Conditions	
	Controlled Room Temperature (20°–25°)	**Refrigerator (2°–8°)**
BUD	≤ 12 hours	≤ 24 hours

<797>: BUDs for Category 2 CSPs

Preparation Characteristics		Storage Conditions		
Sterilization Method	**Sterility Testing Performed & Passed**	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (−25° to −10°)**
Aseptically prepared CSPs	**No**	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 9 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	**No**	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

<797> Next Steps



Questions

Compounding for Non-Human Patients: A Regulatory Update

National Association of Boards of Pharmacy District III Meeting
Asheville, NC
August 13, 2018
Emily Sorah, RPh, PharmD, FSVHP

Disclosures

- *"I declare no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria."*

Objectives

1. Recognize the necessity of compounding to meet the medication needs of non-human patients.
2. Recall past legislature regarding compounding for non-human patients.
3. Describe recent guidance concerning compounding from bulk-drug substances for non-human patients.
4. Strategize how to meet the compounding needs of veterinary patients in the current environment.
5. Identify appropriate veterinary drug and veterinary compounding resources.

Why Do We Compound for Non-Human Patients?

- Doses and strengths for patients ranging from 8 grams to 800 kilograms.
- When commercially available products are inappropriate (strength, dosage form, etc)
- When commercially available products contain toxic excipients
- When no commercially available product exists
- To increase compliance, reduce treatment failure, and support the human-animal bond

The Scope

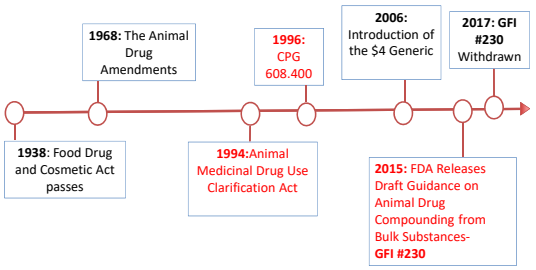
- "We estimate that approximately **75,000 pharmacies** will receive approximately **6,350,000 prescriptions** for compounded animal drugs annually."

U.S. Food and Drug Administration Draft Guidance for Industry #230-Compounding Animal Drugs from Bulk Drug Substances. Accessed July 2018. <https://www.fda.gov/AnimalVeterinary

Who Compounds for Non-Human Patients?

- Pharmacists
  - Valid prescription
  - Valid Veterinarian-Client-Patient Relationship (The "VCPR")
- Veterinarians
  - Within own practice
  - For own patients
  - Within expertise and facilities

Timeline: The Evolution of Veterinary Compounding

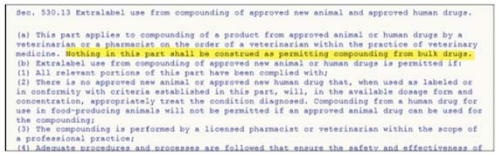


AMDUCA: Animal Medicinal Drug Use Clarification Act

- *"permits veterinarians to prescribe extralabel uses of certain approved new animal drugs and approved human drugs for animals under certain conditions."*
  - ✓ Prescribe approved human drugs off-label
  - ✓ Prescribe approved animal drugs off-label
  - ✓ Prescribe compounded drugs with either of the above as starting ingredients
  - ✗ Prescribe compounded drugs with bulk

AMDUCA: Animal Medicinal Drug Use Clarification Act

- 21 CFR 530.13 (Rules and Provisions for Extralabel uses of Drugs in Animals)
  - Compounding from approved products is already permitted under 21 CFR 530.13


Sec. 530.13 Extralabel use from compounding of approved new animal and approved human drugs.

(a) This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs.
(b) Extralabel use from compounding of approved new animal or human drugs is permitted if:
(1) All relevant portions of this part have been complied with;
(2) There is no approved new animal or approved new human drug that, when used as labeled or in conformity with criteria established in this part, will, in the available dosage form and concentration, appropriately treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;
(3) The compounding is performed by a licensed pharmacist or veterinarian within the scope of a professional practice;
(4) Adequate procedures and processes are followed that ensure the safety and effectiveness of

The Real Issue?

- **Compounding from <u>BULK</u> drug substances**
- Not addressed in AMDUCA
- IS addressed:
  - FDA CPG Sec 608.400
  - FDA GFI #230

FDA CPG Sec 608.400

Compounding of Drugs for Use in Animals

- Written 7/3/1996, revised 7/8/2003
- "FDA position [is] that the [Federal Food Drug and Cosmetic Act *does not permit veterinarians to compound unapproved finished drug products from bulk drug substances, unless the finished drug is not a new animal drug.*"
- FDA is greatly concerned about…manufacturing and distributing unapproved new animal drugs…outside the bounds of traditional pharmacy practice and that violates the Act
  - (e.g., compounding that is intended to circumvent the drug approval process and provide for the mass marketing of products that have been produced with little or no quality control or manufacturing standards to ensure purity, potency, and stability of the product)
  - These activities are the focus of this guidance

FDA CPG Sec 608.400

Compounding of Drugs for Use in

- Contains a list o compounding and u would not normall
- Remember, compl are:
  - Guidance docume of FDA staff
  - Not Law
- FDA CPG Sec 608 May 18, 2015
- Replaced with a <u>DRAFT</u> of GFI #230

Ammonium molybdate
Ammonium tetrathiomolybdate
Ferric ferrocyanide
Methylene blue
Picrotoxin
Pilocarpine
Sodium nitrate
Sodium thiosulfate
Tannic acid

DRAFT Guidance for Industry #230

Compounding Animal Drugs from Bulk Drug Substances

- "Current law does not permit compounding of animal drugs from bulk substances, but the FDA recognizes that there are limited circumstance when an animal drug compounded from bulk drug substances may be an appropriate treatment option."
- Remember, Guidance for Industry is:
  - Guidance document for industry to act in a way that FDA would not normally object
  - Not law

DRAFT Guidance for Industry #230

Compounding Animal Drugs from Bulk Drug Substances

- "Nothing should be construed as permitting compounding animal drugs from bulk drug substances."
- "Generally, **FDA does not intend to take action if** a pharmacy or veterinarian compounds animal drugs from bulk drug substances in accordance with the conditions described below"
  - If compounded by a **State-licensed pharmacy**…
  - If compounded by a **Veterinarian**…
  - If compounded by an **Outsourcing facility**…

DRAFT Guidance for Industry #230

Compounding Animal Drugs from Bulk Drug Substances

- Tolerance of the use of bulk drug to compound for non-food-producing patients when
  - No commercially available starting ingredient exists
  - Commercially available starting ingredients are not suitable
- **Withdrawn** November 2017

GFI #230: State-licensed pharmacies

- Adverse events/product defects be reported to FDA on Form FDA 1932a
- Bulk drug substances must be obtained from FDA-registered manufacturer and have valid COA
- Required to compound in accordance to USP <795>, <797>
- No compounding from bulk drug for food-producing animals.
  - (More on this later)
- Documentation
  - Species (on prescription or compounding record)
  - Rationale for using bulk drug substance

GFI #230: Veterinarians

- Compounding must be done by veterinarian for patient under his or her care
- Adverse events/product defects be reported to FDA on Form FDA 1932a
- No compounding with bulk drug substances for food animals (more later)
- Required to compound in accordance to USP <795>, <797>
- May not sell or transfer any compound prepared using bulk ingredients to another clinic or another veterinarian

GFI #230: Outsourcing Facilities

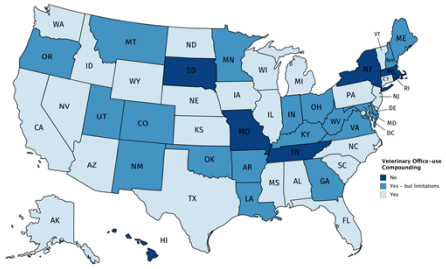
- Drugs compounded by outsourcing pharmacies are limited to bulk drug substances listed [*list to be determined, Appendix A*]
- Required outsourcing pharmacies to include on label of all drugs compounded with bulk drug "*This drug will not be dispensed or administered to food-producing animals.*"
- *(Should already be reporting adverse events to the FDA)*
- *(Again, no compounding from bulk drug substances for food animals)*
- *(Compounds included in biannual report to the FDA, but separate from drugs compounded for humans)*
- *(Compounding must be in accordance to cGMP requirements)*

What about OFFICE USE?

- Office Use: "compounded drug products kept as office stock/ for office use by hospitals, clinics, or health care practitioners to administer to patients who present with an immediate need for a compounded drug product"
- Frequent occurrence in veterinary medicine

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry, December 2016

What's that about OFFICE USE?



What about RESALE?

1. "Not for resale."
2. "For use only in [fill in species and any associated condition or limitation listed in Appendix A]."
3. "Compounded by [name of outsourcing facility]."
4. "Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a."

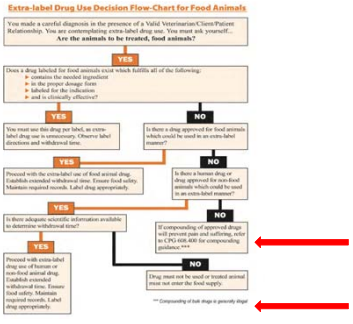
GFI #230: Prescriptions for Compounds from Bulk Drug

- Prescriptions order states species and condition(s) for which the substance is listed in Appendix A (outsourcing facilities)
- Prescriptions contain:
  - a statement that the change between the compounded drug and the FDA approved drug produces a clinical difference for the individual identified patient (state-licensed pharmacies)
  - "This animal is not a food producing animal."
  - "There are no FDA-Approved animal or human drug that can be used as labeled or in an extra-label manner under section 512(a)(4) and (5) and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which this drug is being prescribed"

GFI #230: Labeling of Drugs Compounded From Bulk Drug

- Species of intended animal patient
- Name of animal patient
- Name of owner or caretaker
  - *Required if compounded by pharmacy or veterinarian

Special Considerations: **Food-Producing Animals**



GFI #230: Food-Animals are Defined as:

- Cattle
- Swine
- Chickens
- Turkeys
- Sheep
- Goats
- Non-ornamental fish

- **Regardless of intended use

Compounding for **Food-Producing Animals**

- Likely highest regulatory priority for FDA
- Do not compound with bulk drug*
- Do not compound from "Prohibited and Restricted Drugs in Food Animals" under AMDUCA, 21 CFR part 530
  - Group 1: Drugs with no allowable ELDU in any food-producing animal species
  - Group 2: Drugs with restricted ELDU in food-producing animal species
  - Group 3: Drugs with special restrictions for Grade "A" dairy

*[Unless it is an antidote]

"Prohibited and Restricted Drugs in Food Animals"

GROUP I. Drugs with No Allowable Extra-Label Uses in Any Food-Producing Animal Species

- **CHLORAMPHENICOL**
- **CLENBUTEROL**
- **DIETHYLSTILBESTEROL (DES)**
- **FLUOROQUINOLONE-CLASS ANTIBIOTICS**
- **GLYCOPEPTIDES** – all agents, including **VANCOMYCIN**
- **MEDICATED FEEDS**
- **NITROIMIDAZOLES** – all agents, including **DIMETRIDAZOLE, IPRONIDAZOLE, METRONIDAZOLE** and others
- **NITROFURANS** – all agents, including **FURAZOLIDINE, NITROFURAZONE** and others

GROUP II. Drugs with Restricted Extra-Label Uses in Food-Producing Animal Species

- **ADAMANTANE & NEURAMINIDASE INHIBITORS** – Extra-label use (ELDU) of these drugs is **prohibited** in poultry including chickens, turkeys and ducks in the United States. Although these drugs are **not approved for use in animals in the United States**, some of these drugs are used in other countries for the treatment or prevention of avian influenza in chickens, turkeys and ducks.
- **CEPHALOSPORINS**
  - ELDU of all cephalosporin antibiotics, except CEPHAPIRIN, is **restricted** in the United States.
  - ELDU restrictions differ for Major vs. Minor Food Animal Species as noted below:
  1. **Major Food Animal Species** (Cattle, Pigs, Chickens and Turkeys): ELDU is permissible only for therapeutic indications that are not included on the product label. However, ELDU of cephalosporin antibiotics is **prohibited** in all of the following situations:
     a) the intended use of the product deviates from the approved dose, treatment duration, frequency or administration route on the product label,
     b) the intended use of a product in an unapproved major species or animal production class,
     c) the intended use of the product for the purpose of disease prevention.
  2. **Minor Food Animal Species** (all species that are not major species): ELDU of cephalosporin antimicrobial agents is permitted in these species.
- **GENTIAN VIOLET** – use is **prohibited** in food or feed of all food-producing animal species (details)
- **INDEXED DRUGS** (view here) – ELDU of these drugs is **prohibited** in all food producing animals, with some exceptions for minor-use animal species that are not used as food for humans or other animals.
- **PHENYLBUTAZONE** – all uses of this drug is **prohibited** in female dairy cattle greater than 20 months of age.
- **SULFONAMIDE-CLASS ANTIBIOTICS**
  - ELDU of all sulfonamides and potentiated sulfonamides is prohibited in adult lactating dairy cattle or dairy cattle greater than 20 months of age.
  - only labeled uses of approved sulfonamides are allowed.
  - ELDU of sulfonamides in milking sheep and goats is discouraged but not prohibited.

