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**Report of the Findings and Recommendations of  
the North Carolina Industrial Commission  
Regarding the Implementation of a Drug  
Formulary in Workers' Compensation Claims**

**North Carolina Industrial Commission  
Raleigh, North Carolina**

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## **I. Executive Summary of the Industrial Commission’s Report and Recommendations**

In Session Law 2015-241, the General Assembly directed the North Carolina Industrial Commission (“Commission”) to study the implementation of a drug formulary in workers’ compensation claims filed by State employees, and report its findings and recommendations to the chairs of the North Carolina House of Representatives Health Committee, the Senate Health Care Committee, and the Fiscal Research Division by April 1, 2016. The findings of this study, to date, demonstrate that a drug formulary could potentially generate significant cost savings while improving the process by which medications are delivered safely and efficiently to injured workers. While the Session Law directive was limited to State employee claims, the Commission has also considered system-wide application. As such, the Commission makes the following recommendations:

- The Commission’s study has thus far yielded encouraging results, which suggest that a drug formulary could be beneficial for State employee claims as well as the entire North Carolina workers’ compensation system.
- Due to the complexities surrounding this issue and the brief study period to date, the Commission should continue to study thoroughly the potential adoption of a drug formulary including the possible system-wide cost savings.
- The Commission should investigate the advisability of implementing select medical treatment guidelines necessary to support a drug formulary.
- If the conclusion of additional study so justifies, the Commission should pursue implementation through administrative rulemaking, pursuant to its authority under N.C. Gen. Stat. §§ 97-25.4 and 97-80(a), with an effective date no earlier than July 1, 2018. The Commission requests an exemption from the fiscal note requirement of N.C. Gen. Stat. § 150B-21.4 for purposes of administrative rulemaking for a drug formulary and any related treatment guidelines.
- In the interim, the Commission should immediately begin exploring the implementation of a generic drug mandate applicable to all workers’ compensation claims through administrative rulemaking. The Commission requests an exemption from the fiscal note requirement of N.C. Gen. Stat. § 150B-21.4 for purposes of making rules for a generic drug mandate.

The Commission’s current study has revealed a number of factors that warrant further study to ensure that the potential benefits of a drug formulary are maximized. Among these factors is the implementation of related medical treatment guidelines, which have been adopted by every state that has implemented a drug formulary. A continued period of study will afford the Commission adequate time to thoroughly research the multitude of considerations involved in implementation of a drug formulary.

While further study is recommended before any action is taken regarding implementation of a drug formulary and associated medical treatment guidelines, the Commission has identified two areas where immediate action should be taken. First, the mandatory substitution of generic equivalents for brand name drugs in workers' compensation claims could be implemented relatively quickly to generate savings during the process of studying implementation of a drug formulary. Second, given the current pressing public health problem posed by opioid medications, the Commission should partner with other State agencies at the earliest opportunity to explore how prescribing and dispensing practices and other factors in workers' compensation cases affect or contribute to the prescription opioid problem. The Commission believes that such partnering will further efforts to provide safe and effective treatment for injured workers.

The complete findings from the Commission's study and its full recommendations are set forth in the following report.

## **II. Goals of the Industrial Commission's Study**

### **A. What was the Industrial Commission Directed to Study?**

As set forth in the Executive Summary, Section 15.13A of Session Law 2015-241 directed the Commission to study the implementation of a drug formulary in workers' compensation claims filed by State employees. The legislation also required the Commission to consider the following factors in its study:

- (A) the pharmacy-related expenses incurred by the State on an annual basis in workers' compensation claims;
- (B) the savings, if any, that would result from the use of a drug formulary in workers' compensation claims;
- (C) whether the use of a drug formulary would result in the more efficient delivery of medications, provide workers with reasonable and necessary care, and provide a disincentive for health care providers to utilize costly name brand drugs and habit-forming opioids and narcotics; and
- (D) the adoption of an appeals process that would allow health care providers and injured workers to seek approval for the use of drugs that are not on the formulary's approved list.

Furthermore, Session Law 2015-241 allowed the Commission to consider any other issues relevant to the implementation of a drug formulary in workers' compensation claims. In addition to analyzing State employee claims, the Commission considered, for purposes of this report, the potential savings, benefits, and implementation procedures of a drug formulary if applied to all workers' compensation claims in North Carolina. The Commission also investigated the intersection of narcotic drugs prescribed in workers' compensation claims and opioid abuse as a growing public health problem.

### **B. What is a Drug Formulary and How is it Applied in Workers' Compensation?**

#### **1. What is a Drug Formulary?**

In practice, a drug formulary is a list of approved or covered drugs and/or non-approved drugs, generally applied to outpatient treatment only. Many health insurance plans, Medicare, state Medicaid plans, self-insured employers, and workers' compensation insurance carriers utilize drug formularies. These formularies provide information to physicians, pharmacists, and patients regarding drugs that are automatically covered by the paying entity and which drugs will not be covered or may require review before they will be covered.

## **2. How are Drug Prescriptions and Costs Handled in Workers' Compensation Claims Currently?**

Currently in North Carolina, there is no uniform or mandated drug formulary for workers' compensation claims. However, many self-insured employers and workers' compensation insurance carriers, and the third-party administrators ("TPA") or pharmacy benefit management companies ("PBM") with whom they contract, apply proprietary drug formularies to the workers' compensation claims they administer. Particularly relevant to this study, CorVel, the TPA for State employee workers' compensation claims, and MyMatrixx, the PBM for the Department of Public Instruction's State employee claims, both utilize drug formularies.

Such drug formularies may be developed by a carrier, or by a TPA or PBM in consultation with a carrier or employer, or purchased "off-the-shelf" from institutions or companies that develop them. The considerations for selecting or developing these formularies include factors such as cost, availability of generics, effectiveness, and safety.

Private formularies are applied at the point of filling a prescription at the pharmacy. The injured worker obtains a prescription from his treating physician and presents it at a pharmacy with information or a card provided to the injured worker by the employer or carrier to let the pharmacist know about the applicable workers' compensation coverage. The pharmacy then contacts the designated entity, usually electronically, for authorization. The authorization or denial is usually sent back electronically with various reason codes used to indicate the reason for denial. If the denial has to do with a brand name medication being prescribed when a generic is available or involves another issue that can be resolved by a call to the physician, the pharmacist may call the physician's office to resolve the issue and then dispense medication to the injured worker that day. Other denial reasons may result in the injured worker having to leave the pharmacy and return another day after the issue is resolved.

In other cases, the issue cannot be resolved between the parties. If an injured worker and his physician believe a drug denied by a private formulary is medically necessary and the employer or carrier continues to deny authorization, the injured worker must file a medical motion with the Commission to seek an order directing the employer or carrier to pay for the drug at issue.

Further, the lack of uniformity that results from the use of different formularies can lead to confusion—as a doctor's prescription for the same medication may or may not be filled depending on the employer or carrier administering the claim. Compounding this issue is the fact that the initial determination of authorization may not be known until the pharmacy attempts to process the prescription.

The use of private formularies results in savings on drug costs because many injured workers and physicians may elect not to challenge an initial denial and many injured workers may not object to generic versions of drugs or alternative medications. However, it is unlikely that

private formularies maximize potential savings and result in the most efficient and effective care for injured workers. A consistent state-wide formulary could maximize potential savings while reducing confusion for pharmacists and physicians, and ensure that injured workers receive prompt and appropriate care.

### 3. How Would a Drug Formulary Apply to Workers' Compensation Claims?

Drug formularies adopted by state workers' compensation authorities are generally structured to list drugs that are prescribed on an outpatient basis for workplace injuries, focusing on allowing the safest and least expensive effective medications to be filled without preauthorization by the employer or workers' compensation insurance carrier. Drugs prescribed for conditions less commonly associated with workplace injuries or with high cost or safety issues are flagged as requiring preauthorization.

Discussions of drug formularies for workers' compensation claims typically focus on three models: the *Official Disability Guidelines Treatment in Workers' Comp / Appendix A, ODG Workers' Compensation Drug Formulary* ("ODG") produced by the Work Loss Data Institute,<sup>1</sup> the *American College of Occupational and Environmental Medicine's Practice Guidelines* ("ACOEM") produced by the Reed Group,<sup>2</sup> and the internally developed state models, such as those produced in Washington<sup>3</sup> or Ohio.<sup>4</sup>

If the Commission adopts a drug formulary applying to workers' compensation claims in North Carolina, self-insured employers, carriers, and their TPAs and PBMs would be required to use that drug formulary, though they could choose to authorize non-formulary drugs. If further study supports moving forward to implement a formulary, then the Commission's goal would be to adopt the best formulary and related implementation procedures from the perspectives of medical efficacy, safety, efficiency, and cost.

