

COMPOUND DRUG COVERAGE

ANDREW MAGNAYE, PHARM.D. CANDIDATE 2016
MIDWESTERN UNIVERSITY, CHICAGO COLLEGE OF PHARMACY
PRO PHARMA PHARMACEUTICAL CONSULTANTS, INC.
UNDER THE PRECEPTORSHIP OF DR. CRAIG STERN

OBJECTIVES

- 1) Discuss what compound drugs are and how they are regulated
- 2) Discuss changes in compound drug reimbursement claims
- 3) Discuss changes made by Express Scripts and TRICARE to coverage of compound drugs
- 4) Discuss the impact and backlash of the Compound Management Solution
- 5) Discuss alternative solutions for coverage of compound drugs

COMPOUND DRUGS

COMPOUND DRUGS: THE BASICS

- Combination of **two or more drugs** to create a medication for a patient's individual needs
- Performed or supervised by a **licensed pharmacist**
- Needed if FDA-approved medication **does not meet the health needs** of a patient
- Compound drugs are **not FDA-approved**

TYPES OF COMPOUND DRUGS

- ▣ **Sterile Compounds**

- ▣ E.g., injections
- ▣ **USP <797>**

- ▣ **Nonsterile Compounds**

- ▣ E.g., ointments, creams, liquids, or capsules
- ▣ **USP <795>**

FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT (FDAMA) - 1997

▣ Section 503A

- ▣ Conditions that must be met for compound drugs to be exempt from:
 - ▣ **Current Good Manufacturing Practice (CGMP)**
 - ▣ Labeling with **adequate directions for use**
 - ▣ Approval of drugs under **new drug applications (NDAs)** or **abbreviated new drug applications (ANDAs)**
- ▣ Conditions:
 - 1) **Valid prescription** for compound drug and is necessary for the patient
 - 2) Compounded by a **licensed pharmacist**
 - 3) Compounded in compliance with the **United States Pharmacopoeia (USP)**

DRUG QUALITY AND SECURITY ACT (DQSA) – 2013

■ Section 503B

- Exempts compounding pharmacies from
 - CGMP compliance
 - Labeling directions for use
 - Prior FDA approval

- Allows “**outsourcing facilities**” to sell to hospitals and health care providers if they:
 - Comply with CGMP
 - Agree to FDA risk-based inspections
 - Report adverse events and provide information about products they compound

NATIONAL COUNCIL ON PRESCRIPTION DRUG PROGRAMS (NCPDP)

- Sets **standards for billing** practices
- **Multi-Ingredient Compound (MIC) logic** – 2012
 - NCPDP authorized compounding pharmacies to bill for **all ingredients in a compound drug**
- Prior to 2012, coverage was based on the **most expensive ingredient**
- Contributed to an **increase in prices**

NCPDP (cont.)

■ NCPDP Universal Claims Form

NCPDP UNIVERSAL CLAIM FORM (UCF)
Version 1.2 - 022913

CONTACT INSURANCE COMPANY AT LEFT FOR QUESTIONS REGARDING THIS CLAIM.
FOR OFFICE USE ONLY
16 (Document Control Number)

SIGNATURE OF PROVIDER
(I certify that the information on the reverse apply to this claim and I am a part thereof.)

TENTH DIGIT OF PROVIDER ID
PLEASE READ ATTENTION STATEMENT ON REVERSE SIDE

ME-PD

BOC

DZCWB00

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COMPOUND	69-Dosage Form Description Code		70-Dosing Unit Factor	71-Route of Administration	72-Ingredient Component Count			
	73-Product Name		74-Product ID		75-Dosage	76-Ingredient Qty	77-Ingredient Desig Cost	78-Basis of Cost
1								
2								
3								
4								
5								
6								
7								

Pricing (Format (1,234.56))						
79-Usual & Customary Charge	80-Basis of Cost, Dnt	81-Ingredient Cost Submitted	82-Chapering Fee Submitted	83-Prof Service Fee Submitted	84-Incentive Amount Submitted	85-Other Amount Submitted
86-Sales Tax Submitted	87-Gross Amount Due (Submitted)	88-Patient Paid Amount	89-Other Payer Amount Paid #1	90-Other Payer Amount Paid #2	91-Other Payer Patient Resp. Amount #1	92-Payer Patient Resp. Amount #2
93-Net Amount Due						

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EXPRESS SCRIPTS

EXPRESS SCRIPTS: TRENDS

- ❑ **Cost of prescriptions for compound drugs increased significantly** from 2012 to 2014
- ❑ Average cost of prescriptions **increased from about \$90 to \$1,100**
- ❑ Amount spent by clients for compound drugs **increased from \$28 million** (2012 – first quarter) **to \$171 million** (2014 – first quarter)
- ❑ Resulted in a **change of coverage for compound drugs**

EXPRESS SCRIPTS: TRENDS(cont.)