Now What?

- Watch for the **NEW** draft guidance for industry: Draft GFI #256
  - Intended to publish for public comment early 2018
  - Expected to publish as draft or final by December 2018
  - "FDA will carefully consider the issues that are specific to compounding of animal drugs, including the significance of using compounded drugs as a treatment option in various veterinary settings and animal species."

During the Regulatory Gap..

"..until this draft guidance is finalized, FDA intends to look at the totality of the circumstances when determining whether to take enforcement action for unlawful animal drug compounding activities. "

During the Regulatory Gap..

- Comparison of the CPG and GFI indicate that FDA's primary concern regarding compounding with bulk drug substances are:

1. Copies of FDA approved drugs
2. Resale of office stock compounds
3. Use of bulk drug substances to compound for food-producing animals

During the Regulatory Gap..

Maybe okay to consider compounding with bulk drug when:

a. Justification of medical necessity
   a. no FDA approved product
   b. FDA approved product is not suitable
   c. Rationale for using bulk drug is documented
   d. Bulk drug obtained from FDA registered facility
   e. Compound in accordance to USP <795>, <797>
b. When USP compounded preparation states that bulk powder is one of the ingredients
c. Patient is not a food animal

When **NOT** to compound for veterinary patients

- When commercially- available product exists and can be used appropriately
- Compounding solely to reduce cost (or copies of FDA approved products)
- Compounding for food-producing animals with prohibited drugs or bulk drugs
- With bulk drug not from FDA-Registered suppliers
- Beware of OFFICE USE.

Available Position Statements

- American Veterinary Medical Association (AVMA) Novemeber, 2000)

AVMA
Our Passion. Our Profession.

- Society of Veterinary Hospital Pharmacists

SOCIETY OF VETERINARY HOSPITAL PHARMACISTS

Veterinary Compounding Basics

- Avoid toxic dyes and colorings
  - Azo dyes toxic to birds, cats
- Avoid "toxic" or unsavory flavors
  - Chocolate or grape for dogs
  - Sweet or fruity flavors for cats
- Avoid toxic excipients
  - Xylitol-dogs, birds

- Consider size of the patient vs. size/volume of dose
- Consider species and feasibility of administering medications
- Problem solving to meet patient, veterinarian, client needs

"Specialized Dosage Forms" for Veterinary Patients

- Transdermal Gels
- Medicated Polyox Bandages
- Medicated Pluronic Gel
- Medicated Chew Treats
- Medicated Gummy Worms

Veterinary Compounding Resources: When in Doubt…

- Code of Federal Regulations Title 21 Part 530: Extralabel Drug Use in Animals
- USP Standards for Veterinary Drugs
  - Compounding Monographs
  - Animal Drugs and Use in Animal Feeds
  - Manufactured Drugs and Drug Product Monographs
- USP <795> Pharmaceutical Compounding-Non-Sterile Preparations
- USP <797> Pharmaceutical Compounding-Sterile Preparations

Veterinary Compounding Training & Credentials

- **PCCA Veterinary Compounding Training Program**
  - Pre-requisite: Compounding Boot Camp
  - 10 Online Modules, 2-day Lab
- **American College of Veterinary Pharmacists**
  - Veterinary Compounding Essentials -15 hour program
  - ACVP Fellows
- **Society of Veterinary Hospital Pharmacists**
  - Not compounding specific
  - Fellows, Diplomates of the International College of Veterinary Pharmacists

Veterinary Drug Resources

1. Plumb's Veterinary Drug Handbook
   - Available online, phone app
   - Yearly subscription
2. Saunder's Handbook of Veterinary Drugs
   - Available in print
3. Merck Veterinary Manual
   - Available online
   - No subscription required

References

1. Code of Federal Regulations Title 21 Part 530: Extralabel Drug Use in Animals, Accessed July 2018 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=530>
2. U.S. Food and Drug Administration Compliance Policy Guides. Chapter 6: Veterinary Medicine. Sec. 608.400, Accessed July 2018 <https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/default.htm#2015>
3. U.S. Food and Drug Administration Draft Guidance for Industry #230-Compounding Animal Drugs from Bulk Drug Substances. Accessed July 2018. <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm055752.htm>
4. Food Animal Residue Avoidance Databank: Compounding Guide for the Food Animal Veterinarian. Accessed July 2018 <http://www.farad.org/publications/miscellaneous/FARADCompoundingGuide.pdf>
5. National Dairy Farm Program Milk and Dairy Beef Drug Residue Prevention: Produce Manual of Best Management Practices. 2015 <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm055752.htm>
6. American Veterinary Medical Association. Governance. Councils and Committees: Task Force on Veterinary Compounding Legislation. Accessed July 2018. <https://www.avma.org/About/Governance/Councils/Pages/Task-Force-on-Veterinary-Compounding-Legislation.aspx>
7. Society of Veterinary Hospital Pharmacists. Position Statements: Position Statement of Compounding of Drugs for Use in Animals. Accessed July 2018 <https://svhp.org/new/wp-content/uploads/2012/01/CompoundingStatement.pdf>
8. U.S Food and Drug Administration Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act, December 2016.

Questions?

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NC STATE

Effective Inspection for and Investigation of Medical Supply/Pain Cream Operations

Investigative Staff from the North and South Carolina Boards of Pharmacy

North Carolina Board of Pharmacy Inspections & Investigations Staff

- Krystal Stefanyk: NCBOP Director of Inspections
- Megan "Chase" Kauffman Bissell: NCBOP Investigator/Inspector
- Catherine "Liz" Collier: NCBOP Investigator/Inspector
- Loretta Wiesner: NCBOP Investigator/Field Training Coordinator

- Sheila Young, SCBOP Chairman of Non-Resident Application Review Committee
- Douglas Murray, SCBOP Inspector

Integrity, Excellence, Accountability & Customer Service

South Carolina Department of Labor, Licensing and Regulation

Objectives

- Discuss how to identify pharmacies that may be engaged in illegitimate diabetic supply and pain cream operations when conducting an inspection or investigation.
- Develop and apply strategies for effectively investigating pharmacies suspected of engaging in illegitimate diabetic supply and pain cream operations.
- Develop and apply methods of overcoming frequently encountered obstacles, including interstate practices, when investigating pharmacies suspected of engaging in illegitimate diabetic supply and pain cream operations.

Identify Pharmacies Engaged in Illegitimate Practices

- Inspect/Investigate:
  - Prescriptions
  - Products/Medications
  - Forms of Billing
  - Wholesale Invoices
  - Shipping Practices
  - Business Operations

Discovery Through Inspection

- Physical Space vs Business Model
- Independent Retail Pharmacy New Ownership
- Pharmacist Manager and Person in Charge Inability to Explain Business Practices

Methods of Identifying

- Billing practices
  - Staff billing for multiple NDCs for one RX to see which has best profit
  - Tips from insurance companies
  - Calls from patients regarding unrequested orders

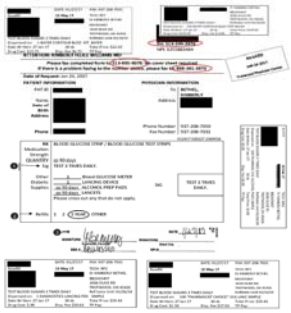
Warning Signs

Multiple phone numbers

Multiple fax numbers

Phone and fax numbers different than what was on application

Pharmacist in this instance did not know where faxes went (did not go to his pharmacy)



Warning Signs

Things just don't add up: stated this is a closed-door pharmacy

- In the middle of medical suites
- Has waiting room, drop off, and consult area

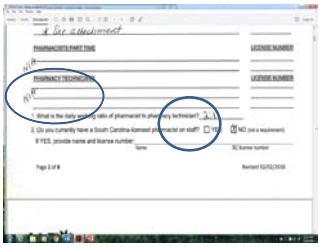
From 'Closed-Door' Pharmacy

Identify Pharmacies Engaged in Illegitimate Practices

- Review Board of Pharmacy Permit Application Information
  - Key items to identify
  - Align with day-to-day operation?

Warning Signs

Application Discrepancies



Strategies for Effectively Investigating

- Reach out to Insurance Companies, Medicaid, Medicare
- Confer with Other Boards of Pharmacy
- Discover Criminal Cases from State and Federal Agencies
- Additional Resources:
  Better Business Bureau, Yelp, & Yellow Pages Reviews

Think outside the box!

Investigative Strategies

THE UNITED STATES DEPARTMENT of JUSTICE

Former Owner of Durable Medical Equipment Company Arrested in Health Care Fraud and Money Laundering Scheme

Diabetic Medical Equipment Companies to Pay More Than $12 Million to Resolve False Claims Act Allegations

Owner of Durable Medical Equipment Company Pleads Guilty to Defrauding Medicaid of More Than $9 Million

Defendant Used Money to Buy Real Estate, Luxury Car

40-43-83(E) The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this jurisdiction and those located outside this State.

Investigative Strategies: Effective Partnering!

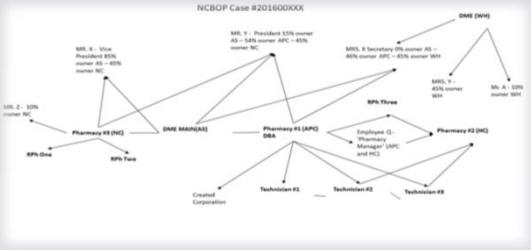
Humana

TRICARE

Quarterly in-person meetings with fraud investigators with various organizations

Overcoming Obstacles

- Compile the Investigative Findings, Permit Application, Complaints, Knowledge from other Criminal Investigations and State Actions
- The Volume of Information Gathered
- Off-site Billing
- Shell Companies and Multiple Corporate Entities



Overcoming Obstacles

- Research on corporation and corporate owners
  - Google
  - Facebook
  - LinkedIn
  - CorporationWiki
- In person interview with PIC
- Requiring all pages of most recent inspection
- Information sharing among states
- Requiring specific photographs

Questions?

Regulating the Practice of Medicine Based on "Standard of Care"

Thomas W. Mansfield, JD
Chief Legal Officer
NC Medical Board

National Association of Boards of Pharmacy
District III Meeting
Asheville, NC
Aug. 13, 2018

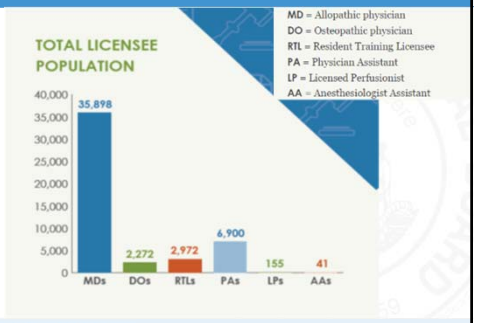
NORTH CAROLINA MEDICAL BOARD

North Carolina Medical Board
1203 Front Street | Raleigh, NC 27609
www.ncmedboard.org | info@ncmedboard.org
800.253.9653

About the NC Medical Board

- Governed by the Medical Practice Act (MPA), Art. 1 of Chapter 90 of the N.C. Gen. Statutes.
- Regulates the practice of medicine and surgery in North Carolina "***for the benefit and protection of the people of North Carolina***."

About the NC Medical Board



About the NC Medical Board

- The NCMB consists of 13 members appointed by either the Governor or the Legislature.
  - 8 licensed physicians
  - 1 licensed physician assistant
  - 1 licensed nurse practitioner
  - 3 members of the public with no financial or professional interest in health care

About the NC Medical Board

- Licenses, disciplines, educates and when appropriate, rehabilitates licensees to assure their fitness and competence in the service of the public.
- NCMB meets monthly. It conduct disciplinary hearings in even months. In odd months, it conducts Board business, holds committee meetings, and interviews.

Disciplinary Authority

- The NCMB has authority to take disciplinary action, such as deny, suspend, or revoke a license, when an applicant/licensee commits certain acts in violation of the MPA. N.C. Gen. Stat. § 90-14(a).

Disciplinary Authority

Violations of the MPA:

- Immoral or dishonorable conduct
- Making false statement to the NCMB
- Unable to practice medicine with reasonable skill and safety due to alcohol or substance abuse, dependence and/or addiction
- Convictions of crimes involving moral turpitude
- False advertising
- Promotion or sale of goods or services in an exploitative manner
- Disciplinary actions taken by other state licensing boards

Disciplinary Authority

Violations of the MPA:

- Failure to complete continuing medical education
- Inappropriate prescribing
- Lack of professional competence to practice medicine or failure to maintain acceptable standards of care of one or more areas of practice.
- Unprofessional conduct

CASES OPENED BY PRIMARY ALLEGATION*

Quality of care	615
Communication issue	423
Action by out of state agency/regulator	362
Prescribing issues	180
Medical records issue/alleged HIPAA violation	118
Policy/procedure within Dept. of Corrections/jail	98
Patient dismissed, abandoned or refused appointment	79
Alcohol/substance use	52
Misdemeanor or felony arrest/conviction	40
Professional sexual misconduct/ boundary issue	35
Unprofessional conduct	30
Corporate practice of medicine issues	15
Misinformation/nondisclosure on license application/renewal	15

* Table displays the most common allegations associated with Board cases opened during 2017. Allegations that resulted in fewer than 10 cases are not shown.