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<sup>1</sup> See generally Work Loss Data Inst., *ODG Evidence-Based Medical Treatment and Return to Work Guidelines*, <http://www.worklossdata.com/drug-formulary.html> (last visited Mar. 22, 2016). See also Tex. Dep't of Ins., Div. of Workers' Comp., *Appendix A, ODG Workers' Compensation Drug Formulary* (last updated Feb. 29, 2016), available at <http://www.tdi.texas.gov/wc/pharmacy/index.html#appendixa>.

<sup>2</sup> See generally Am. Coll. of Occupational and Envtl. Med., *Clinical Practice and Guidance Center, Occupational Medicine Practice Guidelines*, <http://www.acoem.org/practiceguidelines.aspx> (last visited Mar. 22, 2016).

<sup>3</sup> Wash. State Dep't of Labor and Indus., *Outpatient Formulary* (last updated Feb. 1, 2016), available at <http://www.lni.wa.gov/ClaimsIns/Files/Providers/DrugFormulary.pdf>; Wash. State Dep't of Labor and Indus., *Selected Preferred Drug List* (last updated Feb. 1, 2016), available at <http://www.lni.wa.gov/ClaimsIns/Files/Providers/SelectedPDLforworkers.pdf>.

<sup>4</sup> Ohio Admin. Code § 4123-6-21.3 (2015), available at <https://www.bwc.ohio.gov/downloads/blankpdf/OAC4123-6-21.3.pdf> & <https://www.bwc.ohio.gov/downloads/blankpdf/OAC4123-6-21.3Appendix.pdf> (setting forth the Ohio Board of Workers' Compensation Outpatient Medication Formulary).

### III. Data and Information Gathered by the Industrial Commission

To analyze the fiscal effect of a drug formulary as directed by the session law, the Commission contacted the Office of State Human Resources, the Department of Public Instruction, and their workers' compensation administrators CorVel and MyMatrixx to obtain the necessary pharmacy cost data for State employee claims for calendar years 2012-2014. The Commission then engaged the services of the Workers' Compensation Research Institute ("WCRI")<sup>5</sup> to perform the data analysis and make projections within their analytical expertise.

For purposes of the analysis, WCRI and the Commission agreed to apply the closed formulary definition set forth in 28 Tex. Admin. Code § 134.500(3) (2011) as follows:

"All available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but excludes:

- (A) drugs identified with a status of "N" in the current edition of the *Official Disability Guidelines Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates;
- (B) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates; and
- (C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care . . . ."

The ODG-based formulary adopted by Texas was chosen for the analysis because of the availability of detailed results of the impact of Texas' formulary on prescribing patterns and costs in the state.<sup>6</sup> WCRI studied what effect a Texas-like drug formulary might have on the prevalence and costs of drugs prescribed to North Carolina State employees. WCRI's findings are discussed in this report and the complete WCRI study entitled "Texas-Like Formulary for North Carolina State Employees" can be found at Appendix 1.

In addition to obtaining the WCRI analysis of potential savings on State employee claim costs, the Commission also met with stakeholders and solicited written and oral comments, had telephone discussions with other states' workers' compensation officials, reviewed statutes and rules from other states with drug formularies, and researched the effect of drug formularies in other states and other related issues. The Commission provided questionnaires to other states' workers' compensation officials and received written comments from them, as well. See Appendix 2 for the comments on drug formularies received from other states. Though the

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<sup>5</sup> See generally Workers Comp. Research Inst., *About WCRI*, <http://www.wcrinet.org/> (last visited Mar. 22, 2016) (providing general background information on the organization).

<sup>6</sup> Vennela Thumula & Te-Chun Liu, Workers Comp. Research Inst., *Texas-Like Formulary for North Carolina State Employees* 5 n.2 (2016).

Commission dedicated significant time and effort to obtaining an informed and well-rounded understanding of the issues associated with implementing a drug formulary, the Commission recognizes that additional study is needed.

#### **IV. Industrial Commission Findings on Costs, Savings, Efficiency, Effectiveness, Implementation, and Other Related Issues**

This section of the report provides the Commission's findings and recommendations on each of the factors identified for study in Session Law 2015-241, as well as other issues the Commission determined to be relevant to the implementation of a drug formulary.

##### **A. Pharmacy-Related Expenses Incurred in State Employee Workers' Compensation Claims**

According to the data from State employee workers' compensation claims for calendar years 2012 through 2014, the State of North Carolina, on average, incurs pharmacy-related expenses in excess of \$9.7 million on an annual basis. From 2012 through 2014, prescription drug costs increased by more than 10% year-over-year. Over the three-year period studied, the State was responsible for 14,438 claims with at least one prescription filled. The total number of prescriptions filled over this same period for these 14,438 claims was 183,515 prescriptions. Those 183,515 prescriptions cost the State of North Carolina a total of \$29,151,934 over three years.<sup>7</sup>

WCRI analyzed the data to show the distribution of these costs between formulary and non-formulary drugs according to the Texas drug formulary rules. For purposes of their study, formulary drugs were defined as the drugs that would be filled without preauthorization, and non-formulary drugs were the drugs that would require preauthorization.<sup>8</sup>

Applying these protocols to the data from North Carolina State employee claims, WCRI found that non-formulary drugs were associated with 4,184 claims out of the 14,438 claims with prescriptions from 2012 through 2014. There were 40,754 prescriptions for non-formulary drugs out of the 183,515 total prescriptions over the same period as compared to 137,343 prescriptions for formulary drugs. Although only 22% of the total number of prescriptions were attributable to non-formulary drugs, that 22% was responsible for \$11,472,635 or nearly 40% of the total prescription drug costs of \$29,151,934.<sup>9</sup> See Table 1.1 below from the WCRI analysis.

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<sup>7</sup> All statements in this paragraph are attributed to *id.* at 9 tbl.1.1.

<sup>8</sup> *Id.* at 10.

<sup>9</sup> All statements in this paragraph are attributed to *id.* at 9 tbl.1.1.

**Table 1.1 Data Underlying the Study**

	2012	2013	2014	Total
Number of claims with prescription fills in calendar year	6,723	6,575	6,255	14,438
Number of claims with at least one non-formulary drug Rx	2,099	2,148	2,073	4,184
Number of claims with at least one formulary drug Rx	6,427	6,308	6,003	13,935
Total number of prescriptions filled in calendar year <sup>a</sup>	59,766	61,579	62,170	183,515
Number of Rx for non-formulary drugs	12,923	13,707	14,124	40,754
Number of Rx for formulary drugs	45,043	46,070	46,230	137,343
Total prescription costs in calendar year <sup>a</sup>	\$8,601,041	\$9,611,710	\$10,939,184	\$29,151,934
Total Rx cost for non-formulary drugs	\$3,397,247	\$3,819,438	\$4,255,950	\$11,472,635
Total Rx cost for formulary drugs	\$4,987,900	\$5,558,120	\$6,434,083	\$16,980,103

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

<sup>a</sup>Three percent of prescriptions filled in each calendar year were for drugs with "N" status for specific diagnoses under the Texas formulary. They are not considered non-formulary or formulary drugs in this study. Therefore, the total number of prescriptions and prescription costs do not add up to the sum of non-formulary and formulary drug components.

Key: Rx: prescriptions.

Another cost driver is the prescribing of brand name drugs. On average, a brand name drug is 80-85% more expensive than an available equivalent generic product.<sup>10</sup> Over the three-year period studied by WCRI, brand name medications accounted for 40-46% of non-formulary drug prescriptions and 13-17% of formulary drug prescriptions.<sup>11</sup> This correlates to 64-72% of the annual total costs for non-formulary drugs and 34-45% of the annual total costs for formulary drugs.<sup>12</sup> Assuming an average annual cost for non-formulary drugs of \$3,824,211 and for formulary drugs of \$5,660,034, the share of these costs spent on brand name drugs is roughly \$2.4-\$2.8 million and \$1.9-\$2.6 million, respectively.<sup>13</sup> While any possible savings are contingent on the availability of a generic equivalent and the difference in price between the brand name and generic drug, a reduction in the prescribing of brand name drugs could result in a decrease in the \$4.4-\$5.3 million spent annually by the State on brand name drugs.<sup>14</sup>

<sup>10</sup> U.S. Food and Drug Admin., *Facts about Generic Drugs*, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (last updated June 19, 2015).

<sup>11</sup> Thumula & Liu, *supra* note 6, at 18 tbl.3.2.

<sup>12</sup> *Id.*

<sup>13</sup> This data analysis was calculated by the North Carolina Industrial Commission. It has not been tested by WCRI or any other data analytics expert. These statements are based on the following calculations. *Id.* at 9 tbl.1.1 provides the total prescription cost for non-formulary drugs as \$11,472,635 and for formulary drugs at \$16,980,103 over the three years studied. These numbers were divided by three to calculate an average annual cost in each data set. Next, the average annual cost was multiplied by the respective percentage range of the annual total costs attributed to brand name drugs as found in *id.* at 18 tbl.3.2. This resulted in the dollar value of the range spent on brand name drugs.

