Physician Dispensing and Compounded Medications — a Legislative and Regulatory Update

October 22, 2014
About Helios

Helios, the new name for Progressive Medical and PMSI, is bringing the focus of workers’ compensation and auto-no fault pharmacy benefit management, ancillary services, and Settlement Solutions back to where it belongs – the injured party. Along with this new name comes a passion and intensity on delivering value beyond just the transactional savings for which we excel. To learn how our creative and innovative tools, expertise, and industry leadership can help your business shine, visit www.HeliosComp.com.
Today’s Webinar

► The presentation will last one hour

► All attendee phones are muted, but you can ask questions using the chat box on the right side of your screen.

► If we are unable to answer your question during the presentation, we will respond to you via email shortly following the webinar

► There is no CE available for this webinar

► The slide deck will be emailed out to all registrants of this webinar

► At the end of today’s webinar, we ask that you complete a short survey to let us know if the information shared today was helpful and what information you’d like us to cover in the future
Your Presenters

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Physician-Dispensed Medications

- Common in the workers’ compensation industry
- Medically necessary medication therapy
- Bypass many precautionary safety steps taken in pharmacy setting
  - The use of other prescription therapies
  - Potential drug interactions
  - Multiple usage of same medications – opioids, NSAIDS
- Typically dispensed as repackaged medication (New NDC number is created allowing physicians to sidestep state laws and fee schedules which cap workers’ comp drug reimbursement)
**Profit Driver for Physicians**

**Retail Dispensing**

- Standard NDC = AWP x FS = $

**Physician Dispensing**

- Unique NDC = Newly Created AWP x FS = $$$
Growing Cost Driver

► Accounted for more than 35% of work comp drug costs in 2011, up from 28% in 2009

► Total share of workers’ compensation costs for repackaged medications increased from 5% to 12% by 2011

► WCRI study compared physician-dispensing costs vs. pharmacy-dispensing costs; every medication significantly more expensive when physician dispensed:
  - Vicodin + 311%
  - Motrin +215%
  - Mobic +266%
  - Ultram + 232%
  - Flexeril +198%

Source – NCCI Workers’ Compensation Prescription Drug Study – 2013 Update
Between 2007 and 2011 the number of dispensed prescriptions increased 14%

Repackaged medications account for 2/3 of physician-dispensed medications

Since 2011, 22 states have taken policy action

Source – NCCI Workers’ Compensation Prescription Drug Study – 2013 Update
Physician Dispensed vs. Pharmacy Dispensed

Illinois Study

Claims with at least one physician-dispensed medication

- 39% higher medical costs
- 27% higher indemnity costs

Claims with a physician-dispensed opioid within 90 days

- 78% higher medical costs
- 57% higher indemnity costs

PHYSICIAN DISPENSING — LEGISLATIVE AND REGULATORY ACTIONS
State Legislative and Regulatory Actions

**States that have recently taken action on physician prescribing and dispensing**

- **KY**: Prohibits practitioners from dispensing > a 48-hour supply of any Schedule II or III containing hydrocodone, unless done as part of a narcotic treatment program
- **LA**: Physicians may only dispense controlled substances or medications of concern if registered as a dispensing physician and only up to a single 48-hour supply
- **TN**: Physician dispensing of certain controlled substances and medications outside pain management clinic is prohibited

**States that have recently taken action on physician reimbursement**

- **HI**: Reimbursement for repackaged medications based on AWP of original manufacturer’s NDC; If not provided or unknown, reimbursement shall be 140% of AWP for the original manufacturer’s NDC
- **IL**: Reimbursement for repackaged medications based on AWP of original manufacturer’s NDC
- **IN**: Physicians only receive reimbursement for medications dispensed during the first 7 days, including date of injury
- **TN**: Reimbursement for repackaged medications based on AWP of original manufacturer’s NDC
Florida

- Physicians prohibited from dispensing Schedules II & III
  - Limited exceptions (non-WC-specific)

- All bills submitted for repackaged / relabeled prescription medications must include original manufacturer NDC (dispensed NDC also required by rules)

- AWP for repackaged/relabeled prescription medications dispensed by a "dispensing practitioner" calculated using AWP set by original manufacturer of underlying drug dispensed
Following reform, medications that were commonly dispensed by physicians are now less likely to be prescribed.