Disciplinary Authority

Unprofessional conduct, includes, but is not limited to:

- ***Departure from, or failure to conform to, the standards of acceptable and prevailing medical practice***…" (quality of care cases)
- Violating ethics of medical practice
- Committing acts contrary to honesty, justice, or good morals

Examples of Quality of Care Issues

- Failure to diagnose or misdiagnosis
- Misreading or ignoring laboratory results
- Improper medication or dosage
- Improper treatment
- Surgical errors or wrong site surgery
- Failure to or improper follow-up care

Examples of Quality of Care Issues

- Failure to obtain adequate patient history or conduct a physical exam
- Failure to order appropriate labs and screenings
- Documentation errors such as failure to document diagnoses or treatment therapies

What is the Standard of Care?

- What a reasonably prudent physician in NC would do under the same or similar circumstances.
- Depends on various circumstances, such as:
  - Area of practice, training and expertise
  - Patient history and diagnosis
  - Date of diagnosis or treatment

What is the Standard of Care?

- NCMB uses a statewide standard of care to execute its regulatory function. N.C. Gen. Stat. § 90-14.6.
- It does not use the "community standard" which applies to medical malpractice cases. N.C. Gen. Stat. § 90-21.12.

No Requirement of Injury

- The standard of care can be violated even in the absence of patient injury or death.
- NCMB does not have to prove harm to patient to impose discipline

Regulatory Models

Standard of Care Approach

- Vague. Licensees determine how to practice based on profession
- Broad enough to apply to every situation
- Evolves with medical and technological advances
- Various factors are taken into account

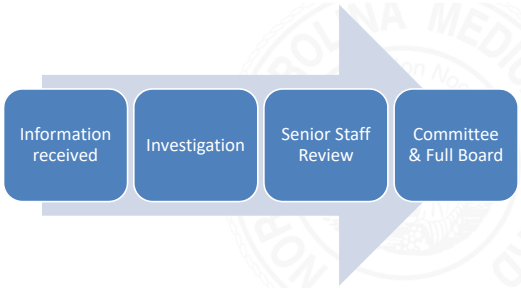
Law or Rule Based Approach

- Licensees' practice is dictated by a specifically prescribed rule or law
- Limited to statutory or rule language
- Modify through legislative or rulemaking processes
- May not take into account various factors

Regulatory Models

- It is impossible for the NCMB to set out by statute or rule how licensees should practice medicine.
  - Medicine is constantly evolving due to research, technological advances, treatment modalities, etc. and the legislative and rulemaking processes are too slow to stay current with the "prevailing medical practice"
  - Too many standards to make an exhaustive list
  - SOC language is intentionally broad so that certain acts not specifically outlined in a law or rule are still subject to disciplinary action

Disciplinary Process



Investigative Process

- **Step 1**. The NCMB will receive a complaint or information alleging substandard care.
- These come from a variety of sources:
  - Patients, family members, and other health care professionals.
  - Malpractice reports from insurance carriers
  - Hospitals reporting changes in staff privileges
  - Other federal or state agencies
- The licensee is notified of any complaint received.

Investigative Process

- **Step 2**. NCMB requests licensee to respond and provide relevant medical records.
- **Step 3**. Matters involving quality of care are reviewed by the Office of the Medical Director (OMD). Forwarded to an independent expert reviewer for an assessment where specialty care is involved. OMD makes recommendation of disciplinary action based on independent reviewer's assessment.

Independent Expert Review Requirement

- Before taking any action against a licensee for violating the standard of care, the NCMB is required to consult with a licensee, or ***independent reviewer***, who routinely utilizes or is familiar with the same modalities and has an understanding of the standards of practice for the modality administered. N.C. Gen. Stat. § 90-14(g)
- Review cases to determine ***whether diagnosis, treatment, and medical records meet the standard of care***. See the NCMB's Expert Reviewer Manual.

Quality of Care Case Manager

- New staff position at NCMB
- Not yet filled
- Requires experience in the private sector handling similar cases
- Must be a paralegal or attorney, prefer training and experience as a nurse
- Job is to **"shepherd"** all independent expert reviews

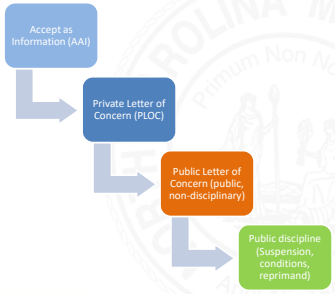
Back to Investigative Process

- **Step 4**. OMD's recommendation is reviewed by in-house Legal Department and then Senior Staff Review Committee (SSRC).
- **Step 5**. The NCMB's Disciplinary Committee reviews SSRC recommendation.
- **Step 6**. The full Board reviews the Disciplinary Committee's recommendation. Determines whether to authorize staff to implement a particular disciplinary action.

Testing Competence

- The Board may order the licensee to submit to an examination, written or oral, to determine their professional qualifications. Examples:
  - CPEP Competency assessments that evaluate clinical knowledge, skills and judgment as well as cognitive state.
  - SPEX (Special Purpose Exam) multiple choice examinations that test particular knowledge.
- Orders for examinations can be issued during the investigative process or be included as a condition in any disciplinary order.

Possible outcomes



Possible Outcomes

- Public Actions can include:
  - Public letter of concern (non-disciplinary)
  - Reprimand
  - Fine
  - Probation
  - Suspension
  - Revocation
- Pubic actions may be determined through a consent order or a public hearing. Most cases are settled by a consent order and do not result in a public hearing.

Investigative and Enforcement Data (2017)

Adverse Actions	
Public letters of concern	47
Conditions on license/practice	26
Suspension	19
Reprimands	14
License surrenders	10
Limitations on license/practice	8
Amended consent order	5
License revocations	5
Non-practice agreement	3
License inactivated in lieu of other action	2
License denials	2
Summary suspensions	1
Annulments	1
TOTAL ADVERSE	143

CAUSES OF ACTION

Quality of care	59
Prescribing issues	39
Alcohol/substance abuse	34
Action by out of state medical authority	25
Prescribing – CS	17
Sexual misconduct/boundary	13
Other unprofessional conduct	12
Modication of consent order	5
Conviction of felony	4
Med/physical condition	2
Medical records issues	2
Failure to cooperate with Board	2
False/deceptive representations	1

Thank you!

Questions?

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Toward Permissionless Innovation: Transitioning Pharmacy to "Standard of Care" Regulation

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Learning Objectives

- Differentiate "Scope of Practice" from "Clinical ability"
- Differentiate the regulatory approaches taken by the nursing and pharmacy professions
- Describe Idaho's approach to updating the following law categories:
  - Professional Practice Standards
  - Facility Standards

Scope of Practice	Clinical Ability
• The activities that a health professional is permitted to engage in as defined by state laws and regulations • Determined by the political process = geographical differences • One-size-fits all: applies to all professionals in class • Static (aside from law changes)	• The true competence and ability of the health professional • Determined by education, training, career experience, and practice environment • Individualistic: recognizes professional heterogeneity • Dynamic; advances with new education, technology, etc

Scope of Practice	Clinical Ability
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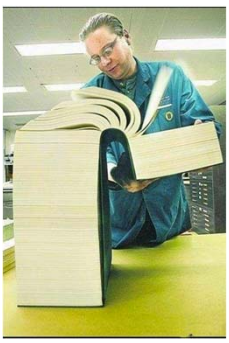

Pharmacy Practice Act and Rules


Medical Practice Act and Rules

External Market Forces

- Consumer acceptance and demand
- Payer policies
- Private accreditation and credentialing
- Facility policies (eg, risk mitigation)
- Liability insurance
- Civil / criminal law
- Professional ethics and self-restraint

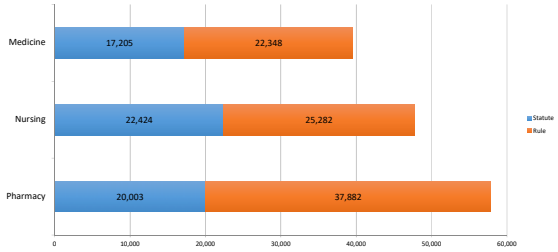
Assessment Question 1

1. The medical profession has specific state laws that delineate when sponges must be removed from the chest cavity following surgery.
   True or False?

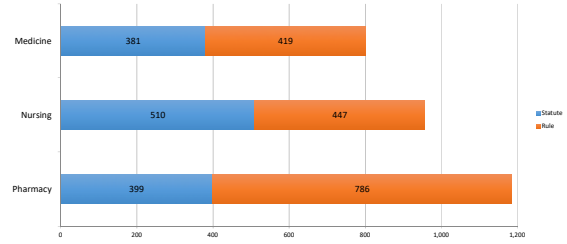
Learning Objectives

- Differentiate "Scope of Practice" from "Clinical ability"
- Differentiate the regulatory approaches taken by the nursing and pharmacy professions
- Describe Idaho's approach to updating the following law categories:
- Professional Practice Standards
- Facility Standards

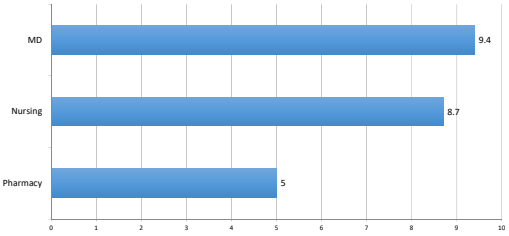
Regulatory Burden by Word Count

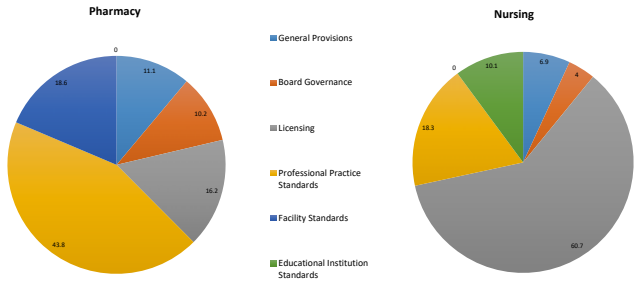


Regulatory Burden by "Restrictions"

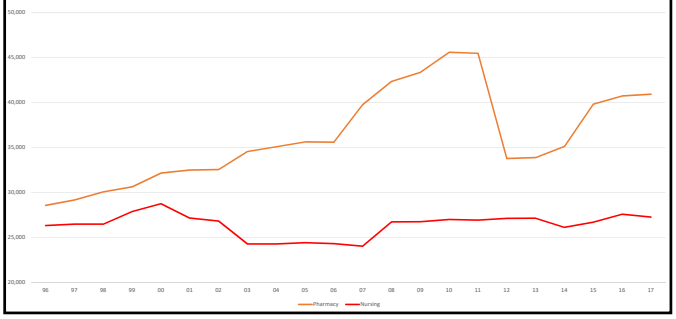


Average Age of Laws (in Years)

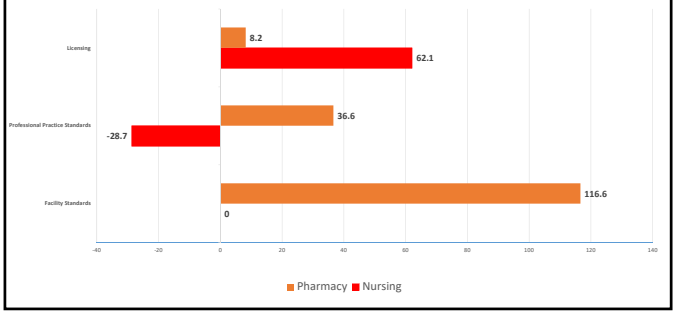




Total Word Count in Regulations from 1996 to 2017



Change in Word Count (By %) from 1996 to 2017



Two Different Approaches

Nursing	Pharmacy

• Stopped defining every individual task that each category of nursing could perform
• Transitioned to a "standard of care" approach
• Provided a decision-making model to identify if something is within a nurse's scope
	• Added new tasks:
	  • CPAs (388 words), vaccines (725), independent practice (130)
	  • Naloxone (312), epinephrine (896), tobacco cessation (267), TB skin testing (247)
	  • Technician delegation (1,184)
	• Added new facility types
	  • Telepharmacy (1,975 words)
	  • ADS (1,715)
	  • Centralized pharmacy services (682)

"Addition by Subtraction"	**"Compensated Addition"**

Learning Objectives

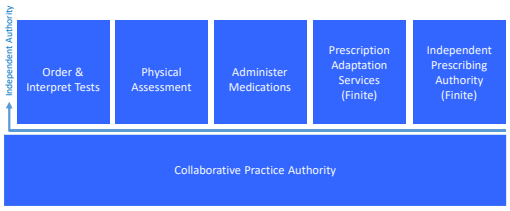
- Differentiate "Scope of Practice" from "Clinical ability"
- Differentiate the regulatory approaches taken by the nursing and pharmacy professions
- Describe Idaho's approach to updating the following law categories:
- Professional Practice Standards
- Facility Standards

Professional Practice Standards

General Approach (Rule 020)

- **Express Prohibition** – is the act expressly prohibited by state or federal law?
- **Education and Training** – is the act consistent with the licensee's education, training, experience?
- **Standard of Care** – is the act within an accepted standard of care that would be provided by a reasonable and prudent licensee with similar education, training, experience.