<sup>14</sup> This data analysis was calculated by the North Carolina Industrial Commission. It has not been tested by WCRI or any other data analytics expert. These statements are based on the calculation of adding together the range data of non-formulary and formulary data sets, *see supra* note 13.

Expanding the view beyond just state employee claims, a November 17, 2015 Circular Letter provided by the North Carolina Rate Bureau to its member insurers indicated that more than \$302,000,000 in medical costs were paid out by workers' compensation carriers in calendar year 2014 for over 77,800 claims.<sup>15</sup> These claims included both indemnity and medical only claims for which there were medical services rendered in 2014 and that were reported via the NCCI medical data call.<sup>16</sup> Attached to the Circular Letter was a report by the National Council on Compensation Insurance ("NCCI") for the North Carolina Rate Bureau published in 2015. The NCCI report stated that drug-related expenses accounted for 13% of medical payments in Service Year 2014.<sup>17</sup> For medical services provided in 2014, drug expenses accounted for approximately \$39 million.<sup>18</sup> The report further indicated that for those prescription transactions reported with an NDC (National Drug Code), brand name drugs accounted for 17% of the prescription counts and 49% of the paid dollars.<sup>19</sup>

### **B. Projected Savings from Use of a Drug Formulary in Workers' Compensation Claims**

The results of the WCRI study, outlined below, indicate that a workers' compensation drug formulary could result in significant cost savings in North Carolina. A clearly defined drug formulary would require preauthorization for non-formulary drugs, which account for, on average, 22%-23% of all annual prescriptions for North Carolina State employees.<sup>20</sup> Requiring such preauthorization can significantly reduce the unnecessary prescribing of non-formulary drugs, as illustrated by other states that have successfully implemented a drug formulary for workers' compensation claims.<sup>21</sup> For example, the impact of a formulary in Texas was a 70% reduction in non-formulary drug prescriptions and 0% substitution with formulary drugs.<sup>22</sup> Similarly, in Ohio, a single payor state, the implementation of a formulary reduced opioid prescriptions by 25%, muscle relaxant prescriptions by 74%, and total prescription drug costs by 15%.<sup>23</sup> Thus, there is significant potential for reducing the number of non-formulary drug prescriptions to North Carolina State employees, and thereby significantly reducing the total prescription costs incurred by the State of North Carolina.

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<sup>15</sup> Joanna Biliouris, *Circular Letter to All Member Companies*, 1 (2015), available at <http://www.ncrb.org/Portals/0/ncrb/circular%20letters/workers%20comp/2015/C-15-22%202015%20Medical%20Data%20Call%20Report%20-%20North%20Carolina.pdf>.

<sup>16</sup> *Id.*

<sup>17</sup> Nat'l Council on Comp. Ins., *Medical Data Report for the State of North Carolina*, 4 chart4 (2015), available at <http://www.ncrb.org/Portals/0/ncrb/circular%20letters/workers%20comp/2015/C-15-22%202015%20Medical%20Data%20Call%20Report%20-%20North%20Carolina.pdf>.

<sup>18</sup> Note that the data and figures in this paragraph apply to the costs for workers' compensation insurers. These amounts do not include costs incurred by self-insured employers in North Carolina.

<sup>19</sup> Nat'l Council on Comp. Ins., *supra* note 17, at 42 chart35.

<sup>20</sup> Thumula & Liu, *supra* note 6, at 17 tbl.3.1.

<sup>21</sup> *Id.* at 25-26.

<sup>22</sup> *Id.* at 11.

<sup>23</sup> *Id.* at 25.

The WCRI study demonstrates that application of a Texas-like drug formulary in workers' compensation claims made by State employees would have saved the State of North Carolina up to \$8.7 million from calendar years 2012 through 2014. WCRI's statistical analysis takes into consideration a number of variables, including potential variations in physician prescribing practices, which could affect the impact of the drug formulary. The ultimate cost savings achieved by a drug formulary would depend on the drug formulary adopted, the degree to which the prescribing of non-formulary drugs is reduced, and the rate of substitution of non-formulary drugs with drugs that do not require preauthorization. WCRI hypothesizes that North Carolina could see a reduction in total prescription costs for State employee claims ranging from 4% up to 30%. This correlates to an average potential savings range of \$1,367,460 to \$8,730,040 over the three years studied. Divided into annual increments, the range of savings per year, on average, would be approximately \$455,820 to \$2,910,013.<sup>24</sup>

The Commission anticipates physician-prescribing patterns in North Carolina to be similar to the Texas trends. Texas physicians adjusted prescribing patterns in two significant ways following the implementation of a drug formulary. First, physicians in Texas reduced prescriptions for non-formulary drugs by 70%.<sup>25</sup> Second, physicians in Texas infrequently substituted formulary drugs for non-formulary drugs, choosing not to write a prescription in lieu of substituting a formulary drug.<sup>26</sup> Various factors may impact the rate of substitution of formulary drugs for non-formulary drugs. Those factors include frequency of physician dispensing<sup>27</sup>, patient needs, and availability of physicians' preferred substitutes.<sup>28</sup> Ultimately, the implementation of a formulary in Texas resulted in a 30% reduction in total prescription costs.<sup>29</sup> By following the Texas model or a similar model, the Commission believes similar results could be achieved in North Carolina, saving up to approximately \$2,900,000 per year for State employee claims.

While the costs associated with workers' compensation claims for employers other than the State of North Carolina will surely differ, it stands to reason that a drug formulary would result in savings on pharmacy costs for all employers and carriers if instituted for all claims. According to a WCRI study published in June 2014 using 2011-2012 claims cost data from private insurance carriers, it was estimated that the application of a Texas-like drug formulary to North Carolina claims could result in a reduction in drug costs up to 18%, depending on physician prescribing practices.<sup>30</sup> A complete copy of this WCRI report entitled "Impact of a Texas-Like Formulary in Other States" can be found at Appendix 3.

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<sup>24</sup> All statements in this paragraph are attributed to *id.* at 23 tbl.3.5.

<sup>25</sup> *Id.* at 11.

<sup>26</sup> *Id.*

<sup>27</sup> See N.C. Gen. Stat. § 97-26.2 (2015) for an example of recent legislation regarding physician dispensing of medication in workers' compensation claims.

<sup>28</sup> Thumula & Liu, *supra* note 6, at 27.

<sup>29</sup> *Id.* at 15.

<sup>30</sup> Vennela Thumula & Te-Chun Liu, Workers Comp. Research Inst., *Impact of a Texas-Like Formulary in Other States* 38 fig.4.2 (2014).

Although the figure of 18% in savings from the 2014 study appears to contrast with the 30% reduction cited in the WCRI study for this report, it is important to keep in mind that there could be several reasons for the range in savings. First, the 2014 study was based on one year of data. Second, the 2014 study report indicated potential limitations due to incomplete data reporting. Finally, a lack of adjustment for differences in the case mix severity between states in the 2014 report could have contributed to the range in savings between the 2014 report and the most recent WCRI report.<sup>31</sup>

The WCRI analyses mentioned here focus on the application of the Texas ODG drug formulary model. The Commission recommends continued study regarding the potential savings and other advantages of selecting a formulary “off the shelf,” such as ODG or ACOEM, or creating its own formulary with the advice of medical and pharmaceutical experts. There are significant costs and benefits associated with each option. The Commission would consider, among other things, initial and ongoing implementation expenses, resources required to maintain the formulary, including regular updates, and the efficiency and efficacy of the treatment provided to the injured worker.

Another important consideration when discussing potential savings is the frequency of prescriptions for brand name drugs. Mandating the substitution of an available generic equivalent over a brand name drug could also result in cost savings to the State of North Carolina workers’ compensation system. When available, a generic would be required for all drugs, absent specifically defined exceptions for medical necessity. A generic mandate could be implemented relatively quickly and be effective while a comprehensive drug formulary is further studied.

On average, a brand name drug is 80-85% more expensive than the generic equivalent.<sup>32</sup> A reduction in the prescribing of more costly brand name drugs would correlate to significant savings in overall prescription drug costs.<sup>33</sup> Per WCRI’s data analyzing calendar year 2014, approximately 2.5% of all brand name prescriptions filled for State employee workers’ compensation claims had an equivalent generic drug available.<sup>34</sup> Accordingly, a generic mandate would have realized approximately \$360,000 in savings in 2014.<sup>35</sup> CorVel’s private formulary, which applied to State employee claims over the year analyzed, explicitly set forth a preference for substituting a generic equivalent over brand name drugs. For employers, carriers, TPAs, and PBMs that do not already have such a control in place, the Commission would anticipate even greater savings.