Price per pill fell by 22–36% post reforms.

Many physicians continued to dispense medication from their office - 35% of prescribers pre-reform and 28% post reform.

Source – WCRI Impact of Reform on Physician Dispensing and Prescription Prices in Georgia - 2013
## Table A: Impact of Georgia’s Fee Schedule Reform on Prices Paid to Physician-Dispensers

<table>
<thead>
<tr>
<th>Rx Drug Commonly Dispensed by Physicians (74% of all physician-dispensed Rx in pre-reform Georgia)</th>
<th>Average Price Per Pill Paid for the Physician-Dispensed Drug</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen (Motrin®)</td>
<td>$0.59</td>
<td>$0.38</td>
</tr>
<tr>
<td>Tramadol HCL (Ultram®)</td>
<td>$1.44</td>
<td>$0.96</td>
</tr>
<tr>
<td>Hydrocodone-Acetaminophen (Vicodin®)</td>
<td>$1.05</td>
<td>$0.67</td>
</tr>
<tr>
<td>Naproxen (Naprosyn®)</td>
<td>$1.57</td>
<td>$1.32</td>
</tr>
<tr>
<td>Cyclobenzaprine HCL (Flexeril®)</td>
<td>$1.44</td>
<td>$1.31</td>
</tr>
<tr>
<td>Acetaminophen (Tylenol®)</td>
<td>$0.27</td>
<td>$0.15</td>
</tr>
<tr>
<td>Naproxen Sodium (Aleve®)</td>
<td>$1.25</td>
<td>$0.98</td>
</tr>
<tr>
<td>Ranitidine HCL (Zantac®)</td>
<td>$2.03</td>
<td>$2.50</td>
</tr>
<tr>
<td>Mollioxacin (Mobic®)</td>
<td>$4.83</td>
<td>$3.76</td>
</tr>
<tr>
<td>Omprazone (Prinop®)</td>
<td>$6.03</td>
<td>$4.16</td>
</tr>
<tr>
<td><strong>Carisprodol (Soma®)</strong></td>
<td><strong>$2.54</strong></td>
<td><strong>$0.63</strong></td>
</tr>
</tbody>
</table>

**Notes:**
- The underlying data included prescriptions associated with claims with more than seven days of lost time over the defined pre- and post-reform periods (see below). Prescriptions are those prescription drugs and over-the-counter drugs that were dispensed at pharmacies or physicians’ offices paid under workers’ compensation.
- Effective April 1, 2011, Georgia adopted a fee schedule change aimed at reducing prices paid for physician-dispensed drugs. To assess the impact of the reform, we defined pre- and post-reform periods. The pre-reform period covers claims with injuries from April 1, 2010 to September 30, 2010, with prescriptions filled through March 31, 2011. The post-reform period covers claims with injuries from April 1, 2011 to September 30, 2011, with prescriptions filled through March 31, 2012.

Source: WCRI Impact of Reform on Physician Dispensing and Prescription Prices in Georgia – 2013
North Carolina

- Original manufacturer's NDC required for all physician-dispensed repacks

- Reimbursement for physician-dispensed medication not to exceed 95% of AWP of original manufacturer's NDC
  - If original NDC not included, reimbursement limited to 100% of the AWP of the least expensive, clinically equivalent drug

- No outpatient provider, other than a licensed pharmacy, may receive reimbursement for a Schedule II or III controlled substance dispensed > initial 5-day supply, commencing upon the employee's initial treatment following injury
Pennsylvania