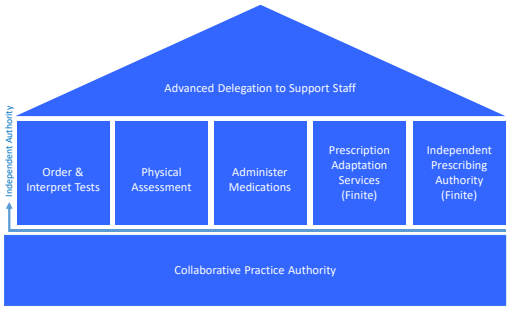
Professional Practice Standards



Prescription Adaptation Services

- Renewals
  - Continuation of Therapy: 30 day supply 1 time in 6 month period
- Changes
  - Therapeutic Substitution
  - Dispensing Quantity
  - Medication Synchronization
  - Formulation / Route
  - Complete Missing Information

Professional Practice Standards



Advanced Delegation

- Supervision
  - The function is performed under a pharmacist's supervision
- Education, Skill and Experience
  - The function is commensurate with the education, skill, and experience of the technician or pharmacist intern
- Professional Judgment Restriction
  - Any function that requires the use of a pharmacist's professional judgment may be performed by a pharmacist intern

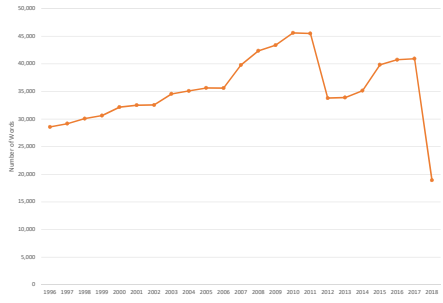
Facility Standards

- Leverage existing accountability mechanisms: theft/loss, errors, adulteration, misbranding, etc.
- Minimum Filling Requirements
  - Valid Prescription Drug Order
  - Prospective Drug Review
  - Labeling
  - Verification of Dispensing Accuracy
  - Patient Counseling
- Select exclusions (e.g., institutional setting) and augmenters (e.g., no pharmacist on site)
- Ability to move any step "off site"

Unprofessional Conduct

- The following acts or practices are declared to be unprofessional conduct and conduct contrary to the public interest:
- **"Standard of Care**. Providing health care services which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting."

Growth in BOP Rule Word Count



Assessment Question 2

1. Idaho law allows a pharmacist to perform:
   a. Only those acts that are expressly stated in its state laws
   b. Any act that is not expressly prohibited that is consistent with the education/training of the pharmacist and is consistent with a standard of care

Success Factors

- Kept the focus on public safety
- Strategic planning meetings aligned the Board around direction and framework before getting into the weeds
- Empowered staff to draft new rules and did not wordsmith in public meetings
- Started aggressively – "kidney filtration model" of deregulation
- Put the burden of proof on those advocating to add back in a regulation

Barriers to Reform

- General reticence
  - Fear of every conceivable "what if"; "bodies in the street"
  - Protectionist instincts masquerading as "safety" concerns
- Judging policy by your own personal interests
  - "I don't want to do [x]."
  - "I wouldn't trust my technicians to do [y]."
- Treating every issue as brand new and not learning from the experiences of other professions or jurisdictions

Assessment Questions

1. The medical profession has specific state laws that delineate when sponges must be removed from the chest cavity following surgery.
   True or False?
2. Idaho law allows a pharmacist to perform :
   a. Only those acts that are expressly stated in its state laws
   b. Any act that is not expressly prohibited that is consistent with the education/training of the pharmacist and is consistent with a standard of care

Thank You

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NABP
National Association of Boards of Pharmacy

Occupational Licensing Under Fire?

Federal and State Focus on License Necessity and Portability and the Role of NABP Programs

Josh Bolin, Associate Executive Director
National Association of Boards of Pharmacy® (NABP®)

Learning Objectives

- Identify state and federal legislative initiatives that could impact state boards of pharmacy and occupational licensing as a whole.
- Compare emerging license portability models among health care regulatory boards.
- Describe opportunities for the boards of pharmacy and NABP to enhance the existing Electronic Licensure Transfer Program® (e-LTP™) for pharmacists.

Self Assessment Question 1

California has the most occupational license types of any state in the nation. According to the National Conference of State Legislatures, as of 2017, they have:

a) 77
b) 177
c) 217

Self Assessment Question 2

What policy group is pushing for temporary licensure compacts in state legislatures?

a) National Governors Association
b) National Association of Boards of Pharmacy
c) Western Governors Association

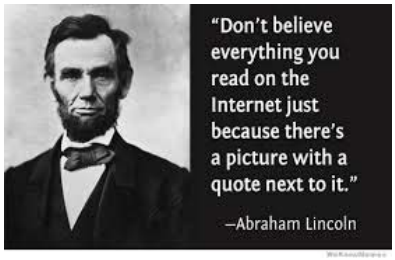
Self Assessment Question 3

True or False: NABP has processed the transfer of more than 150,000 pharmacists' licenses over the past 10 years.

Current Narrative on Occupational Licensing

- Increase economic opportunity by reducing occupational licensing requirements
- Too many occupational licenses – 177 in California
- False equivalence – no differentiation between regulation of florists and pharmacists
- "Cartels"

#FakeNews



Federal Activities

- United States Department of Labor Grant
  - Barriers to entry into the workforce
  - Military
  - Disenfranchised populations
  - Portability
- Federal Trade Commission
  - Economic Liberty Task Force
  - Roundtable discussions – license portability and data

Federal Activities

- *HR 3446: Restoring Board Immunity Act*
  - Introduced 9/6/2017
  - Incentivizes occupational licensing *regimes* to make necessary changes for active state supervision
- House Committee on Education and the Workforce Hearing
  - Hearing held on June 20, 2018
- HR 6515
  - Introduced 7/25/2018
  - Limits private antitrust damages against occupational licensing boards

State Activities

- Executive orders
  - Arkansas, Massachusetts, and Oklahoma
- Legislation to clarify state oversight
  - Legislation passed in 2018
    - Louisiana: HB 372
    - Nebraska: LB 299
    - Oklahoma: SB 1475 and HB 2311
- Western Governors Association – pushing interstate compacts for temporary licensure
  - Legislation introduced in Arizona, Missouri, New Hampshire, and South Dakota
    - 18-month temporary licensure with active license in good standing in another state
    - No state jurisprudence exam requirement (MPJE)
    - None of the bills passed in 2018 sessions

What Should Boards of Pharmacy Do?

What Should Boards of Pharmacy Do?

- Active state supervision
  - Review of new and existing regulations with public health protection lens
    - Regulatory sunset and readoption processes
    - Legislative review process for new regulations
- Look for areas of friction in licensing processes – **before** you are told to do so
- Be prepared to give the complete and accurate picture of how pharmacy is regulated in your state

Nursing Licensure Compact (NLC) Enhanced NLC (eNLC)

- Established in 2000, enhanced in 2017
- ~30 states enacted
- In person/telehealth practice
- No additional state license issued beyond home state

Interstate Medical Licensure Compact

- Enacted in 2017
- 24 states and one territory
- State licenses issued
- Managed by a Commission

Psychology Interjurisdictional Compact

- 6 states enacted (needs 7 to become operational)
- Allows practice of telepsychology; or temporary licensure for in person practice while obtaining full licensure

e-LTP Today: By the Numbers

- NABP was founded to solve the reciprocity riddle
- Available in all 54 states/jurisdictions
- Processing time down to a single business day
- 164,500 pharmacists' licenses transferred over the last 10 years

Resolution at 114th Annual Meeting: *Cooperative Interstate Registration System*

Tasks NABP with exploring the development of an interstate registration system "to provide for pharmacists' participation in interstate dispensing models while maintaining boards of pharmacy jurisdiction to initiate possible administrative proceedings to protect the public health."

Enhancing e-LTP

- Potential areas to explore:
  - Remote practice
  - Telepharmacy
  - Temporary licensure
- Exploration must account for:
  - State sovereignty and control
  - Mitigate financial impacts on states

What's Next?

- Task Force on Mutual Recognition of Licensure: September 11-12, 2018

Is Occupational Licensing Under Fire?

- Yes, but boards should:
  - Keep calm
  - Be prepared
  - Practice smart regulation

Self Assessment Question 1

California has the most occupational license types of any state in the nation. According to the National Conference of State Legislatures, as of 2017, they have:

a) 77
b) 177
c) 217

Self Assessment Question 2

What policy group is pushing for temporary licensure compacts in state legislatures?

a) National Governors Association
b) National Association of Boards of Pharmacy
c) Western Governors Association

Self Assessment Question 3

True or False: NABP has processed the transfer of more than 150,000 pharmacists' licenses over the past 10 years.

True

Licensure Compacts as a Means of Facilitating Interstate Portability: The Physical Therapy Experience

National Association of Boards of Pharmacy – District III Meeting
August 13, 2018

Kathy O. Arney, PT, MA, Executive Director
NC Board of Physical Therapy Examiners

Physical Therapy Compact

Increasing Consumer Access, Interstate Mobility, and Cross-State Practice

Objectives

- Provide an overview of the development Physical Therapy Licensure Compact (PTLC) as an enhancement of public protection
- Describe the purpose of the Physical Therapy Licensure Compact (PTLC)
- Identify the benefits of the PTLC to primary stakeholders
- NC Implementation of the PTLC – Discuss implementation challenges and successes

Acknowledgment and Disclaimer

Physical Therapy Licensure Compact - Purpose

- Facilitate interstate practice of physical therapy with the goal of improving public access to physical therapy services

Is the Portability of Healthcare Workers a regulatory/public protection issue?

1. Purpose statement of the compact
2. The FSBPT membership
3. The Federal Government
4. Public policy groups and private entities
5. Other regulatory professions
6. Other countries

Identified Ways the Compact will Potentially Increase Access

- Consumers living near state borders and underserved areas
- Utilization of telehealth technologies
- Access to Specialists
- Cross Board delivery models – Medical Homes, Accountable Care Organizations
- Traveling therapists
- Traveling groups: Teams and Performers
- Disasters
- Military spouses

Other options to achieve the same objectives?

FSBPT

- 2012 Licensure Portability paper
  - Credentials verification
  - Review and evaluate licensure requirements/exemptions
  - Alternative models such as limited reciprocity agreements
  - Limited Compacts
- Licensure Portability Resource Guide – 2013 (in addition to above jurisdictions should:)
  - Furnish and allow electronic licensure verifications

Other options to achieve the same objectives? (cont.)

FSBPT

- Licensure Portability Resource Guide – 2013 (in addition to the previous slide) Jurisdictions should:
  - Furnish and allow electronic licensure verifications
  - Change any state practice act language with specific exam score requirements to more general language
  - Fully participate in the Exam, Licensure, Disciplinary Database
  - Utilize the national continuing competence requirement tracker
  - Utilize ProCert approved courses to increase uniform standards for CE
  - Support a Common Licensure Application Service and credential verification service

Physical Therapy Licensure Compact - Purpose

Practice of physical therapy
- Occurs in state where patient is located
- Follows the scope of practice of state where patient is located

Preserves
- State's regulatory authority to protect public health & safety through current system of state licensure

Supports
- Spouses of relocated military members

Enhances
- Exchange of licensure, investigatory, and disciplinary information between member states

Compact Benefits for the Public

- Improve continuity of care
- Improve portability for military spouses
- Improve access to physical therapy providers
- Increase choice of physical therapy providers
- Eye to the future
  - New health care delivery models
  - International access to care
  - Alternate physical therapy delivery methods…Telehealth?

Compact Benefits for Jurisdictions

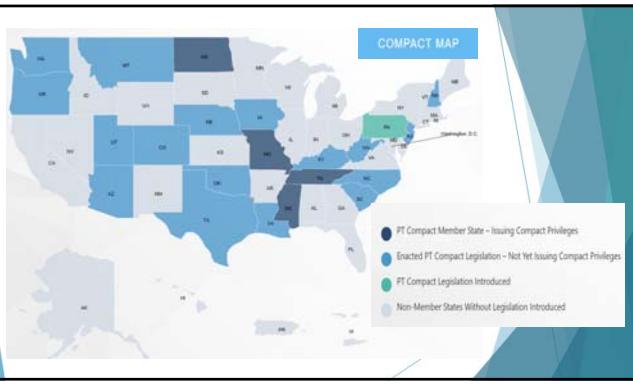
- Preserves the current state-based licensure system
- Full participation in the Exam, Licensure, and Disciplinary Database (ELDD)
- Requires criminal background checks for applicants for initial licensure
- Requires continuing competence
- Allows sharing of investigatory information
- Demonstrates PT regulators responsiveness to issues
  - E.g.: portability

Steps in Compact Development

- 2010
  - Motion to Explore a Compact
- 2011
  - Request a Study
- 2012
  - Report
  - Motion to Recommend Tools
- 2013
  - Resource Guide
  - Motion to Support Compact
- 2014
  - Advisory Task Force Recommends Development of a Compact

Steps in Compact Development (cont.)