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<sup>31</sup> *Id.* at 11.

<sup>32</sup> U.S. Food and Drug Administration, *supra* note 10.

<sup>33</sup> See Washington’s comments *infra* Section VI Appendix 2 at 7 (“L&I has saved millions through its industry-leading, high generic use rate. Of all prescriptions paid by L&I in fiscal year 2015, only 8% are for brand drugs.”).

<sup>34</sup> Thumula & Liu, *supra* note 6, at 17 n.2.

<sup>35</sup> *Id.*

The Commission acknowledges that there would necessarily be administrative costs associated with formulary implementation. For this and other reasons, the Commission wishes to study formulary implementation further to ensure that if a drug formulary is put in place, it will maximize cost savings without imposing heavy ancillary implementation costs. As part of this study, the Commission has considered the importance of streamlined administrative procedures.<sup>36</sup> The Commission anticipates extensive stakeholder input as it continues to study implementation of a drug formulary and related procedures.

### **C. Additional Benefits of a Drug Formulary**

While adoption of a drug formulary and associated treatment guidelines may result in significant cost savings to the State and to the workers' compensation system, the more pressing and significant motivator is improvement in the care provided to injured workers. The pharmacy-related cost savings would accrue to the direct benefit of self-insured employers or private insurance carriers and the indirect benefit of privately insured employers. Conversely, the benefits for injured workers would come in the form of streamlined access to appropriate medical treatment. The Commission recognizes that a formulary should have the primary effect of providing an injured worker with the safest and least expensive effective medication for his or her condition. The substantial benefits of a drug formulary for the injured worker will be discussed below.

#### **1. More Efficient and Responsible Delivery of Medications to Injured Workers**

An improved method for the delivery of medications to injured workers is a substantial potential benefit to be derived if North Carolina adopts a drug formulary. A drug formulary and related treatment guidelines take into account the worker's injury and diagnosis in specifying the medications that are most appropriate for that specific diagnosis. The drugs on the formulary would be automatically approved, as these drugs do not require preauthorization by the carrier in order for the pharmacist to fill the prescription for the injured worker. Drugs not on the formulary may still be obtained by going through the preauthorization procedures, if approved by carriers.

Additionally, a streamlined decision process for review of a preauthorization denial of non-formulary drugs would help injured workers receive care without waiting for an unspecified amount of time to begin their treatment. An expeditious appeals process, with defined timeframes for decisions at each stage, would play a large role in realizing the efficiency of the formulary.<sup>37</sup>

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<sup>36</sup> See discussion *infra* Section IV.D.

<sup>37</sup> See discussion *infra* Section IV.D.

The Commission would consider a number of tools to promote the efficient and safe dispensing of medication. The Commission will explore the possibility of a first fill protocol that would allow an injured worker to fill a prescription for a limited period of time. This protocol would ensure the injured worker access to medication during the initial preauthorization process. At present, North Carolina's State employee workers' compensation program limits the initial prescription of any medication to 10 days. This short supply can allow the injured worker and physician to re-evaluate and adjust the medication based on the individualized need. Not only does this cut costs by limiting surplus medications, but it also reduces the risk that potent medications will be abused or diverted to other users.<sup>38</sup>

If a formulary is adopted, the Commission anticipates that a stakeholder education and training campaign would be required at first to ensure understanding of and adherence to the enacted formulary. As physicians prescribe appropriate medication on the formulary, pharmacists would be able to fill these prescriptions without preauthorization at the point of dispensing. A consistent jurisdiction-wide drug formulary would alleviate confusion and save physicians, pharmacists, employers, carriers, TPAs, and PBMs considerable time and resources. Similarly, it would also save the injured worker from the frustration of being denied medication at the pharmacy, the hassle of making multiple trips to the pharmacy, and the discomfort of extended delays to receive prescribed medication. Reducing the "hassle factor" for all parties involved in workers' compensation claims would support a more efficient system in which injured workers timely receive necessary care that promotes good outcomes.

## **2. Provision of Reasonable and Necessary Medical Care to Injured Workers**

The North Carolina Workers' Compensation Act, specifically N.C. Gen. Stat. 97-2(19), defines "medical compensation" as medical treatment, including, but not limited to, medicines, that "may reasonably be required to effect a cure or give relief and for such additional time as, in the judgment of the Commission, will tend to lessen the period of disability . . . ." Any drug formulary established for the State should focus on providing the safest and least expensive effective medicines for workers' compensation injuries without compromising the provision of reasonable and necessary care to the injured worker. While other states that have adopted formularies have experienced cost savings, without exception each state with which the Commission has consulted emphasized that the primary benefit derived from a drug formulary is the improvement in medical care provided to the injured worker.<sup>39</sup> If the implementation of a formulary and associated treatment guidelines prove justified after further study, the

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<sup>38</sup> See Arkansas' comments *infra* Section VI Appendix 2 at 9 ("Several clinical management tools can be employed through the drug formulary that can further enhance patient care. For example, quantity limits (dispensing limits) can be applied to drugs prone to wastage or overdone. . . . This can steer usage to safer, better or more cost-effective alternatives.").

<sup>39</sup> See Tennessee's comments *infra* Section VI Appendix 2 at 8 (anticipating the impact of a formulary on the treatment of injured workers to "provide safer patient care by monitoring of drug-drug interactions, potentially dangerous combinations and help with the epidemic of prescription drug abuse by encouraging more conversation between physician and patient.").

Commission would anticipate extensive consultation with North Carolina medical experts to assist with the selection or development and application of a drug formulary.

To further this end, supporting treatment guidelines could be adopted contemporaneously with or prior to implementation of a drug formulary. Treatment guidelines are applied in conjunction with a drug formulary in every state that has adopted a formulary.<sup>40</sup> Medication-related treatment guidelines would help structure the appropriate medication regimens for each individualized case to treat the injury and rehabilitate the worker. In practice, physicians would refer to both the treatment guidelines and the drug formulary to inform their selection of the safest effective medications for each injured worker they treat.<sup>41</sup>

The Commission recognizes the need to transition existing claims off of dangerous medication regimens in conjunction with implementation of a formulary. If a drug formulary is adopted, one tool that the Commission might consider is a phase-in approach. While new claims as of a date certain would automatically fall under the formulary, legacy claims with an injury date prior to the date certain would be grandfathered in over a period of time, allowing physicians to gradually and safely taper their patients' treatment regimen into compliance with the drug formulary, if appropriate for their conditions.

This was the process adopted by Texas. The Texas Department of Insurance, Division of Workers' Compensation, used a two-year phased implementation process as a part of an overall strategy for their drug formulary. Texas began using the Official Disability Guidelines (ODG) Appendix A on September 1, 2011 for injuries occurring on or after that date. Claims predating September 1, 2011 were then gradually folded into the formulary, allowing two years to transition legacy claims into compliance with the formulary by September 1, 2013. This multi-stage phase-in gave physicians time to evaluate older claims and modify their treatment regimens, if necessary, to comply with the formulary. In appropriate cases, the injured workers were tapered off of high-risk opioid and narcotic drugs and transitioned onto the safest effective medication regimen. Based on the physician's evaluation of the most appropriate and safest effective medication, exceptions to the formulary could be carved out on a case-by-case basis.<sup>42</sup>

A drug formulary and related treatment guidelines can set parameters for when opioid and other high-risk pharmaceutical treatment is appropriate. Steering the trend away from early and ongoing reliance on opioids for pain management can improve treatment outcomes,<sup>43</sup>

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<sup>40</sup> See table *infra* Section VI Appendix 4. See also comments *infra* Section VI Appendix 2 (discussing the importance of treatment guidelines in conjunction with a drug formulary).

<sup>41</sup> See Washington's comments *infra* Section VI Appendix 2 at 7 ("It is important to recognize that a formulary can help control prescription drug cost but is not effective in managing the prescription benefit as a stand-alone effort. In particular, it does not ensure that opioids and other high risk drugs are prescribed appropriately. For this, treatment guidelines and coverage criteria play an important role.").

<sup>42</sup> Thumula & Liu, *supra* note 6, at 15. See also comments *infra* Section VI Appendix 2 at 2-4.