Express Scripts 2014 Drug Trend Report

- **Compound Drugs:**
\$46.04 PMPY
- **Trend:** +128%
- **Prescriptions:** 0.04 PMPY
- **Avg. Cost:** \$1,164.12 per prescription

COMPONENTS OF TREND FOR THE TOP 10 TRADITIONAL THERAPY CLASSES

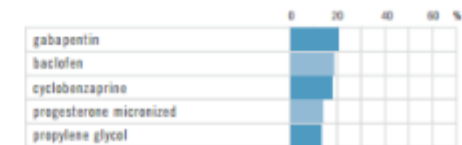
RANKED BY 2014 PMPY SPEND

RANK	THERAPY CLASS	PMPY SPEND	TREND		
			UTILIZATION	UNIT COST	TOTAL
1	Diabetes	\$97.68	1.7%	16.3%	18.0%
2	High Blood Cholesterol	\$48.73	-2.9%	-3.9%	-6.8%
3	Compounded Drugs	\$46.04	0.2%	128.2%	128.4%
4	Pain/Inflammation	\$45.98	0.3%	15.7%	16.0%
5	High Blood Pressure/Heart Disease	\$36.06	-0.4%	-12.2%	-12.6%
6	Heartburn/Ulcer Disease	\$33.40	-1.4%	-9.2%	-10.6%
7	Asthma	\$29.59	-3.2%	-11.6%	-14.9%
8	Attention Disorders	\$27.97	3.4%	2.9%	6.3%
9	Depression	\$25.98	2.1%	-20.5%	-18.4%
10	Mental/Neurological Disorders	\$24.85	-0.5%	9.6%	9.1%
TOTAL TRADITIONAL		\$668.75	-0.1%	6.5%	6.4%

Total trend for compounded drugs – **128.4%** – was higher than trend for any other top 10 traditional therapy class.

TOP INGREDIENTS

BY VOLUME



EXPRESS SCRIPTS: SOLUTION

- **Compound Management Solution – 2014**
 - Allows Express Scripts to **evaluate every ingredient** in a compound drug
 - Created a comprehensive **list of compound ingredients to exclude**
 - **Will not cover** any ingredient in the prescribed compound drug that is **an excluded ingredient**

EXPRESS SCRIPTS: EXCLUSIONS

■ Top 25 Exclusion List – 2014

Compound Ingredient	Indication or Base
FLUTICASONE PROPIONATE POWDER	Topical Pain
GABAPENTIN POWDER	Topical Pain
LIPO-MAX CREAM	Vehicle (Base)
PRACASIL TM-PLUS GEL	Vehicle (Base)
KETAMINE HCL POWDER	Topical Pain
FLURBIPROFEN POWDER	Topical Pain
LIPODERM BASE	Vehicle (Base)
CYCLOBENZAPRINE HCL POWDER	Topical Pain
BACLOFEN POWDER	Topical Pain
BUPIVACAINE HCL POWDER	Topical Pain
ETHOXY DIGLYCOL LIQUID	Solvent

EXPRESS SCRIPTS: EXCLUSIONS (cont.)

■ Top 25 Exclusion List – 2014 (cont.)

MELOXICAM POWDER	Topical Pain
VERSAPRO CREAM BASE	Vehicle (Base)
MOMETASONE FUROATE POWDER	Topical Pain
SPIRA-WASH GEL	Vehicle (Base)
DICLOFENAC SODIUM POWDER	Topical Pain
LEVOCETIRIZINE DIHYDROCHL POWDER	Scar Gel
VERSATILE CREAM BASE	Vehicle (Base)
LIOPEN ULTRA CREAM BASE	Vehicle (Base)
NABUMETONE MICRONIZED POWDER	Topical Pain
LIOPEN PLUS CREAM	Vehicle (Base)
TRAMADOL HCL POWDER	Topical Pain
KETOPROFEN MICRONIZED POWDER	Topical Pain
PRILOCAINE HCL POWDER	Topical Pain
RESVERATROL POWDER	Anti Inflammatory

EXPRESS SCRIPTS: EXCLUSIONS (cont.)