- 2015 – 2017
  - Compact Drafting Team
- 2017
  - March, 2017 - Oregon - first state to adopt the PT Compact
  - April 25, 2017 – 10th State adopts Compact – Compact Officially enacted
  - June 14, 2017 – PTLC holds first Commission Meeting; elects Officers
  - July – October, 2017 Rules and Bylaw Drafted, Exec Board Meeting, Administrative Entity created and staff hired
  - November 5, 2017 – First Annual meeting of the Compact Commission
- 2018
  - First Compact Privileges Issued



Key Provisions of PT Compact

- Compact Privilege – Different than a license. Compact Privilege is purchased for each desired state.
- Eligibility Requirements – Licensees must meet and maintain all requirements to obtain and keep Compact Privileges.
- Home State – defined as the licensees primary state of residence. Licensee must have active license in his/her home state. Home state's requirements and disciplinary authority unchanged for licensee.

Key Provisions of PT Compact cont.

- Remote State – Remote states have authority to take action against a Compact Privilege.
- Disciplinary Actions - All adverse actions and disciplinary actions will be reported regularly to Commission and shared with member states including availability of investigatory information.
- Continuing Competence Required (for those states that did not previously require it)
- FBI Criminal Background Checks Required on initial licensure decisions

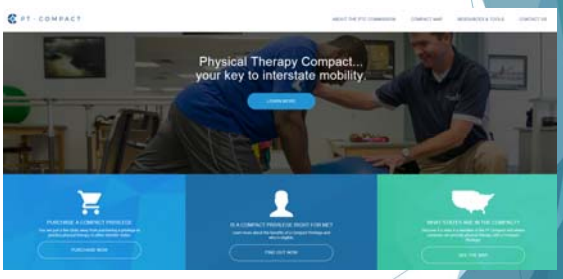
Lessons from North Carolina – Legislative Process

- Would this enhance the public protection mission of the NCBPTE?
- Is the state chapter of the national PT association in agreement with the concept?
- Advocacy team
  - State Association
  - State Association Lobbyist
  - Information provided by NCBPTE – it's a regulatory bill
- Bill sponsors
- Provide Information as requested by legislators and Legislative Research division

Lessons from North Carolina - Implementation

- Criminal Background Checks
- Unique Identifier
- Data sharing with the Commission
- Public Protection via Privilege Holder "look up" in NCBPTE database
- Are Rules other than Compact Rules needed?
- Jurisprudence Exercise for privilege holders

PTCompact.org Informational Site



Want More Information?

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Executive Director
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919-490-6393

References

- www.fsbpt.org
  - http://www.fsbpt.org/FreeResources/RegulatoryResources/LicensurePortabilityResourceGuide.aspx
- ptcompact.org

The Opioid Crisis in the United States: How bad science and a great marketing campaign got us into this mess.

8/14/18
Campbell University
Asheville, NC

BLAKE FAGAN, MD

Don Teater, MD, MPH
Teater Health Solutions

Meridian Behavioral Health Services
Waynesville, NC

Blake Fagan, MD
Chief Education Officer, MAHEC

- I have no disclosures.
- Everything I present is evidence-based.
- If I give an opinion, I will note that it is my opinion based on the evidence I have reviewed.

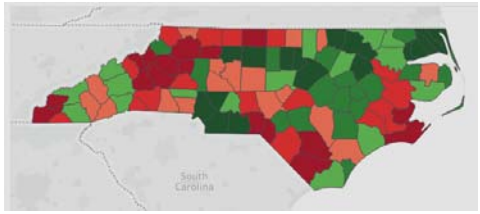
254,000[81]

Number of deaths in the last 10 years from opioids.

More than 4 times the number of American deaths in the Vietnam War[2]

This is an epidemic. And providers are the vector!

Opioid Prescribing Rates by County in North Carolina[2]



Confession

Goals

1) Describe the impact of the opioid crisis.

2) Describe the (bad) science behind the way providers have prescribed opioids.

3) Describe what providers are/should be doing now.

4) How you can help.

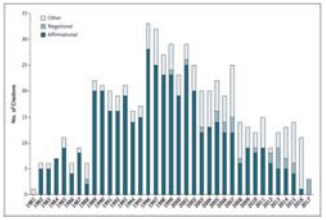
Opioid Facts

The U.S. accounts for 4% of the world's population. We consume 80% of the world's opioids.

83% of the world's population has no access to any opioids.[9]

95% of the Vicodin is dispensed in the USA.[120]

NEJM Letter Misrepresented Risk of Opioid Addiction Has Been Heavily Cited



122

Porter and Jick Article

Heavily cited by pain specialists, nurses, and pharmaceutical representatives, using the letter to support the statistic that "less than 1% of opioid users become addicted to the drugs."[123]

72% use as evidence of lack of addiction.

80% fail to note that this was inpatient use and misrepresent findings.[121]

Sharp uptick after Oxycontin in 1995.

"This one-paragraph letter may have launched the opioid epidemic."

by Harrison Jacobs, Business Insider, May 26, 2016

122

Portenoy Article

"In 1996, the American Pain Society and the American Academy of Pain Management issued a 'landmark consensus,' written in part by Portenoy, saying that there is little risk of addiction or overdose in pain patients." Harrison Jacobs, Business Insider, May 26, 2016

Portenoy later admitted to using the Porter and Jick letter to encourage more liberal prescribing of opioids: "None of [the papers] represented real evidence, and yet what I was trying to do was to create a narrative . . . because the primary goal was to destigmatize [opioids], we often left evidence behind."

—Dr. Russell Portenoy in *Opioids for Chronic Pain: Addiction is NOT Rare*

123

Pain is the Fifth Vital Sign

In 1996 the American Pain Society trademarked "Pain as the 5th Vital Sign" – implying that practitioners were bad at both recognizing and treating pain.

2001 – JCAHO issues new standards telling hospitals to regularly ask about pain and make treating it a priority.

2001 – JCAHO published guide sponsored by Purdue Pharma: some clinicians have inaccurate and exaggerated concerns about addiction, tolerance, and risk of death, stating that this attitude stands even though there is no evidence that opioids for pain control increase risk for addiction.[125]

Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015[27]

FIGURE 1. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of days' supply* of the first opioid prescription — United States, 2006–2015[27]

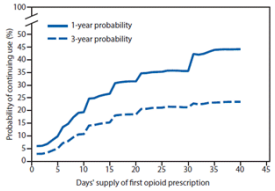
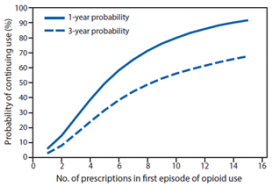


FIGURE 2. One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of prescriptions* in the first episode of opioid use — United States, 2006–2015[27]



What We Know (and Don't Know)

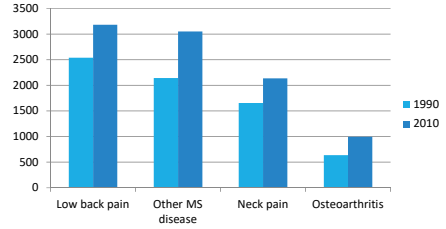
- Everything that we know has been programmed by the pharmaceutical industry… (my opinion)
- Science rarely guides our current treatment of pain. (Fact)

The Center for Public Integrity:

https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis

The State of US Health[16]

Years lived with disability (in thousands)

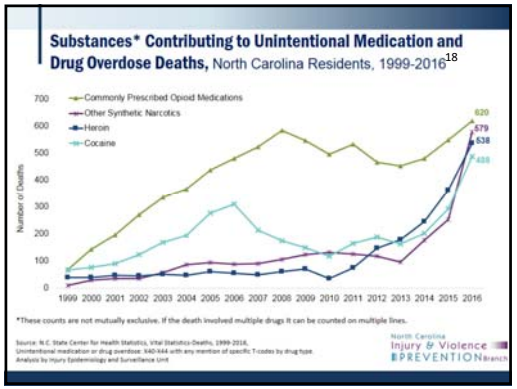


Efficacy of Opioids for Chronic Pain[43]

Annals of Internal Medicine

Martell et al. (2007): Systemic Review: Opioid treatment for chronic back pain: prevalence efficacy and association with addiction

- 4 studies indicated that opioids did not show reduced chronic back pain when compared with placebo or non-opioid control
- Prevalence of life time substance use disorders ranged from 36% to 56%
- Prevalence of current substance use disorders were estimated to be as high as 43%



Opioid Receptors

Enable us to achieve a goal (short term).[23,24]

- Decrease pain
- Increase motivation
- Increase confidence
- Increase reward
- Reduce depression and anxiety
- Increase pleasure in current activity
- Increase "warmth-liking"[29]
  - Liking warm things
  - Love
  - Interpersonal bonding

Safe Opioid Prescribing

NC STOP Act

Went into effect January 1st, 2018

If you prescribe opioids for acute pain, initial prescription must be 5 days or less

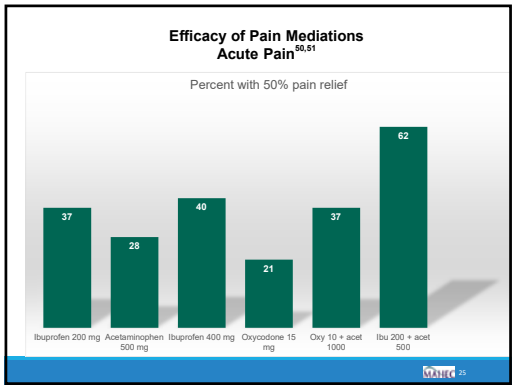
For post-op pain, 7 days or less

Must look patient up in the NC CSRS and document in your chart that you did look them up (Delayed)

CDC Guideline for Chronic Pain

In general, DO NOT prescribe opioids as the first-line treatment for chronic pain

1) Assess pain and function
2) Consider if non-opioid therapies are appropriate
3) Talk to patients about treatment plan
4) Evaluate risk of harm or misuse



Oral Opioid vs. Non-opioid Analgesics in ED

Chang et al. (2017)

- Randomized control trial in the emergency department for patients with acute strains, sprains, and fractures
- Tylenol 1000 mg and ibuprofen 400 mg were found to be equivalent to opioids at treating acute pain[52]

2005 Cochrane Review

- NSAID medications and opioids have equal effectiveness in treatment of acute renal colic…
- But opioids have more side effects.[53]

Post-Op Pain Studies

- UNC – CH hand surgeon[55]
- Dartmouth Study[56]
- Enhanced recovery after surgery (ERAS): Lower MME, more ambulation, fewer complications, better satisfaction
- Opioids increase the risk of post-op wound infections[37]
- Increase falls
  - Geriatrics[58]
  - Pediatrics[59]
- The longer one is on opioids the greater the risk of being on permanent disability[60]

Why MAT

- The use of the opioid agonists methadone and buprenorphine reduces:
  - Overdose[116]
  - Illicit drug use[117]
  - Transmission of infectious diseases[117]
- Every $1 invested in returns a yield of $4 - $7 in reducing drug-related crimes, criminal justice, and theft[118]
- Those receiving treatment are 75% less likely to die due to their addiction than those not receiving medication[119]
- Treatment is less expensive than alternatives
  - Full year of methadone = $4,700 per person on average
  - Full year of imprisonment = $18,400 per person on average

Summary: So I hope you can

1) Describe the impact of the opioid crisis

2) Describe the (bad) science behind the way providers have prescribed opioids

3) Describe what providers are/should be doing now

4) Explain how you can help with this crisis

References:

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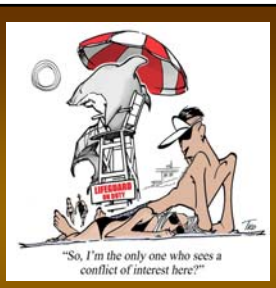
NCBOP Opioid Crisis Outreach Efforts

Jay Campbell, Executive Director
North Carolina Board of Pharmacy



I have no relationships with commercial interests related to the content of my presentation.

L. Stanley Haywood Recovery Fund

- Honors Stan Haywood, long-time Board member who passed away on May 22, 2018.

L. Stanley Haywood Recovery Fund

- $1.1 million endowment.
- Assist qualifying pharmacists and pharmacy personnel to access substance use disorder assessment, treatment, and monitoring services.
- Administered by North Carolina Physicians Health Program (www.ncphp.org)

Opioid Public Service Announcement Campaign

- Beginning February 8, 2018, the Board of Pharmacy opened an opioid public service announcement campaign on Wilmington and Greenville-area television stations and on social media platforms.
- PSAs feature Joe Adams, a pharmacist and past president of the National Association of Boards of Pharmacy, sharing his deeply personal story of losing his son to an opioid overdose in 2014. These ads emphasize the important of obtaining help and the critical role pharmacists can play.

Opioid Public Service Announcement Campaign

- The ads come in 30-second, 60-second, and 6-minute versions, and are available for download on the Board website.
- Board members and staff welcome and encourage pharmacists using these ads to educate their patients and communities about proper medication use and the dangers of opioid abuse.

Questions?

Innovative Board Approaches to the Opioid Crisis

Brenda McCrady, PD
&
John Clay Kirtley, PharmD
Arkansas State Board of Pharmacy

1

Disclosures and Objectives

- We do not have any financial interests or other disclosures of conflict for this program.