<sup>43</sup> See, e.g., Gary M. Franklin et al., *Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries*, 33 Spine 199, 199 (2008) (concluding that injured workers with acute back injuries who received opioids for more than 7

while providing high quality care to injured workers. Medical research supports the combination of acetaminophen and a nonsteroidal anti-inflammatory drug (“NSAIDs”), such as Ibuprofen, as a substitute treatment in lieu of opioids.<sup>44</sup> The Centers for Disease Control and Prevention (“CDC”) addressed the effectiveness of alternative medications, such as acetaminophen and NSAIDs, for the treatment of pain instead of prescribing opioids in the recently released CDC Guideline for Prescribing Opioids for Chronic Pain.<sup>45</sup> Their evaluation found that several nonpharmacological and non-opioid treatments have been effective in managing chronic pain, including use of acetaminophen as a first-line treatment for pain management.<sup>46</sup> In fact, the Guideline explicitly states that “[n]onpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.”<sup>47</sup>

While individual patient needs and outlier cases must be considered to provide reasonable and necessary care for all injured workers, the implications of the growing body of evidence regarding current pain treatment methods should not be ignored. Additional research and consideration would be needed on this and other medical issues in order to select or develop a drug formulary and related treatment guidelines.

### **3. Disincentives for Medical Providers to Prescribe Expensive or Habit-Forming Drugs**

#### **i. Disincentives to Prescribe Brand Name Drugs**

As discussed above in Section IV.A, brand name drugs are a cost driver in workers’ compensation cases. A drug formulary that requires the substitution of generic medications that are clinical equivalents to the brand name medication would assist in lowering costs by guiding physicians and pharmacists to prescribe and dispense generic drugs where appropriate. If a brand name drug has no generic equivalent and is not on the formulary, preauthorization would be required. This may result in physicians choosing instead to prescribe a drug that is

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days and received more than 1 opioid prescription were associated significantly with work disability at 1 year) (for a copy of this journal article, please contact the Industrial Commission); Barbara S. Webster et al., *Relationship Between Early Opioid Prescribing for Acute Occupational Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery at Late Opioid Use*, 32 *Spine* 2127, 2127 (2007) (concluding that those who received more than 450 mg MEA [morphine equivalent amount] were, on average, disabled 69 days longer than those who received no early opioids, suggesting that the use of opioids for the management of acute LBP may be counterproductive to recovery) (for a copy of this journal article, please contact the Industrial Commission).

<sup>44</sup> See, e.g., Christopher J. Derry et al., *Single Dose Oral Ibuprofen plus Paracetamol (Acetaminophen) for Acute Postoperative Pain*, 6 *Cochrane Database of Systematic Rev.* 1, 2 (2013), available at <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010210.pub2/epdf>; Donald Teater, Nat’l Safety Council, *Evidence for the Efficacy of Pain Medications* 4 (2014), available at <http://www.nsc.org/learn/about/Pages/Over-the-counter-pain-medications.aspx>.

<sup>45</sup> Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain*, 65 *Morbidity & Mortality Wkly. Rep.*, Mar. 2016, at 13, available at <http://www.cdc.gov/media/modules/dpk/2016/dpk-pod/rr6501e1er-ebook.pdf>.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.* at 17.

on the formulary or to not prescribe medication at all. This is the pattern that emerged in Texas and could reasonably be expected to occur here in North Carolina.<sup>48</sup>

Generic medications have the same FDA standards as brand name drugs, utilize the same active ingredients, and have the same strength, quality, and purity standards. Additionally, the dosage and intended uses are the same for generics as they are for brand name drugs. Generic drugs that meet the above criteria are considered to be equivalent to brand names even though they may differ in shape, packaging, coloring, flavoring, expiration date, labeling, or other characteristics.<sup>49</sup>

The Commission recommends that a generic drug substitution mandate be implemented through administrative rulemaking during its continued study of drug formularies and related treatment guidelines. A generic mandate could later be incorporated into a more comprehensive drug formulary. States that have adopted a generic mandate have adopted procedures to account for situations where a brand name drug is shown to be medically necessary.<sup>50</sup> Such procedures provide guidelines for physicians to request a brand name medication when they believe it is appropriate.<sup>51</sup> In establishing a generic mandate, the Commission would analyze the experience of other states and consider the most efficient method for requesting a brand name medication when needed.

## **ii. Disincentives to Prescribe Habit-Forming Opioids and Narcotics**

Adoption of a drug formulary in conjunction with related treatment guidelines could aid in curbing unnecessary access to opioids and other habit-forming narcotics at the point of prescription.<sup>52</sup> A drug formulary can give the physician a concrete foundation upon which to rely in justifying a refusal of an opioid prescription when such a treatment is not necessary or appropriate. A drug formulary and related treatment guidelines can also offer alternative medication regimens more suitable for first-line therapy, though opioids would be available when medically necessary.<sup>53</sup>

Opioids have commonly been prescribed in workers' compensation claims due to the nature of many work-related injuries. Recent studies have addressed the dangerous potential of these

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<sup>48</sup> Thumula & Liu, *supra* note 6, at 17-18.

<sup>49</sup> All statements in this paragraph are attributed to U.S. Food and Drug Administration, *Orange Book Preface*, <http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm> (last updated Sept. 29, 2015).

<sup>50</sup> See, e.g., Jesse C. Vivian, *Generic Substitution Laws*, 33 US Pharm. Generic Drug Rev. 30, tbl. 2. (2008), available at <http://www.uspharmacist.com/content/s/44/c/9787/>.

<sup>51</sup> See, e.g., *id.*

<sup>52</sup> Denise Johnson & Don Jergler, *Opioid Epidemic Plagues Workers' Comp*, Ins. J., May 17, 2013, <http://www.insurancejournal.com/news/national/2013/05/17/292528.htm>. See also comments *infra* Section VI Appendix 2 (discussing the reduction in opioid prescribing as a result of the adoption of a drug formulary and treatment guidelines).

<sup>53</sup> See discussion *supra* Section IV.C.2.

drugs.<sup>54</sup> Reliance on opioids for the treatment of injured workers carries specific implications in workers' compensation claims.<sup>55</sup> While opioids may mask an injured workers' pain, they may not provide optimal treatment to improve the injured workers' condition.<sup>56</sup> A study of the relationship between early opioid prescribing and treatment outcomes concluded, "Early use of higher morphine equivalent amounts of opiates in acute LBP [lower back pain] was significantly associated with worse long-term outcomes, including prolonged disability, increased medical utilization including surgery, and continued opioid use. Given the negative association between early opioid prescribing and outcomes, it is suggested that the more intensive use of opioids for the management of acute LBP may be counterproductive to recovery."<sup>57</sup> A drug formulary that deters the unnecessary dispensing of opioids could positively impact the treatment provided in workers' compensation claims and the ultimate healing and outcome for the injured worker.

After the adoption of a formulary and treatment guidelines, other states saw a decrease in opioid prescriptions. In Ohio, from calendar year 2011 when their drug formulary went into effect, through calendar year 2015, 26% fewer injured workers received opioids, and narcotic prescriptions dropped by 41%.<sup>58</sup> Over the same study period, Ohio's total prescription drug costs decreased 28.6%, netting a \$38.6 million savings.<sup>59</sup> In 2014, the prescription costs of opioids specifically were down 36% from 2010, a reduction of \$19.9 million.<sup>60</sup> WCRI's data analysis of North Carolina State employees' workers' compensation claims determined that opioids accounted for 30% of all non-formulary drug prescriptions from calendar years 2012 through 2014.<sup>61</sup> Additionally, WCRI found that one-third of the non-formulary drug spending was for long-acting opioids.<sup>62</sup> The results achieved in other states bolster WCRI's hypothesis that adoption of a drug formulary can decrease opioid use and supports the Commission's recommendation to move forward with further study regarding the implementation of a drug formulary in North Carolina.<sup>63</sup>

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<sup>54</sup> See discussion *infra* Section IV.C.4.

<sup>55</sup> See, e.g., Nat'l Safety Council, *Prescription Pain Medications: A Fatal Cure for Injured Workers 2* (2014), available at <http://safety.nsc.org/workerscomp>.

<sup>56</sup> Cf. Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications 2* (2015), available at <http://www.nsc.org/RxDrugOverdoseDocuments/900006497-ADV-Rx-Side-Effects-WhitePaper.pdf>.

<sup>57</sup> Webster, *supra* note 43, at 2131.

<sup>58</sup> See Ohio's comments *infra* Section VI Appendix 2 at 5.

<sup>59</sup> See Ohio's comments *infra* Section VI Appendix 2 at 5.

<sup>60</sup> *Ohio BWC: Formulary Driving Decline in Opioid Prescriptions*, Work Comp. Wire (May 22, 2015), <http://www.workcompwire.com/2015/05/ohio-bwc-formulary-driving-decline-in-opioid-prescriptions-focus-turns-to-dangerous-drug-regimens/>.

<sup>61</sup> Thumula & Liu, *supra* note 6, at 19.

<sup>62</sup> *Id.* at 26.

<sup>63</sup> *Id.* at 6. See also Texas' comments Section VI Appendix 2 at 3 ("The Texas formulary has resulted in a 65% reduction in the number of [nonformulary] opioid prescriptions for new claims and a 9% reduction in the number of [formulary] opioid prescriptions for new claims.").