- Accounted for 29% of all prescriptions and 48% of all prescription payments
- Hydrocodone-acetaminophen & Oxycodone-acetaminophen contrive 12% of all physician-dispensed medications
- Prices paid for commonly dispensed medications range from 79% higher to 841% higher
- Carisoprodol/Soma $.51 per pill at retail vs $4.84 per pill
- Vicodin $.40 per pill at retail vs $1.38 per pill
- HB 1846 - To the rescue!!
Pennsylvania

% of Rx Payments for Physician Dispensed Rx vs % of All RX for Physician Dispensed Rx

Workers’ compensation statutes/regulations limit physician dispensing and/or repackaging (Restrictions on dispensing, billing and/or reimbursement)

No clear legal or workers’ compensation limits on physician dispensing and/or repackaging

Legal restrictions (Practice Act) in addition to workers’ compensation controls

Legal restrictions on physician dispensing (Medical/Pharmacy Practice Act restrictions)

Note – States such as AR, DE, FL, KY, NY and TN have overlapping workers’ compensation and state Practice Act controls

Data – Reflects published state statutes/regulations/case law on Physician Dispensing/Repackaging

* Not in effect until December 2014

Current as of Sept 2014
COMPONOUNDED MEDICATIONS — CLINICAL PERSPECTIVE
Compounded Medications

► The practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to needs of an individual patient

► May be an injectable, oral, or topical formulation

► Often include prescription medications as the active ingredient combined with inactive ingredients

► Are not FDA approved; individual active and inactive drug components typically are

► Must be dispensed by a licensed pharmacist, a licensed physician, or a person under supervision of a licensed pharmacist (as in the case of an outsourcing facility) and require prescriptions from licensed prescribers

► Questionable efficacy

► Frequently more expensive than standard medication counterparts
Growing Cost Drivers

► Several recent voluntary recalls related to compounding:
  - New England compounding center issues nationwide recall of all products
  - Apothécure, Inc. and Clinical Specialties Compounding Pharmacy nationwide recall due to sterility assurance concerns
  - Pallimed Solutions, Inc recall due to visible particulates observed

► June 2014 a prescription topical cream prescribed and dispensed to a CA injured worker a contributing factor in tragic death

► CompPharma reported the following results from a survey completed on 117 compounding pharmacies:
  - Almost 33% had not established policies and procedures & did not provide specific new hire training
  - 17% used a quantitative analytic measurement to verify active ingredients
  - Only 46% would agree to send products for dosing and sterility verification at a lab

Source – NCCI Workers’ Compensation Prescription Drug Study – 2013 Update
There is questionable effectiveness of these medications being applied as a topical compound (versus orally).

Very few clinical trials with any statistical significance exist for the products, especially when there are multiple ingredients in the formulation.

ODG states that compounded medications are not first-line medications:
- “In general, FDA-approved medications should be tried prior to prescribing a compound drug, unless specific patient issues with any appropriate FDA-approved medications have already been identified.”
Therapeutic Concern - Safety

► The unique nature of how medication is absorbed through the skin presents concerns about actual dose received during each application.

► Topical compounded medications are promoted as being safer due to less absorption than oral medications, but there is little evidence to back this claim.

► Potential for drug-drug interactions if the claimant is taking other medications.

► Adverse effects from a compound are difficult to tie back to a specific ingredient.

► Duplication of therapy with other medications taken orally (which can lead to additional adverse effects).
In Treatment

► In workers’ compensation, most compounded medications are pain management medications delivered through topical creams.

► Compounded products administered topically are considered 2nd or 3rd line; primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed or when an injured worker is allergic to certain inactive ingredients that can be altered in a compounded product.

► Outside of workers’ compensation, compounded medications are most often used for hormone replacement, dermatology, children’s formulations, and anti-cancer treatment.
Utilization

- % of all prescription medications: 2012 - 0.60%, 2013 - 0.53%
- % of total drug spend: 2012 - 2.08%, 2013 - 3.81%
On average, there are **four to five individual ingredients** in compounded medications.