Objectives

- Explore the need for and delivery of interprofessional summits to discuss and educate on drug abuse issues facing our communities.

2

Background

- Drug overdose is now the leading cause of injury death in the United States.
- Opioid analgesics, such as ***prescription painkillers***, account for about 80 percent of those deaths.
- Overdose rates have increased five-fold since 1990.

3

Power in Videos

Hey Charlie: https://youtu.be/qWqafUoBAJc

Vimeo link: https://vimeo.com/stopthespiral/heycharlie

Stop the Spiral website: https://www.stopthespiral.com/

5

More Videos

Governor Hutchinson PSA
https://www.dropbox.com/s/5gy94wnad4k27gb/180326_Drug%20Take%20Back%20PSA%20v5.mp4?dl=0

Jonesboro Out of the Dark!
https://youtu.be/rsZ3psDPWe8

Let's Talk Jonesboro Interview
https://www.youtube.com/watch?v=xxJfBkH_sxo&feature=youtu.be

US Surgeon General
https://www.youtube.com/watch?v=W9Ndw8AsgMs&feature=youtu.be

Columbus Police
https://www.10tv.com/article/body-cam-footage-shows-columbus-police-officer-receiving-narcan-during-drug-arrest

6

DRUG TRENDS OVER THE DECADES

…Our Economy

$78.5 billion

Cost of prescription opioid dependence, abuse, and overdose in the United States in 2013

25%

Percentage of worker's compensation prescription drug claims that were for opioids in 2011

Question

- What is the value of prescription opioids (hydrocodone, oxycodone) on the street?
  - Penny per mg
  - Dime per mg
  - Quarter per mg
  - Dollar per mg

9

What you do not know can kill you!

Do The Math

One kilogram = 1,000,000 milligrams X $10 each = **$10,000,000**

One ounce = 28,349.5 milligrams X $10 each = **$283,495**

One gram = 1,000 milligrams X $10 each = **$10,000**

TO

The initial Investment of 1 kilogram of Fentanyl (analog) cost $1,700 to $3,500 each

10

AMA Sees Progress in Declining Opioid Prescriptions, Urges Continued Focus on Evidence-Based Treatment

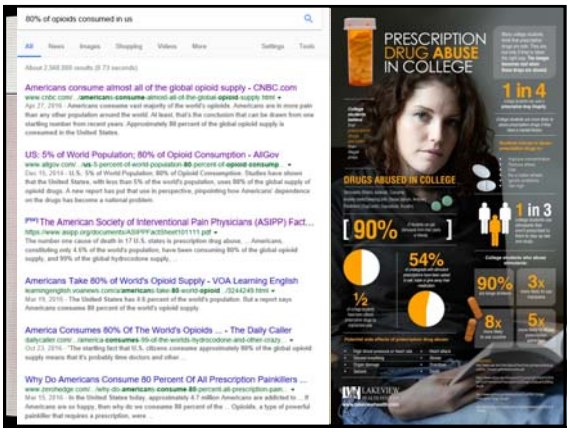
"A 22-percent decrease in opioid prescriptions nationally between 2013 and 2017 reflects the fact that physicians and other health care professionals are increasingly judicious when prescribing opioids. It is notable that every state has experienced a decrease, but this is tempered by the fact that deaths related to heroin and illicit fentanyl are increasing at a staggering rate, and deaths related to prescription opioids also continue to rise…"

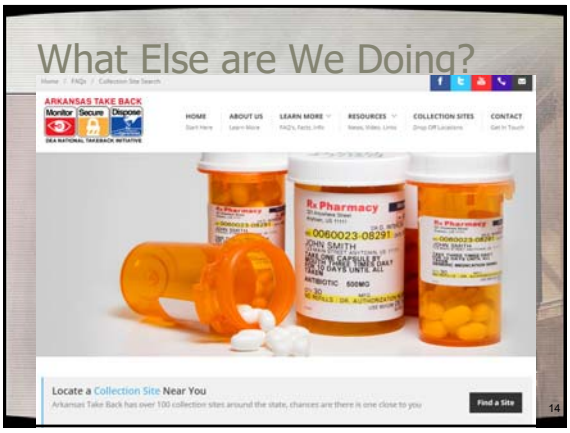
- Patrice A. Harris, MD, MA, chair of the AMA Opioid Task Force

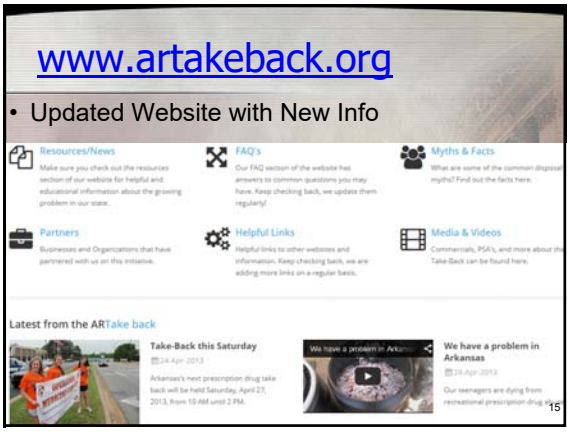
11

U.S. State Opioid Prescribing Rates 2016 per 100 People

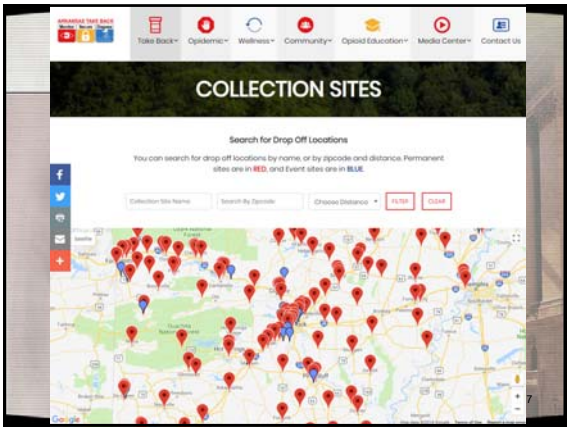
Alabama	121	Illinois	56.8	Montana	69.8	Rhode Island	60.3
Alaska	58.9	Indiana	83.9	Nebraska	62.8	South Carolina	89.4
Arizona	70.2	Iowa	64	Nevada	80.7	South Dakota	54.8
Arkansas	114.6	Kansas	76.9	New Hampshire	64.3	Tennessee	107.5
California	44.8	Kentucky	97.2	New Jersey	52.6	Texas	57.6
Colorado	59.8	Louisiana	98.1	New Mexico	65.1	Utah	70.4
Connecticut	55.9	Maine	66.9	New York	42.7	Vermont	58.6
Delaware	79.2	Maryland	58.7	North Carolina	82.5	Virginia	63.4
District of Columbia	32.5	Massachusetts	47.1	North Dakota	47.8	Washington	64.9
Florida	66.6	Michigan	84.9	Ohio	75.3	West Virginia	96
Georgia	77.8	Minnesota	46.9	Oklahoma	97.9	Wisconsin	62.2
Hawaii	41.9	Mississippi	105.6	Oregon	76.3	Wyoming	71.1
Idaho	77.6	Missouri	80.4	Pennsylvania	69.5		


80% of opioids consumed in us
PRESCRIPTION DRUG ABUSE IN COLLEGE
1 in 4
DRUGS ABUSED IN COLLEGE
1 in 3
[90%]
54%
90%
3x
8x
5x
Americans consume almost all of the global opioid supply - CNBC.com
US: 5% of World Population; 80% of Opioid Consumption - AllGov
The American Society of Interventional Pain Physicians (ASIPP) Fact...
Americans Take 80% of World's Opioid Supply - VOA Learning English
America Consumes 80% Of The World's Opioids ... - The Daily Caller
Why Do Americans Consume 80 Percent Of All Prescription Painkillers ...


What Else are We Doing?
ARKANSAS TAKE BACK
Monitor Secure Dispose
DEA NATIONAL TAKEBACK INITIATIVE
HOME
ABOUT US
LEARN MORE
RESOURCES
COLLECTION SITES
CONTACT
Rx Pharmacy
JOHN SMITH
ANTIBIOTIC 500MG
Locate a Collection Site Near You
Arkansas Take Back has over 100 collection sites around the state, chances are there is one close to you
Find a Site
14


www.artakeback.org
• Updated Website with New Info
Resources/News
Make sure you check out the resources section of our website for helpful and educational information about the growing problem in our state.
FAQ's
Our FAQ section of the website has answers to common questions you may have. Keep checking back, we update them regularly!
Myths & Facts
What are some of the common disposal myths? Find out the facts here.
Partners
Businesses and Organizations that have partnered with us on this initiative.
Helpful Links
Helpful links to other websites and information. Keep checking back, we are adding more links on a regular basis.
Media & Videos
Commercials, PSA's, and more about the Take Back can be found here.
Latest from the ARTake back
Take-Back this Saturday
Arkansas's next prescription drug take back will be held Saturday, April 27, 2013, from 10 AM until 2 PM.
We have a problem in Arkansas
Our teenagers are dying from recreational prescription drug
15

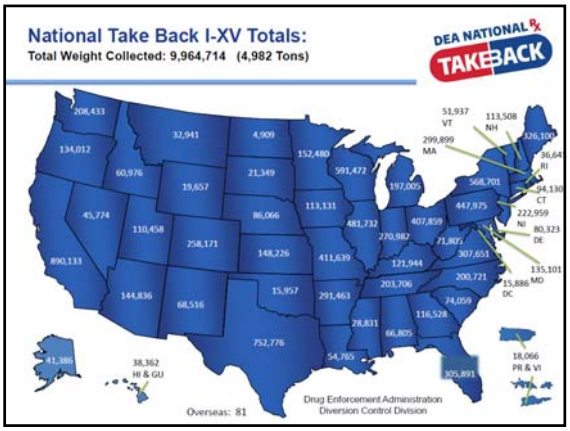

Monitor, Secure and Dispose
Patients should
• Know what they are taking and how much they have
• Secure their prescription medications
• Properly dispose of prescription drugs
– www.smarxtdisposal.net
– www.ioit2me.com
– www.artakeback.org
16


Take Back
Epidemic
Wellness
Community
Opioid Education
Media Center
Contact Us
COLLECTION SITES
Search for Drop Off Locations
You can search for drop off locations by name, or by zipcode and distance. Permanent sites are in RED, and Event sites are in BLUE.
FILTER
CLEAR
Google
7

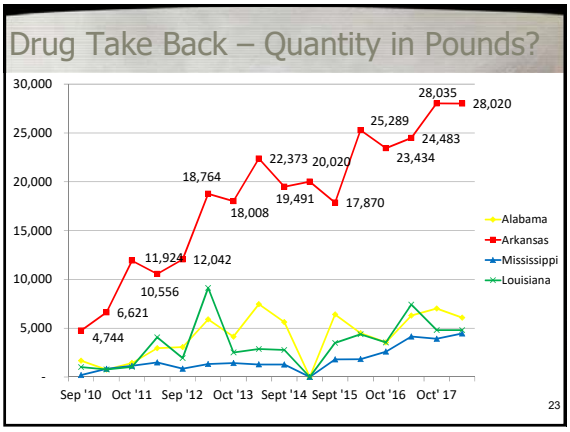

15th National Take Back Day: April 28, 2018
Total Law Enforcement Participation: 4,683
DEA NATIONAL Rx TAKEBACK
63
52
31
10
192
61
18
18
4
84
303
18
35
63
84
88
168
164
171
82
212
217
69
141
77
155
86
49
58
53
57
57
23
170
54
60
302
11
2 HI & Guam
121
29 PR & VI
34 VT
120 NH
130
157 MA
32 RI
20 CT
186 NJ
22 DE
1 DC
46 MD
*American Indian and Alaskan Native Communities: 80 Partners
Drug Enforcement Administration
Diversion Control Division


15th National Take Back Day: April 28, 2018
Total Collection Sites: 5,842
DEA NATIONAL Rx TAKEBACK
Drug Enforcement Administration
Diversion Control Division
*American Indian and Alaskan Native Communities: 142 sites


15th National Take Back Day: April 28, 2018
Total Weight Collected: 949,046 lbs. (474.5 Tons)
DEA NATIONAL Rx TAKEBACK
Drug Enforcement Administration
Diversion Control Division
*American Indian and Alaskan Native Communities: 2,270 lbs.