#### 4. Supplemental Information Regarding Opioid Overuse, Abuse, and Overdose as a Public Health Crisis

Opioid use dates back thousands of years in the treatment of pain.<sup>64</sup> The strong psychotherapeutic agents in opioids cultivated heavy reliance on these powerful drugs for the treatment of pain.<sup>65</sup> Before the 1980s, opioid treatment was “reserved for only the most severe chronic pain conditions, primarily terminal cancer.”<sup>66</sup> Yet a trending shift in the late 1980s and 1990s resulted in growing acceptance of the use of opioids for chronic pain and acute pain management.<sup>67</sup> In the last 20 years, consumption of opioids in the United States has increased by more than 600 percent.<sup>68</sup> However, the negative side effects of opioids are often overlooked. These include the damage opioid usage can have on the body, as well as the potential for tolerance, dependence, addiction, and overdose death.<sup>69</sup>

Opioids are highly addictive and potentially lethal scheduled controlled substances.<sup>70</sup> “Opioids account for more deaths than any other medication. More than 16,000 people die every year from opioid overdose.”<sup>71</sup> North Carolina is not exempt from this pervasive epidemic of unintentional poisoning deaths. In a recent report, the CDC indicated that, in year 2012, 96.6 opioid prescriptions were written per 100 persons in North Carolina.<sup>72</sup> According to the North Carolina Injury and Violence Prevention Branch of the Division of Public Health, the number of drug overdose deaths has increased 330% from calendar years 1999 to 2014.<sup>73</sup> In fact, prescription opioids are involved in more drug deaths than cocaine

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<sup>64</sup> See, e.g., Teater, *supra* note 56, at 2; Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16(5) *Experimental & Clinical Psychopharmacology* 405, 406 (2008), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/>.

<sup>65</sup> Teater, *supra* note 44, at 6.

<sup>66</sup> Webster, *supra* note 43, at 2127.

<sup>67</sup> See, e.g., *id.* at 2127; Laxmaiah Manchikanti et al., *Opioid Epidemic in the United States*, 15 *Pain Physician J.* ES9, ES10 (2012) (“Starting in the late 1990’s, state medical boards curtailed restrictions on laws governing the prescribing of opioids for the treatment of chronic non-cancer pain, resulting in a dramatic increase in the number of prescriptions.”), available at <http://painphysicianjournal.com/2012/july/2012;15;ES9-ES38.pdf>.

<sup>68</sup> See, e.g., Teater, *supra* note 44, at 6; Teater, *supra* note 56, at 2.

<sup>69</sup> See Nora D. Volkow, *America’s Addiction to Opioids: Heroin and Prescription Drug Abuse*, National Institute on Drug Abuse (May 14, 2014), <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse> (“The consequences of this abuse have been devastating and are on the rise. For example, the number of unintentional overdose deaths from prescription pain relievers has soared in the United States, more than quadrupling since 1999. There is also growing evidence to suggest a relationship between increased non-medical use of opioid analgesics and heroin abuse in the United States.”). See also Teater, *supra* note 56 (discussing the numerous side effects associated with opioid use).

<sup>70</sup> U.S. Drug Enforcement Admin., *Drug Schedules*, <http://www.dea.gov/druginfo/ds.shtml> (last visited Mar. 22, 2015).

<sup>71</sup> Teater, *supra* note 56, at 6.

<sup>72</sup> Leonard J. Paulozzi et al., *Vital Signs: Variation among States in Prescribing of Opioid Pain Relievers and Benzodiazepines*, 63(26) *Morbidity and Mortality Wkly. Rep.* 563, Table (2014), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm>.

<sup>73</sup> North Carolina Injury & Violence Prevention Branch, *Prescription and Drug Overdoses*, [ncdhhs.gov](http://www.injuryfreenc.ncdhhs.gov/About/PrescriptionDrugOverdoseFactSheet-2014-7-JAN-2016.pdf) (last reviewed Jan. 2016), <http://www.injuryfreenc.ncdhhs.gov/About/PrescriptionDrugOverdoseFactSheet-2014-7-JAN-2016.pdf>.

and heroin combined.<sup>74</sup> Furthermore, drug overdoses are “more numerous than motor vehicle crash deaths in the United States.”<sup>75</sup>

Based on a preliminary review, the Commission is aware of at least nine death claims filed for the overdose deaths of injured workers who received opioids for treatment of their work injuries and then died from accidental overdose. Although this number is not large, and likely only represents a fraction of injured workers who battle addiction and substance abuse issues stemming from opioid prescriptions related to their work injury, any such deaths are to be prevented where possible.

Opioids are prevalent in treatment regimens for workers’ compensation claims.<sup>76</sup> Despite the widespread prescription of opioids, growing research and evidence suggest that “the increased use of these drugs does not result in better treatment outcomes.”<sup>77</sup> A study by Washington’s Department of Labor and Industries concluded that “receiving more than a one week supply of opioids soon after an injury doubles a worker’s risk of disability one year later.”<sup>78</sup> Another study found that “receipt of higher amounts of morphine equivalent medications in early treatment was significantly associated with adverse outcomes including higher medical costs and prolonged disability, higher risk for surgery, and continued use of opioids.”<sup>79</sup> “In other words, for those with equivalent injuries and levels of pain, those with no opioids did better than those with higher dose opioid treatment.”<sup>80</sup> In some cases, the negative side effects associated with opioids appear to exceed the treatment benefits.<sup>81</sup>

While a number of measures must be taken by physicians, law enforcement, policymakers, and others to combat the growing problems that are associated with opioid abuse, one positive step the Commission could take in the context of the workers’ compensation system specifically is the enactment of a drug formulary and associated treatment guidelines. Treatment guidelines can establish thresholds and precautions in prescribing opioids.<sup>82</sup> A

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<sup>74</sup> *Id.*

<sup>75</sup> Johnson & Jergler, *supra* note 52, (quoting Dr. Leonard J. Paulozzi, a medical epidemiologist with CDC’s National Center for Injury Prevention and Control).

<sup>76</sup> See, e.g., Workers Comp. Research Inst. *Interstate Variations in Use of Narcotics* (2nd ed. 2014), available at [https://www.wcrinet.org/STUDIES/protected/exec\\_summaries/use\\_narcotics2-es.html](https://www.wcrinet.org/STUDIES/protected/exec_summaries/use_narcotics2-es.html).

<sup>77</sup> Nat’l Safety Council, *supra* note 55, at 2.

<sup>78</sup> Franklin, *supra* note 43, at 199.

<sup>79</sup> Webster, *supra* note 43, at 2130.

<sup>80</sup> Teater, *supra* note 56, at 2 (discussing Webster, *supra* note 43).

<sup>81</sup> Cf. Gary M. Franklin, *Opioids for Chronic Noncancer Pain*, 83 *Neurology* 1277, 1277 (2014) (Proposing that “the risk of death, overdose, addiction or serious side effects with prescription opioids outweigh the benefits in chronic, non-cancer conditions such as headache, fibromyalgia and chronic low back pain.”) available at <http://www.neurology.org/content/83/14/1277.full>.

<sup>82</sup> See Int’l Ass’n of Indus. Accident Bds & Comm’ns, *Reducing Inappropriate Opioid Use in Treatment of Workers* 7 (2013) (“Implementation of treatment guidelines can improve the chances that a doctor will comfortably prescribe opioids when indicated, avoid inappropriate use of opioids, and assist the patient in finding other therapies and aids for dealing with chronic pain.”) available at <http://www2.leg.state.vt.us/CommitteeDocs/2014/House%20Commerce/Workers%60%20Compensation%20Issues/W~Peter%20Rousmaniere~Reducing%20Inappropriate%20Opioid%20Use%20in%20Treatment%20of%20Injured%20Workers~2-5-2014.pdf>.

formulary, requiring preauthorization before dispensing opioids, could provide a level of protection, allowing opioid prescriptions in cases in which such treatment is medically necessary.<sup>83</sup>

As part of its continued study of this issue, the Commission believes it is important to reach out to entities that work more directly with opioid abuse issues and consider tools they have already developed. For example, the North Carolina Medical Board's *Policy for the Use of Opiates for the Treatment of Pain* emphasizes the importance of screening a patient for a history of addiction or depression before prescribing certain addiction-forming medications.<sup>84</sup> There is also a database called the North Carolina Controlled Substances Reporting System ("CSRS") that physicians can check prior to prescribing a controlled substance.<sup>85</sup> It may also be possible to require injured workers who show opioid abuse tendencies to participate in a pharmacy "lock-in" similar to the program Medicaid uses requiring patients to fill all prescriptions at one pharmacy.<sup>86</sup> If effective and appropriate, such tools could be incorporated into a drug formulary and related treatment guidelines for workers' compensation claims.