### Therapeutic Classes

<table>
<thead>
<tr>
<th>Therapeutic Classes</th>
<th>Commonly used agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAIDs</td>
<td>Ibuprofen, diclofenac, ketoprofen, flurbiprofen</td>
</tr>
<tr>
<td>Opioids</td>
<td>Tramadol</td>
</tr>
<tr>
<td>Local anesthetics</td>
<td>Lidocaine, benzocaine, ketamine</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Amitriptyline, nortriptyline</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>Gabapentin, Lyrica</td>
</tr>
<tr>
<td>Muscle relaxants</td>
<td>Cyclobenzaprine, baclofen</td>
</tr>
<tr>
<td>Other topical analgesics</td>
<td>Capsaicin, menthol, methyl salicylate, clonidine</td>
</tr>
</tbody>
</table>
Concerns

- Grand jury indictment of Landmark Medical Management, who was accused of accepting millions of dollars in kickbacks to prescribe and dispense compounded creams, was more than 1,500 liens worth more than $3.7 million (according to EAMS data).

- The California Workers’ Compensation Institute cited significantly higher payments and more ingredients per prescription; orally ingested Gabapentin costs $165/month vs. to $1,400/month for powdered Gabapentin from compounded medications.

- Difficult to track; 80% of compounded medications are filled and billed outside a PBM network and a majority don’t comply with NCPDP billing standards.
COMPOUNDED MEDICATIONS — LEGISLATIVE AND REGULATORY ACTIONS
2007 reforms register a 90% decline in volume and amounts paid by 2011 for physician dispensing

In same period average amount paid for a compounded medication prescription jumped 68%

CWCI Study – Claims involving physician dispensing (including compounded medications) show 17% higher medical costs and 9% more lost-time days

CWCI study reports that in CA, compounded medications fell from 3.1% of WC prescriptions to 2.0%; average $ per compound RX increased 68.2%; from $460.42 to $774.21

- AB 378 in 2012 attempted to control cost of physician dispensing but increased compounded medications
Distribution of California Workers’ Compensation Prescriptions

<table>
<thead>
<tr>
<th>Prescription Type</th>
<th>Pre-AB 378 (Jan-June 2011)</th>
<th>Post-AB 378 (Jan-June 2012)</th>
<th>% of Change Pre-Post AB 378</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Compounded Medication</td>
<td>96.9%</td>
<td>98.0%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Compounded Medication</td>
<td>3.1%</td>
<td>2.0%</td>
<td>(35.4%)</td>
</tr>
</tbody>
</table>

Distribution of California Workers’ Compensation Prescription Payments

<table>
<thead>
<tr>
<th>Prescription Type</th>
<th>Pre-AB 378 (Jan-June 2011)</th>
<th>Post-AB 378 (Jan-June 2012)</th>
<th>% of Change Pre-Post AB 378</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Compounded Medication</td>
<td>88.4%</td>
<td>87.4%</td>
<td>(1.1%)</td>
</tr>
<tr>
<td>Compounded Medication</td>
<td>11.6%</td>
<td>12.6%</td>
<td>9.0%</td>
</tr>
</tbody>
</table>

Compounded medications must be billed by a compounding pharmacy

Reimbursement for non-sterile medications is only allowed for preparations containing no more than three FDA-approved ingredients

If the compound includes a repackaged drug, the maximum allowable reimbursement (MAR) for the repackaged drug shall be determined based on AWP of the original manufacturer

MAR for compounded medications shall be the sum of the AWP for each active ingredient minus 50 percent, plus a single compounding fee of $20.00
Hawaii

- Compounded medications not previously addressed or reimbursement capped

- Hawaii Senate Bill 2365 effective July 1, 2014

- Established reimbursement method for compounded medications
  - The sum of 140% of AWP by gram weight of each underlying prescription drug contained in the compounded prescription medications
  - AWP shall be set by the original manufacturer of the underlying prescription medication as identified by its NDC as published in “Red Book

- All pharmaceutical claims submitted for repackaged, relabeled or compounded medications shall include NDC of original manufacturer
  - If original manufacturer of the underlying drug product used is not provided or is unknown, reimbursement shall be 140% of AWP for the original manufacturer
Bills for compounded medications must list each included drug and its NDC.