National Take Back I-XV Totals:
Total Weight Collected: 9,964,714 (4,982 Tons)
DEA NATIONAL Rx TAKEBACK
Drug Enforcement Administration
Diversion Control Division
Overseas: 81


Take BACK
October 2017 Take BACK
28,035 Pounds
APRIL 2018 Take BACK
28,020 Pounds
22


Drug Take Back – Quantity in Pounds?
30,000
25,000
20,000
15,000
10,000
5,000
-
4,744
6,621
10,556
11,924
12,042
18,764
18,008
22,373
19,491
20,020
17,870
25,289
23,434
24,483
28,035
28,020
Sep '10
Oct '11
Sep '12
Oct '13
Sept '14
Sept '15
Oct '16
Oct' 17
Alabama
Arkansas
Mississippi
Louisiana
23

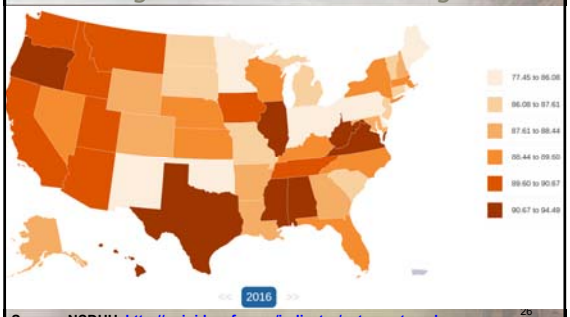

What is Next? Labels Save Lives
Burlington Drug Company
HealthWise
artakeback.org
PROTECT OUR CHILDREN.
DISPOSE OF YOUR MEDS SAFELY.
October 27, 2018
Drug Takeback Day
24

→ Prescription Drug Summit

- Medication Assisted Treatment
- Re-education of prescribers
- Opioid guidelines
- Opioid limitations
- Review of published studies
- Drug Takeback Initiatives

25

Percent population needing but not receiving treatment for illicit drug use



Source: NSDUH, http://opioid.amfar.org/indicator/pctunmetneed

26

Tiger Woods case underscores role of drugs in driver impairment

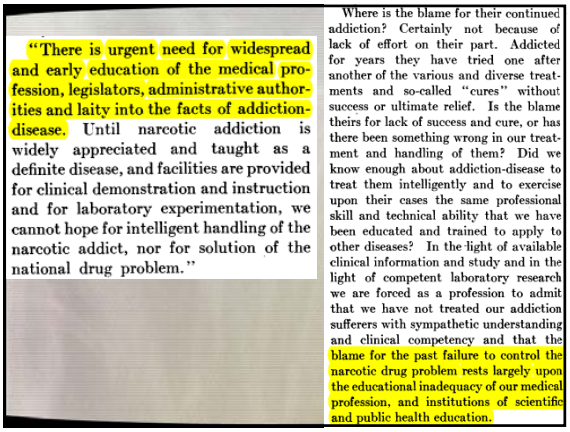
By Susan Perry | 05/31/17

The arrest of the 41-year-old golf great Tiger Woods near his Florida home on Monday for driving under the influence underscores the growing role that drugs — prescription and otherwise — are playing in motor vehicle crashes.

According to media reports, Woods was arrested after police officers found him sleeping in his car with the engine running. His speech was slurred, and he failed roadside sobriety tests. Yet he registered zero on a breathalyzer test, indicating he hadn't been drinking alcohol.

Instead, as a contrite Woods explained in a statement released to the press later that evening, his behavior had been caused by prescription medications.

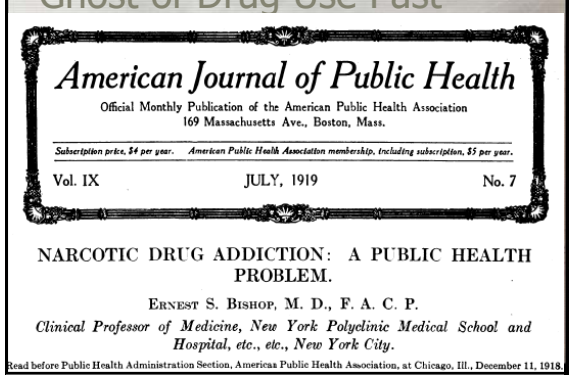
"I want the public to know that alcohol was not involved," he said in the statement. "What happened was an unexpected reaction to prescribed medications. I didn't realize the mix



"There is urgent need for widespread and early education of the medical profession, legislators, administrative authorities and laity into the facts of addiction-disease. Until narcotic addiction is widely appreciated and taught as a definite disease, and facilities are provided for clinical demonstration and instruction and for laboratory experimentation, we cannot hope for intelligent handling of the narcotic addict, nor for solution of the national drug problem."

Where is the blame for their continued addiction? Certainly not because of lack of effort on their part. Addicted for years they have tried one after another of the various and diverse treatments and so-called "cures" without success or ultimate relief. Is the blame theirs for lack of success and cure, or has there been something wrong in our treatment and handling of them? Did we know enough about addiction-disease to treat them intelligently and to exercise upon their cases the same professional skill and technical ability that we have been educated and trained to apply to other diseases? In the light of available clinical information and study and in the light of competent laboratory research we are forced as a profession to admit that we have not treated our addiction sufferers with sympathetic understanding and clinical competency and that the blame for the past failure to control the narcotic drug problem rests largely upon the educational inadequacy of our medical profession, and institutions of scientific and public health education.

Ghost of Drug Use Past



American Journal of Public Health

Official Monthly Publication of the American Public Health Association
169 Massachusetts Ave., Boston, Mass.

Subscription price, $4 per year. *American Public Health Association membership, including subscription, $5 per year.*

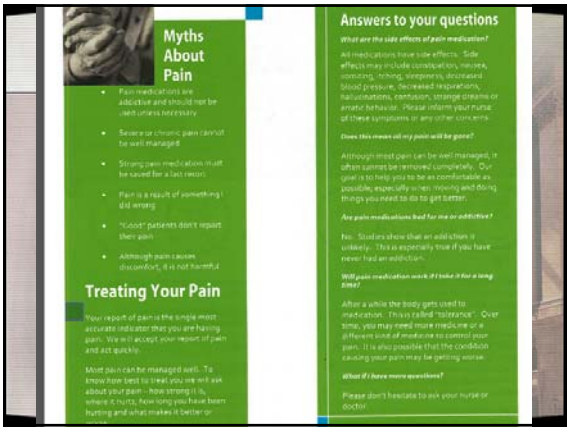
Vol. IX JULY, 1919 No. 7

NARCOTIC DRUG ADDICTION: A PUBLIC HEALTH PROBLEM.

ERNEST S. BISHOP, M. D., F. A. C. P.

Clinical Professor of Medicine, New York Polyclinic Medical School and Hospital, etc., etc., New York City.

Read before Public Health Administration Section, American Public Health Association, at Chicago, Ill., December 11, 1918.



Myths About Pain

- Pain medications are addictive and should not be used unless necessary.
- Severe or chronic pain cannot be well managed.
- Strong pain medication must be saved for a last resort.
- Pain is a result of something I did wrong.
- "Good" patients don't report their pain.
- Although pain causes discomfort, it is not harmful.

Treating Your Pain

Your report of pain is the single most accurate indicator that you are having pain. We will accept your report of pain and act quickly.

Most pain can be managed well. To know how best to treat you, we will ask about your pain – how strong it is, where it hurts, how long you have been hurting and what makes it better or

Answers to your questions

What are the side effects of pain medication?

All medications have side effects. Side effects may include constipation, nausea, vomiting, itching, sleepiness, decreased blood pressure, decreased respirations, hallucinations, confusion, strange dreams or erratic behavior. Please inform your nurse of these symptoms or any other concerns.

Does this mean all my pain will be gone?

Although most pain can be well managed, it often cannot be removed completely. Our goal is to help you to be as comfortable as possible, especially when moving and doing things you need to do to get better.

Are pain medications bad for me or addictive?

No. Studies show that an addiction is unlikely. This is especially true if you have never had an addiction.

Will pain medication work if I take it for a long time?

After a while the body gets used to medication. This is called "tolerance". Over time, you may need more medicine or a different kind of medicine to control your pain. It is also possible that the condition causing your pain may be getting worse.

What if I have more questions?

Please don't hesitate to ask your nurse or doctor.

Programming

- Whole Group Plenary Presentations
- Break-out Tracks
  - Clinical Track
    - CE for Pharmacists, Prescribers, Nurses…
  - Criminal Justice Track
    - Law enforcement only at times
  - Education/Prevention Track
  - Counseling/Recovery Track

31

What does it take?

- Partnerships – Who is available and interested
- Audience – Who is targeted for attendance
- Expertise
- Money

33

Partnerships

34

Partnerships

- State Drug Director or Senior Drug Policy Person from Governor
- Board of Pharmacy and Other Health Licensure Boards
- Criminal Justice Institute
- Attorney General's Office

35

Audience

- Healthcare Professionals
  - Pharmacy folks are the largest group
  - Nursing licensees are second
  - Doctors very small turnout
- Law Enforcement Officers
- Social Workers / Counselors
- Prevention
- What about Attorneys, Judges, Elected Officials

36

Expertise

- Local Efforts and National Trends/Issues
- SAMHSA – MAT the Right Way
  - ARImpact – CE for Health professionals delivered Wednesdays at lunch via web
- State Grants for Naloxone and Training
- "Parent Panel"
  - Stories of Hope from Tragedy

37

Money

- $5,000 each from Pharmacy Board, Medical Board and Nursing Board
- $1,000 from NABP Foundation
- $4k-10k Prevention Money from Dept of Health and State Drug Director's Office
- Attorney General's Office picking up the tab
- Total could be up to $70,000 but all depends on costs and quantities

38

Costs

- Speaker Travel and possible honoraria
  - Local Expertise is generally free!
- Location ?
- Program Printing and Supplies
- FOOD IS THE MOST EXPENSIVE PART
  - Food Truck Festival for the day would be my idea but you either feed folks with a keynote lunch or send them out hoping to get them back

39

- Please plan to attend the **2018 Arkansas Prescription Drug Abuse Prevention Summit on November 1, 2018** at the Hot Springs Convention Center.
- We will offer four breakout tracks: **Clinical**, Criminal Justice, Education/Prevention and Counseling/Recovery.
- Early bird registration is open! Reserve your seat now as space is limited.
- https://arkansasag.eventsmart.com/

40

Answers → Future Impact

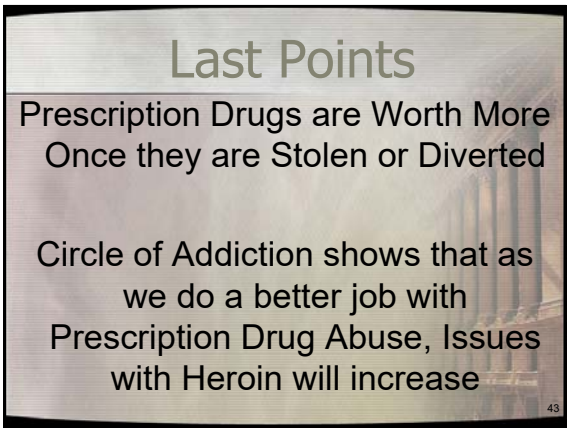
- Medication Assisted Treatment
- Re-education of prescribers
- Opioid guidelines
- Opioid limitations
- Review of published studies
- Drug Takeback Initiatives

41

Question

- What is the value of prescription opioids (hydrocodone, oxycodone) on the street?
  - Penny per mg
  - Dime per mg
  - Quarter per mg
  - Dollar per mg

42


Last Points
Prescription Drugs are Worth More Once they are Stolen or Diverted
Circle of Addiction shows that as we do a better job with Prescription Drug Abuse, Issues with Heroin will increase
43

VIDANT HEALTH

Pharmacoinformatics: Practice and Business

Christopher R. Dennis, PharmD, MMCi, BCPS, CPHIMS

Learning Assessment

Informatics is more about _____ than _____?

A. technology; people

B. systems; equipment

C. equipment; systems

D. people; technology

Objectives

- Define the discipline of healthcare informatics
- Evaluate the role of the pharmacist informatician in the provision of patient care services
- Describe how thoughtful implementation of healthcare technologies can be leveraged to achieve the IHI Triple Aim of improving patient experiences, improving the health of populations, and reducing costs
- Illustrate the role informatics can play in helping to curb the opioid epidemic and in managing issues such as medication shortages

Defining Informatics

- What is NOT healthcare informatics?
  - Deployment and configuration of systems
    System Analysts/Engineers
  - Health Information Management
    Separate discipline
  - Analysis of datasets
    Data Scientists
  - Tinkering with computers
    Hobbyists?