#### **D. Adoption of an Efficient Review and Appeal Process for Requests for Off-Formulary Drugs**

##### **1. Development of Review and Appeal Process through Further Study and Stakeholder Input**

If adopted, successful implementation of a drug formulary for workers' compensation claims in North Carolina would require efficient preauthorization, utilization review ("UR"), and appeals procedures for those claims in which a physician or injured worker desires to pursue authorization of a drug excluded from the adopted formulary. Such review and appeals procedures would be created through formal administrative rulemaking with wide stakeholder

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<sup>83</sup> See Nat'l Safety Council, *supra* note 55, at 13 ("PBMs have begun to institute drug formularies and system flags to identify dangerous prescribing combinations and suspicious prescribing patterns that may indicate misuse or inappropriate prescribing. Drug formularies can require medical review and approval before payment for opioid pain medication prescriptions is authorized. Several state workers' compensation programs, most notably Texas, have implemented formularies requiring prior approval for opioid pain medications.").

<sup>84</sup> N.C. Med. Bd., *Policy for the Use of Opiates for the Treatment of Pain* 8 (2014), available at [http://www.ncmedboard.org/images/uploads/other\\_pdfs/Policy\\_for\\_the\\_Use\\_of\\_Opiates\\_for\\_the\\_Treatment\\_of\\_Pain\\_June\\_4\\_2014.pdf](http://www.ncmedboard.org/images/uploads/other_pdfs/Policy_for_the_Use_of_Opiates_for_the_Treatment_of_Pain_June_4_2014.pdf).

<sup>85</sup> E.g., N.C. Dep't of Health & Human Servs., *Controlled Substance Reporting System: Practitioner's Training Guide* 5 (2015) ("The system materially assists state regulators and practitioners authorized to prescribe and dispense controlled substances in the prevention of diversion, abuse, and misuse of controlled substance prescription medication."), available at [https://nccsrsp.hidinc.com/NC\\_RxSentry\\_TrainingGuide\\_Practitioners\\_v.1.1.pdf](https://nccsrsp.hidinc.com/NC_RxSentry_TrainingGuide_Practitioners_v.1.1.pdf).

<sup>86</sup> See S. Rose Werth et al., *North Carolina Medicaid Recipient Management Lock-In Program: The Pharmacist's Perspective* 20(11) J. Managed Care & Specialty Pharmacy 1122, 1122 (2014), available at <https://www.communitycarenc.org/media/publications/north-carolina-medicaid-recipient-management-lock-.pdf>; Lisa Weeks, *Curbing Prescription Drug Abuse in Medicaid*, J. Legis. Health Care Oversight Comm. (Oct. 12, 2010), <http://www.ncleg.net/documentsites/Committees/JLHCOC/2010%20Interim%20Committee%20Meetings/October%202012,%202010/Lisa%20Weeks.pdf>.

input. The Commission has broad authority pursuant to N.C. Gen. Stat. § 97-25.4 to adopt rules and guidelines for medical treatment. In order to fulfill the statutory mandate that the guidelines “ensure that injured employees are provided the services and care intended by” the Workers’ Compensation Act, such guidelines must include procedures to follow in cases where the injured worker or physician seeks a variation from the standard.

In general, under a formulary, employers and insurance carriers would pay for non-formulary drugs if preauthorization is obtained from the carrier or if the drug is found to be medically necessary through a UR and appeals process. As part of its continued study, the Commission would explore the most efficient procedures for two scenarios: (1) how physicians could request preauthorization from a carrier before writing a prescription and (2) how carriers could review and approve or decline non-formulary prescriptions presented for filling by the injured worker at a pharmacy. These procedures would need to be developed with input from advocates for injured workers, physicians, pharmacists, self-insured employers, carriers, and PBMs to ensure swift access to needed medications and minimum disruption to business.

Implementation of a drug formulary and treatment guidelines would also require procedures to follow if a non-formulary prescription issued by a treating physician is denied by the carrier upon UR and the injured worker wants to make a legal appeal to the Commission. The Commission already has a streamlined medical motion procedure pursuant to N.C. Gen. Stat. § 97-25, but additional rules may be necessary to apply the procedure specifically to issues arising under a drug formulary.

## **2. Important Features of a Drug Formulary Review and Appeal Procedure**

Based on its study conducted so far and its experience and knowledge of the workers’ compensation system in North Carolina, the Commission projects that development of a successful drug formulary review and appeals procedure for North Carolina would require consideration of the basic features outlined below:

- 1) Initial Preauthorization by the Payor (carrier or self-insured employer)
  - i. A streamlined process and form for contacting the payor to obtain preauthorization.
  - ii. A brief, reasonable turnaround time for a decision by the payor.
  - iii. A limited-supply fill for prescriptions of certain non-formulary drugs during initial review.
  - iv. A streamlined process and form for communication of the payor’s decision to the injured worker and physician.
  - v. Requirements for including in the decision information about UR for the injured worker or physician.

- 2) UR by the Payor or a contracted Utilization Review Agent (“URA”)
  - i. A streamlined process and form for contacting the payor or its URA to obtain UR.
  - ii. A brief, reasonable turnaround time for a decision by the payor.
  - iii. A streamlined process and form for communication of the payor’s decision.
  - iv. Requirements for including appeal process information in the UR decision.
  - v. Requirements for licensure and specialization or certification for individuals who conduct UR and render denials.
- 3) Appeal to Industrial Commission following UR Decision
  - i. Streamlined form and procedure for appeal pursuant to G.S. 97-25.
  - ii. Reasonable, swift turnaround times for decisions.
- 4) Special procedures for emergency situations

Expedited procedure to request authorization directly from the Commission at any stage if a carrier denies a medication that has been previously authorized if denial could result in a detriment to the injured workers’ health.

The table found in Appendix 4 provides a basic summary of the preauthorization and UR procedures adopted by other states that have mandated drug formularies and related treatment guidelines in workers’ compensation claims. In addition, a number of other states are in the process of exploring drug formulary and/or treatment guideline implementation. See Appendix 5 for a sample flowchart of basic steps a drug formulary review and appeal procedure could have in North Carolina.

Further stakeholder input and research and evaluation are needed to develop an efficient set of review procedures to go with any drug formulary and related treatment guidelines adopted in North Carolina. While the Commission believes that further study is warranted, the Commission is confident that an efficient and effective set of procedures could be developed to implement a drug formulary without creating unreasonable burdens on stakeholders.<sup>87</sup>

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<sup>87</sup> See Texas’ comments *infra* Section VI Appendix 2 at 2 (“Texas has not seen an increase in complaints from injured employees or an increase in medical disputes since the implementation of the closed formulary.”).

## V. Industrial Commission Recommendations to the General Assembly

The results discussed in this report indicate that implementation of a drug formulary in North Carolina could result in lower pharmacy and treatment costs while still providing the necessary care to the injured worker. Given the complexity of drug formulary implementation, the Commission recommends additional time and resources be spent evaluating the costs and benefits associated with a formulary to ensure that any decided course of action would be the best fit for North Carolina.

In order to devote the necessary time and effort to fully exploring the nuances of implementing a formulary and medical treatment guidelines, as well as allowing for the opportunity to engage further with stakeholders, a no-sooner-than date could be stipulated. The Commission recommends, should a formulary be implemented, it would not take effect before July 1, 2018.

In the interim, potential savings can be realized through implementation of a generic mandate. As noted in Section IV.B above, a potential cost savings of \$360,000 could have been realized in calendar year 2014 for State employee claims had generic substitution been required during that time. Implementation of a generic mandate would not be contingent upon the outcome of the additional study of formulary implementation. Accordingly, this could be a straightforward and relatively quick action to reduce year-over-year drug costs. To facilitate this action, the Commission requests an exemption from the fiscal note requirement of N.C. Gen. Stat. § 150B-21.4 for purposes of making rules for a generic drug mandate.

Regarding action on the issue of opioid medications referenced above in Section IV.C, strong consideration will be given as to how opioids are treated in the North Carolina workers' compensation system. Recognizing that opioid abuse is an issue that does not restrict itself to the workers' compensation system, we recommend that the Commission's efforts be combined with those of other State agencies. This would help establish consistency in addressing the problem across State government.

Our study of drug formularies for State workers' compensation claims has revealed that all states that have adopted a drug formulary also adopted, or had in place already, medical treatment guidelines for treatment of injured workers. During its continued evaluation process of a drug formulary, the Commission will simultaneously consider the adoption of related treatment guidelines that would maximize the effectiveness of a drug formulary.