■ Expanded Compound Exclusions – 2015

Acne	Gout
Allergies	High Blood Cholesterol
Alternative Therapies	Impotence
Anxiety	Infertility
Asthma	Inflammation/Immune Disorders
Attention Disorders	Low Blood Pressure
Blood Modifying – Pentoxifylline Only	Migraine Headaches
Bone Conditions	Misc. Conditions
Cancer- Tamoxifen and Imbruvica Only	Muscle Relaxant
Chemical Dependence	Nausea/Vomiting
Circulation Disorders	Nutrition
Constipation	Pain/Inflammation
Contraceptives	Parkinsons Disease
Cough and Cold	Skin Conditions
Diarrhea	Sleeping Disorders
Endocrine Disorders	Urinary Disorders
Enzyme Deficiencies	Vitamins and Minerals
Fungal Infections	Weight Loss

TRICARE

TRICARE

- In 2015, **TRICARE** revised their coverage for **compound drugs**
- Express Scripts **began screening ingredients** in compound drugs
- TRICARE will **only cover ingredients with FDA-approval**
- Compound drugs will need to be **reformulated with FDA-approved ingredients** or will **require prior authorization**

TRICARE: CLAIMS PROCESS

Step 1: Electronic Screen

- TRICARE covers it?
- Safe and effective?
- Medically necessary?

Step 2

- Remove the non-covered ingredient or replace with covered ingredient
- Request different drug

Step 3: Prior Authorization

- Request if cannot substitute ingredient or prescribe a different drug

TRICARE: PRIOR AUTHORIZATION

- To ensure the prescribed drug is **safe, effective, medically necessary, and cost effective**
- **Usually takes 5 days** from when Express Scripts receives necessary paperwork
- If compound is not approved, patient has **90 days to request an appeal**

TRICARE: PRIOR AUTHORIZATION_(cont.)

❑ TRICARE Prior Authorization Request Form for Compounded Medications

Step
2

*** Please note that only 1 form is required for each compounded product.*

Document the active ingredient(s) in this compound:

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Step **Please complete the clinical assessment:**

3

1. What is the diagnosis?

2. What is the route of administration?

3. What are the directions for use?

4. What is the proposed duration of therapy?

5. What is the reason that a compounded product is being prescribed rather than a commercially-available product?

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EXPRESS SCRIPTS & TRICARE

EXPRESS SCRIPTS & TRICARE: IMPACT

Express Scripts 2014 Drug Trend Report

September 2014

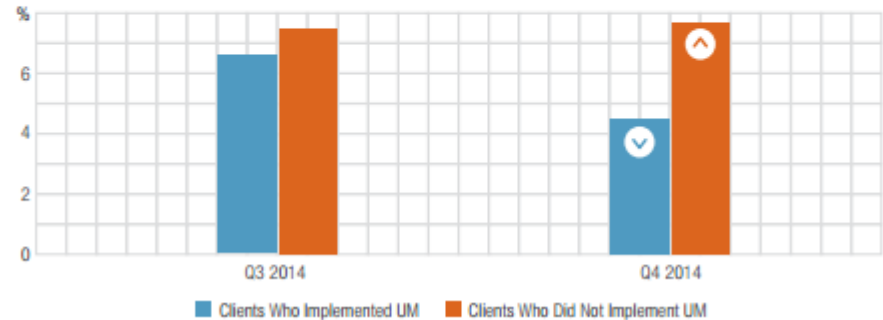
- Implemented: **6.6%**
- Did Not Implement: **7.5%**

December 2014

- Implemented: **4.5%**
- Did Not Implement: **7.7%**

COMPARISON OF TRADITIONAL DRUG TREND IN CLIENTS WHO DID AND DID NOT IMPLEMENT OUR COMPOUNDED DRUG UTILIZATION MANAGEMENT (UM) SOLUTION

IN 2014



EXPRESS SCRIPTS & TRICARE: IMPACT

(cont.)