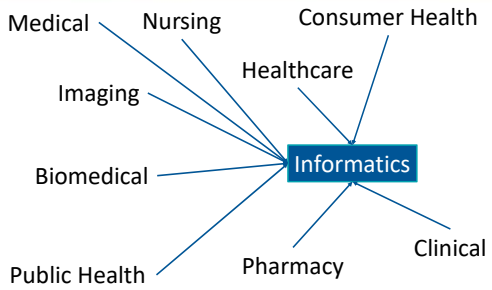
Defining Informatics

- Informatics
  - Information Science
    - the collection, classification, storage, retrieval, and dissemination of recorded knowledge treated both as a pure and as an applied science

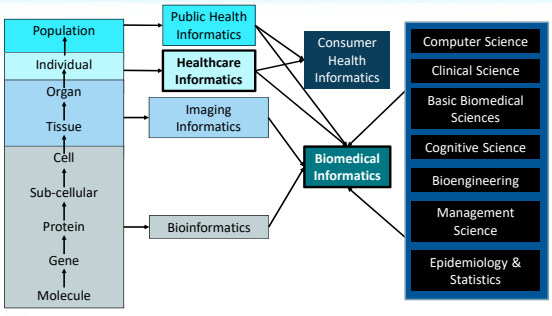
Technology side of things

https://www.merriam-webster.com/dictionary/informatics

Defining Informatics



Defining Informatics



Adapted from Zhang, Duke MMCi Lecture August 2016

VIDANT HEALTH

7

Friedman's Theorem of Biomedical Informatics

- "A person working in partnership with an information resource is 'better' than that same person unassisted"
- "Informatics is only 20% about technology"
- "Informatics is more about people than technology"

J Am Med Inform Assoc. 2009 Mar-Apr; 16(2): 169-170

VIDANT HEALTH

8

Healthcare Informatics

- **Healthcare Informatics**
  - "the integration of health-care sciences, computer science, information science, and cognitive science to assist in the management of healthcare information
  - Often referred also to as Clinical Informatics

https://www.himss.org/library/healthcare-informatics

VIDANT HEALTH

9

Pharmacoinformatics

- **Pharmacoinformatics**
  - "An integral discipline within the clinical informatics domain, centered on the effective management and delivery of medication related data, information, and knowledge across systems that support the medication-use process"
  - Often referred also to as simply Pharmacy Informatics

https://www.ashp.org/-/media/assets/pharmacy-informaticist/docs/sopit-terminology-glossary.ashx?la=en&hash=73918D04193285ED12B5084F784DAA329509AC3E

VIDANT HEALTH

10

Objectives

- Define the discipline of healthcare informatics
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Informaticist or Informatician? Tom-ay-to, Tom-ah-to?

- -ician
  - Specialist: practitioner
  - e.g. Beautician, Physician, Musician
- -ist
  - One that specializes in a (specified) art or science or skill
  - e.g. Geologist, Physicist, Pharmacist, Scientist

https://www.merriam-webster.com/dictionary/-ician
https://www.merriam-webster.com/dictionary/-ist

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Informaticist or Informatician? Tom-ay-to, Tom-ah-to?

- Reality is that these groupings do not have clear margins
- Informatician and informaticist are often used interchangeably
- Roles and responsibilities can vary dramatically even though the same title may be used

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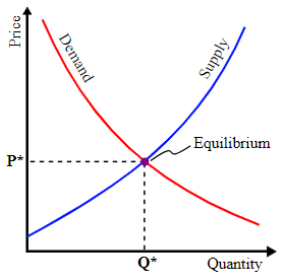
Simple Business Model (Not Healthcare)



How do we think of value outside of the healthcare sector?

https://upload.wikimedia.org/wikipedia/commons/8/8c/Supply-demand-equilibrium.svg

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Healthcare as a Business

- High functioning organizations actually <u>decrease</u> the demand for goods and services
  - Fewer hospitalizations (rehospitalizations)
  - Decrease length of stay
  - Minimize use of costly medications and equipment

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Evolution of Pharmacy Practice

Product Dispensed → Total Care of the Patient (i.e. outcomes)

- How does the pharmacy generate revenues?
- How do pharmacist activities impact the generation of these revenues?

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Expanding Pharmacy Services

- Demonstrate return on investment (ROI)
  - Hard dollars vs. Soft dollars
- Demonstrate return on health (ROH)
  - Focus on the outcomes → the benefits that directly relate to the quality of the care being provided
- Increase efficiency with existing resources to enable the organization to do more with less

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Pharmacist Informaticians

- Developing algorithms to support therapy protocols
- Developing and maintaining clinical decision support tools
- Ensuring optimal operation of the various technologies deployed in pharmacy practice
  - Robotics
  - Carousels
  - Automated Dispensing Stations
  - Secure drug cabinets

https://healthinformatics.uic.edu/resources/articles/the-role-of-the-pharmacist-in-health-informatics/

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Pharmacist Informaticians

Leveraging information and technologies to enable pharmacists and other clinicians to function at the top of their licenses to provide the best possible care to patients.

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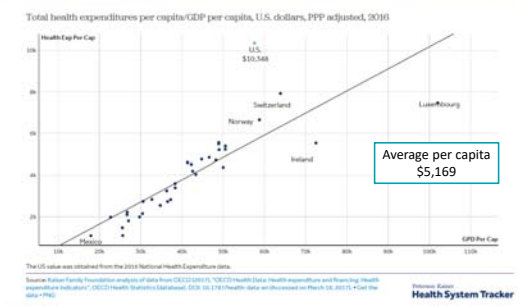
Cost of Care



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https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-relative-size-wealth-u-s-spends-disproportionate-amount-health

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Cost of Care

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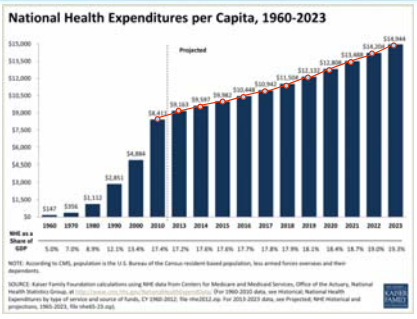
https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-relative-size-wealth-u-s-spends-disproportionate-amount-health

22

Cost of Care



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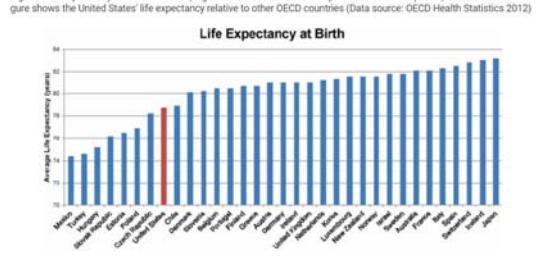
https://www.kff.org/health-costs/slide/national-health-expenditures-per-capita-1960-2023/

23

Life Expectancy



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https://www.researchgate.net/figure/Life-expectancy-at-birth-for-OECD-Organization-for-Economic-Co-operation-and_fig2_277869024
Berwick DM, Nolan TW, Whittington J. The Triple Aim: Care, health, and cost. Health Affairs. 2008 May/June;27(3):759-769.

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Patient Experience

- Focuses on the range of interactions that patients have with the health care system
  - Health plans
  - Clinical staff
  - Timely appointments
  - Easy access to information
  - Communication

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https://www.ahrq.gov/cahps/about-cahps/patient-experience/index.html

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Patient Experience

- NOT to be confused with satisfaction
  - Satisfaction has more to do with expectations
  - Two patients can have the same experience, but have differences in satisfaction

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https://www.ahrq.gov/cahps/about-cahps/patient-experience/index.html

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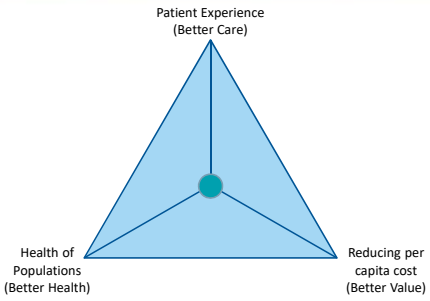
Institute for Healthcare Improvement Triple Aim



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https://www.healthcatalyst.com/improving-healthcare-outcomes-keep-triple-aim-in-mind

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Achieving the Triple Aim

- Important to recognize the interdependence of each component of the Triple Aim
- Pursuing improvement in one area has the potential of adversely impacting one or both of the others
  - e.g. purchase of a new technology or drug therapy designed to improve outcomes
- However, some initiatives can be synergistic
  - e.g. Eliminating misuse/overuse of therapies

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Berwick DM, Nolan TW, Whittington J. The Triple Aim: Care, health, and cost. Health Affairs. 2008 May/June;27(3):759-769.

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Leveraging Technologies

- **Interoperability**
  - "The ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities."

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https://www.ashp.org/-/media/assets/pharmacy-informaticist/docs/sopit-terminology-glossary.ashx?la=en&hash=73918D041932B5ED12B5084F784DAA329509AC3E

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Leveraging Technologies

- **Interoperability**
  - Improve access to information across systems and organizations
    - Improves ability to care for patients
    - Reduces costs related to repeat exams and tests
    - Improve care efficiency → patient experience

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Leveraging Technologies

- **Telemedicine**
  - "A telecommunications system that links healthcare organizations and patients from diverse geographic locations and transmits text and images for medical consultation and treatment."

https://www.ashp.org/-/media/assets/pharmacy-informaticist/docs/sopit-terminology-glossary.ashx?la=en&hash=73918D041932B5ED12B5084F784DAA329509AC3E

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Leveraging Technologies

- **Telemedicine**
  - Improve access to healthcare professionals
    - Specialists can reach patients over a larger geographical region
    - Pharmacists can oversee aspects of the medication use process remotely to ensure consistent delivery of services any time of the day
    - Patients may be able to receive more timely care which could prevent escalations of care (e.g. hospitalizations)

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Leveraging Technologies

- Organizations must have a clear understanding of their priorities since resources are finite
- Maximize the VALUE delivered

http://www.pmwares.com/blog/balancing-triple-constraints-triangle/

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Opioid Epidemic

- NC Strengthen Opioid Misuse Prevention (STOP) Act
  - July 1, 2017
    - PAs and NPs must consult with supervising physicians prior to prescribing "targeted controlled substances"
    - Hospice or palliative care providers must provide information to a patient and his/her family regarding disposal of "targeted controlled substances"
  - September 1, 2017
    - Pharmacies must report required information on all controlled substances dispensed into the CSRS

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http://www.ncbop.org/PDF/GuidanceImplementationSTOPACTJuly2017.pdf

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Opioid Epidemic

- NC Strengthen Opioid Misuse Prevention (STOP) Act
  - November 1, 2017
    - All pharmacists required to register for CSRS access in order renew their licenses for 2018
  - January 1, 2018
    - Restrictions on initial prescriptions for "targeted controlled substances" went into effect
  - January 1, 2020
    - ePrescribing of Controlled Substances will be required

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http://www.ncbop.org/PDF/GuidanceImplementationSTOPACTJuly2017.pdf

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Leveraging the Data
Opioid Risk Tool

	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16 – 45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring Total		

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https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

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Leveraging the Data
Morphine Equivalent Daily Dose

Opioid Morphine Equivalent Conversion Factors[1]

Type of Opioid	MME Conversion Factor
Buprenorphine patch[2]	12.6
Buprenorphine tab or film	10
Butorphanol	7
Codeine	0.15
Dihydrocodeine	0.25
Fentanyl buccal or SL tablets, or lozenge/troche[3]	0.13
Fentanyl film or oral spray[4]	0.18
Fentanyl nasal spray[5]	0.16
Fentanyl patch[6]	7.2
Hydrocodone	1
Hydromorphone	4
Levorphanol tartrate	11
Meperidine hydrochloride	0.1
Methadone	3
Morphine	1
Nalbuphine	1
Opium	1
Oxycodone	1.5
Oxymorphone	3
Pentazocine	0.37
Tapentadol	0.4
Tramadol	0.1

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https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-March-2015.pdf

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Leveraging the Data
Morphine Equivalent Daily Dose

HOW MUCH IS 50 OR 90 MME/DAY FOR COMMONLY PRESCRIBED OPIOIDS?

50 MME/day:
- 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15 mg)
- 12 mg of methadone (<3 tablets of methadone 5 mg)

90 MME/day:
- 90 mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325)
- 60 mg of oxycodone (~2 tablets of oxycodone sustained-release 30 mg)
- ~20 mg of methadone (4 tablets of methadone 5 mg)

≥ 50 MME per day – Increased risk of an overdose
≥ 90 MME per day – Increased risk of **death** from an overdose

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https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

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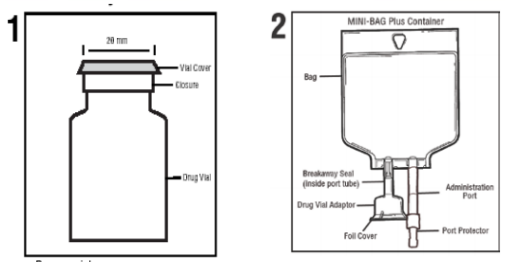
Medication Shortages



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https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020178s013lbl.pdf

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Medication Shortages

https://www.localsyr.com/news/local-news/nationwide-saline-shortage-after-hurricane-maria-impacting-cny-hospitals/917608718
https://cbs12.com/news/local/palm-beach-county-doctors-concerned-about-local-impact-created-by-slow-puerto-rico-recover
https://www.youtube.com/watch?v=3rHde69vwRc

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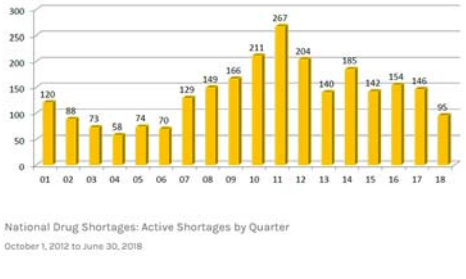
Medication Shortages



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https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics

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Leveraging the Data

- Understand medication usage patterns
  - Monitor for changes over time
- Leverage available drug shortage resources
- Maintain communication with clinicians and staff
- Engage with your pharmacist informaticians early and often

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Learning Assessment

Informatics is more about _____ than _____?

A. technology; people

B. systems; equipment

C. equipment; systems

D. people; technology

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Pharmcoinformatics: Practice and Business

Christopher R. Dennis, PharmD, MMCi, BCPS, CPHIMS