Reimbursement for compounded medications = sum of AWPs of each underlying NDC drug product + single $5 dispensing fee.

Compounded medications limited to max of $300 or a quantity of 120 grams per month.
- Any additional quantity requires further documentation & prior-auth./pre-cert.
### Regulation vs. Legislation

#### Regulation
- Allow participation in WC stakeholder meetings
  - South Carolina
  - Michigan
  - Illinois
  - Oklahoma
- Opportunity for submission of comments to state proposals
- Not subject to political pressures and lobbying
- Consideration for impact on costs and premiums
- Subject to some political oversight
- Usually a slower implementation process

#### Legislation
- Allows for proper response to crisis levels
  - Florida
  - Indiana
  - Tennessee
  - California
- Eager to work with stakeholders towards compromise
- Often quick but delegates to state agency
- More politically driven
- Easier to kill a bill than to pass one
- Highly subject to lobbying and influence
State Legislative and Regulatory Actions

**States that have recently taken action on compounded medications**

- **OK:** Enacted guidelines which require pre-authorization for all compounded medications as part of their closed formulary
- **TX:** Any compounded medication containing an ODG non-formulary medication requires prior authorization

**States that have recently taken action on reimbursement**

- **NY:** Reimbursement = sum of allowable fee for each ingredient + a single dispense fee per compound; bills must be by/at ingredient level
- **RI:** Reimbursement reduced from AWP + 20% to AWP – 10%; Required to bill by/at ingredient level and include original NDC for unpackaged medications
- **MS:** Cap of $300 or a quantity of 120 grams per month (any additional quantity requires further documentation & prior-auth./pre-cert.)
2014 Policy Action by State

Data – Reflects published statutes/regulations/fee schedules related to workers’ compensation compounded drug billing/reimbursement

Current as of Sept 2014

Not addressed by specific WC Regulations/Fee Schedules

Individual ingredient(s) NDC required on compound bills

Language explicitly permits denial of reimbursement for individual ingredients lacking an NDC

* Additional state regulatory/statutory language regarding billing and reimbursement for compounded medications (including physician-dispensed compounded medications)
LOOKING AHEAD
Policy Goals and Clinical Insight

Physician Dispensing

- Cap reimbursement for physician dispensing (repackaged medications) at same level as retail pharmacies
- Cap reimbursement based upon AWP (NDC) of the underlying medication
- Standardized billing process requiring inclusion of both the underlying and dispensed NDC
- No dispensing fee for physicians
Policy Goals and Clinical Insight

*Compounded Medications*

- Require all ingredients to be billed separately and include the underlying NDC
- Reimburse only active medication, and limited number of ingredients with valid NDC
- Pay dispensing fee only to pharmacies
- Require pre-authorization for all compounded medications except those with demonstrated efficacy
Public Policy Changes

- Pennsylvania – What’s next in the Keystone State?
- Maryland Data Call – Purpose behind the call
- Louisiana – Rulemaking Efforts
- Texas – Y-Drug Compounded Medications
Texas – Y-Drug Compounded Medications

In Texas, there is still a high use of compounded medications, but the typical ingredients have changed to non-N medications (highlighted medications are ODG-N)