- TRICARE's **cost for compound drugs decreased by 74%** in less than one month
- Reimbursements for approved compounds **decreased from \$1 billion** (January to April 2015) **to \$4 million** (May 2015)
- Compound prescriptions filled: **105,200** (April 2015) **to 41,800** (May 2015)

EXPRESS SCRIPTS & TRICARE: BACKLASH

- In November 2014, **three pharmacies sued Express Scripts** for their plan to change coverage on compound ingredients
 - Alleged that Express Scripts was violating federal regulations by denying claims
 - US Appeals Court ruled against the pharmacies

- **Precision RX Compounding L.L.C. et al. v. Express Scripts Holding Co. et al.** – January 2016
 - Alleging that Express Scripts is driving them out of the marketplace

ALTERNATIVE SOLUTIONS

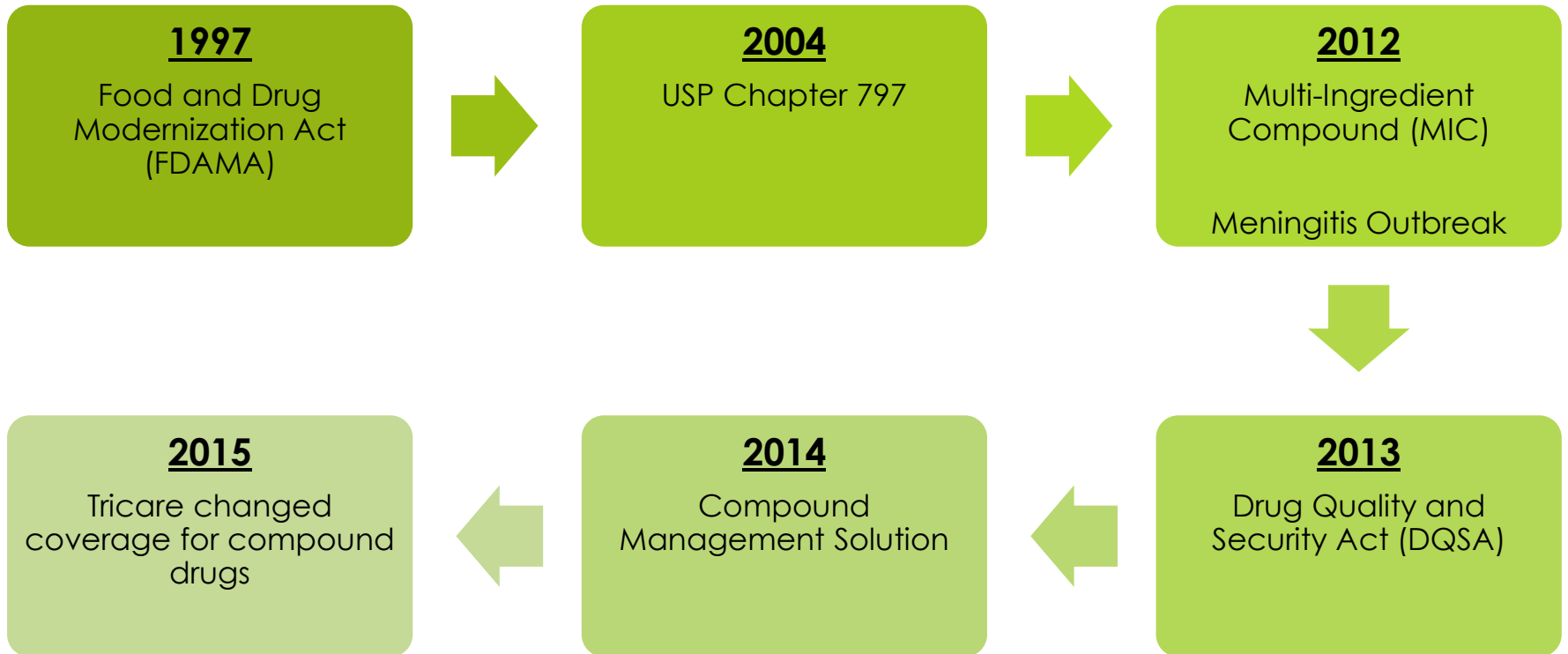
- ❑ **CIGNA HealthCare**

- ❑ **Prior authorization** for compound drug prescriptions greater than \$200
 - ❑ Reviews cost and medical necessity

- ❑ **Audit Program**

- ❑ Certain pharmacies where there are **concerns about dispensing and billing practices**
- ❑ Compound **prescription was valid and the charge was reasonable** (i.e., ingredients AWP and dispensing fee)

SUMMARY



FINAL THOUGHTS

- Abruptly ending coverage for certain ingredients in compound drugs has made a significant impact in health care
- Express Scripts' move to create an exclusion list for compound drugs is going to create even more controversy as other PBMs and health plans follow suit
- There is now a necessity to establish management programs for compound drugs

THANK YOU

□ *Questions?*

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