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>% use in other states</th>
<th>% use in TX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin Powder</td>
<td>17.7%</td>
<td>13%</td>
</tr>
<tr>
<td>Cyclobenzaprine HCl Powder</td>
<td>17.6%</td>
<td>12%</td>
</tr>
<tr>
<td>Baclofen Powder</td>
<td>13.7%</td>
<td>22%</td>
</tr>
<tr>
<td>Diclofenac Sodium (Bulk) Powder</td>
<td>11.2%</td>
<td>1%</td>
</tr>
<tr>
<td>Ketamine HCl (Bulk) Powder</td>
<td>10.2%</td>
<td>1%</td>
</tr>
<tr>
<td>Lidocaine (Bulk) Powder</td>
<td>14.3%</td>
<td>7%</td>
</tr>
<tr>
<td>Ketoprofen Powder</td>
<td>7.3%</td>
<td>4%</td>
</tr>
<tr>
<td>Flurbiprofen Powder</td>
<td>6.6%</td>
<td>23%</td>
</tr>
<tr>
<td>Bupivacaine HCl Powder</td>
<td>5.4%</td>
<td>22%</td>
</tr>
<tr>
<td>Tramadol HCl (Bulk) Powder</td>
<td>3.3%</td>
<td>5%</td>
</tr>
<tr>
<td>Dimethyl Sulfoxide - Solution***</td>
<td>3.3%</td>
<td>0%</td>
</tr>
<tr>
<td>Amitriptyline HCl Powder</td>
<td>3.0%</td>
<td>7%</td>
</tr>
<tr>
<td>Pentoxifylline (Bulk) Powder</td>
<td>2.9%</td>
<td>1%</td>
</tr>
<tr>
<td>Clonidine HCl Powder</td>
<td>2.0%</td>
<td>0%</td>
</tr>
<tr>
<td>Tetracaine (Bulk) Powder</td>
<td>1.8%</td>
<td>1%</td>
</tr>
<tr>
<td>Ibuprofen Powder</td>
<td>1.7%</td>
<td>2%</td>
</tr>
<tr>
<td>Menthol Crystals</td>
<td>1.7%</td>
<td>1%</td>
</tr>
<tr>
<td>Orphenadrine Citrate Powder</td>
<td>1.5%</td>
<td>0%</td>
</tr>
<tr>
<td>Prilocaine HCl Powder</td>
<td>1.4%</td>
<td>1%</td>
</tr>
<tr>
<td>Tetracaine HCl Powder</td>
<td>1.4%</td>
<td>0%</td>
</tr>
<tr>
<td>Capsaicin Powder</td>
<td>1.3%</td>
<td>0%</td>
</tr>
<tr>
<td>Meloxicam (Bulk) Powder</td>
<td>0.9%</td>
<td>14%</td>
</tr>
<tr>
<td>Nifedipine Powder</td>
<td>0.7%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Public Policy Changes

Compounding pharmacies unite to push back against restrictions

► Associations launching public media campaign

► Increased efforts in statehouses

Source – NYTimes; 08/14/2014, Pharmacies Turn Drugs Into Profits, Pitting Insurers vs. Compounders
Monitoring Potentially New Loopholes

► Boutique Manufacturers
  - Original NDC with an inflated AWP
  - Research efforts underway

► Mail Order Compounded Medications
  - Marketing Questions
  - First Fills

► Medical Foods
  - FL HB 785
  - Physician Dispensed
Positive Outcomes

► By banning or restricting physician dispensing the states hope to push RX dispensing back to pharmacy and reduce disability periods

► After Massachusetts banned physician dispensing, the average payment per claim for workers’ compensation prescriptions dropped by $289

► A 2012 WCRI study found that prior to a California fee schedule change in 2007, physicians charged nearly double that of a retail pharmacy; post change volume and cost declined by 90%

► A recently released WCRI study on the impact of the Georgia reforms shows that the cost of physician-dispensed medication deceased 25-40%, but still remained 20-40% higher than the reimbursement to retail pharmacies for the same medications.
Thank You!

Questions?

► The slide deck will be sent out to all of today’s registrants
► Visit us at NWCDC Booth #1223
► Visit helioscomp.com to register for our upcoming webinars:
  – **Bending the Curve of Opioid Misuse and Abuse**
    Wednesday, November 5, 2014, 2:00 pm – 3:00 pm ET
  – **Controlling Utilization Through Formularies**
    Wednesday, December 3, 2014, 2:00 pm – 3:00 pm ET
► Please take our short survey