If the results of further study support efforts to implement a drug formulary and corresponding treatment guidelines, the Commission will utilize the broad authority granted to it in N.C. Gen. Stat. §§ 97-25.4 and 97-80. These statutes allow the Commission to adopt utilization rules and guidelines for medical treatment through administrative rulemaking, a process that ensures all stakeholders have the opportunity to participate in the discussion. Given the recommended ongoing study and anticipated engagement with stakeholders, the Commission requests an exemption from the fiscal note requirement of N.C. Gen. Stat. §

150B-21.4 for purposes of establishing rules for a drug formulary and any related treatment guidelines.

## **VI. Appendices**

Appendix 1 – Texas-Like Formulary for North Carolina State Employees  
(March 2016)

Appendix 2 – Comments on Drug Formularies from Other States' Workers'  
Compensation Officials

Appendix 3 – Impact of a Texas-Like Formulary in Other States (June 2014)

Appendix 4 – Table of Procedures in States with Drug Formularies

Appendix 5 – Sample Flowchart of Basic Steps in a Drug Formulary Review  
and Appeal Procedure

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## Appendix 1

### **Texas-Like Formulary for North Carolina State Employees (March 2016)**



# TEXAS-LIKE FORMULARY FOR NORTH CAROLINA STATE EMPLOYEES

*Vennela Thumula*

*Te-Chun Liu*

WC-16-19

March 2016

WORKERS COMPENSATION RESEARCH INSTITUTE  
CAMBRIDGE, MASSACHUSETTS

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Finally, any errors in the report are the sole responsibility of the authors.

**Vennela Thumula**  
**Te-Chun Liu**

Cambridge, Massachusetts  
March 2016

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## SUMMARY OF MAJOR FINDINGS

Session Law 2015-241 directed the North Carolina Industrial Commission to study the implementation of a drug formulary for workers' compensation claims filed by state government employees. The study was expected to consider the pharmacy-related expenses incurred by the state on an annual basis in state employee workers' compensation claims and the savings, if any, that would result from the use of a drug formulary for these claims, among other issues.<sup>1</sup> This report focuses on two major issues in the mandate—specifically, how a Texas-like closed formulary might affect the prevalence and costs of drugs prescribed to North Carolina state employees.<sup>2</sup> The report does not study the impact on patient outcomes and overall medical costs. Between January 1, 2012, and December 31, 2014, approximately 14,000 state employee claims received at least one prescription paid under the state employee workers' compensation program, and 183,000 prescriptions were associated with those claims. Over the three-year period, the state paid approximately \$29 million for prescription drugs filled by injured state employees, and there may be potential to save \$1.4 to \$8.7 million dollars with the adoption of a Texas-like formulary under a range of scenarios.

The major findings address the following questions:

- How frequently are non-formulary drugs that require preauthorization under the Texas closed formulary prescribed to North Carolina state employees? And what are the frequently prescribed non-formulary drugs?<sup>3</sup>
- What proportion of the prescription costs are for non-formulary drugs?
- If a Texas-like closed formulary is implemented, what are the potential prescription cost savings?

### THE PREVALENCE AND COST OF NON-FORMULARY DRUGS

- Non-formulary drug use was prevalent among North Carolina state employees. These drugs accounted for 23 percent of all prescriptions and 39 percent of total prescription costs filled in calendar year 2014. Non-formulary drug use was more frequent among older injuries because some non-formulary drugs, like long-acting opioids, are typically prescribed more often at a later stage of medical treatment. For instance, 10 percent of all prescriptions filled in calendar year 2014 were for non-formulary drugs among claims that were less than a year old, whereas the same measure was 27 percent among claims that were

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<sup>1</sup> Session law 2015-241 also required the Commission to study (1) whether the use of a drug formulary would result in a more efficient delivery of medications, provide workers with reasonable and necessary care, and provide disincentives for health care providers to utilize costly brand name drugs and habit-forming opioids; and (2) the adoption of an appeals process that would allow health care providers and injured workers to seek approval for the use of drugs that are not on the formulary's approved list. This report does not directly address these issues.

<sup>2</sup> We chose to study the impact of a Texas-like formulary over other workers' compensation state-mandated closed drug formularies mainly because of the availability of detailed results of the impact of Texas' formulary on prescribing patterns and costs in the state. In this study, we made certain assumptions to estimate the cost savings with a formulary that relied on Texas' experience and we present other scenarios illustrating deviations from the Texas experience. A brief description of formularies in Oklahoma, Ohio, and Washington and the characteristics they do and do not share with Texas are detailed on page 13.

<sup>3</sup> Non-formulary drugs are drugs that are excluded from the Texas closed formulary. Preauthorization to substantiate medical necessity is required for the excluded drugs. Examples include OxyContin®, Lidoderm®, and Soma®.

more than a year old.<sup>4</sup> Similar rates were seen in calendar years 2012 and 2013.

- Diclofenac sodium (Voltaren®), lidocaine patches (Lidoderm®), extended-release oxycodone (OxyContin®), short- and long-acting tapentadol (Nucynta®), topiramate (Topamax®), trazadone (Desyrel®), alprazolam (Xanax®), fentanyl patches (Duragesic®), extended-release morphine (Kadian®), and diazepam (Valium®) were the most commonly prescribed non-formulary drugs in calendar year 2014. These 10 drugs accounted for more than half of non-formulary drug prescriptions filled by North Carolina state employees.
- Several of the commonly dispensed non-formulary drugs listed above are long-acting Schedule II opioids.<sup>5</sup> All long-acting opioids are considered non-formulary drugs by the Texas formulary, effective February 1, 2016.<sup>6</sup> This category of medications accounted for 23 percent of non-formulary drug prescriptions and 33–34 percent of non-formulary drug payments across the three years. Thirteen to fourteen percent of total prescription drug costs paid for North Carolina state employees were for long-acting opioids between 2012 and 2014. Adoption of a Texas-like formulary may decrease opioid use, particularly for long-acting opioids, in the state.
- Topical analgesics were the next major cost driver among non-formulary drugs, with 18 to 21 percent of non-formulary prescription costs paid for this class of medications over the three-year study period. Topical analgesics include patch and gel/ointment formulations of lidocaine (e.g., Lidoderm® and Lidopro®)<sup>7</sup> and diclofenac (e.g., Flector® Patch and Pennsaid®).<sup>8</sup>
- Brand name drugs comprised 40 percent of non-formulary prescriptions and 64 percent of payments for non-formulary drugs in 2014.<sup>9</sup> Slightly higher rates of brand name drug use and costs were seen in earlier years. For instance, 46 percent of non-formulary prescriptions and 72 percent of payments were for brand name medications in 2012. The reduction was driven partly by the availability of generic versions of Lidoderm® since September 2013.

<sup>4</sup> A previous WCRI study examined the impact of a Texas-like closed formulary on the utilization and cost of prescription drugs among newly injured workers (claims with one year average maturity) in 23 other states, including North Carolina (Thumula and Liu, 2014). In 2011/2012, the study reported that 13 percent of prescriptions and 23 percent of prescription payments for North Carolina workers with at least seven days of lost time were for non-formulary drugs. 2011/2012 data include claims with injuries occurring from October 1, 2010, to September 30, 2011, that had prescriptions filled through March 31, 2012. State employees were not included in the earlier study.

<sup>5</sup> Controlled substances classified by the Drug Enforcement Administration as Schedule II have the highest abuse potential among the controlled substances for medical use. Long-acting opioids are typically in extended-release formulations with a higher dosage or strength that lasts longer. Official Disability Guidelines (ODG) specify that long-acting opioids are not recommended as first-line treatment of acute or chronic non-malignant pain.

<sup>6</sup> Note that all extended-release tramadol HCL products (with the exception of Conzip®) are considered formulary drugs.

<sup>7</sup> ODG specifies that only FDA approved topical lidocaine products are currently recommended for localized neuropathic pain after first-line treatment with anticonvulsants is tried. While Lidocaine patches are less invasive and have a lower adverse effect profile, it is costly over time and there are other low cost topical treatments available over-the-counter at drug stores that provide analgesia (including heat, ice, capsaicin, and salicylates).

<sup>8</sup> Diclofenac-containing topical formulations are not recommended as first-line treatment by ODG. Topical diclofenac is only recommended if the patient does not respond to oral NSAIDs, has contraindications to oral NSAIDs, or cannot swallow oral dosage forms, after considering the increase in hepatic risk of diclofenac compared with other NSAIDs.

<sup>9</sup> Most of these non-formulary brand name drugs are drugs for which generic equivalents were not available during the study period, such as OxyContin®, Nucynta®, and Abilify®.

## IMPACT ON PRESCRIPTION DRUG COST SAVINGS

- In response to the closed formulary, Texas physicians adjusted prescribing patterns in two significant ways, on average. When prescribing drugs to newly injured workers as well as legacy claims, physicians significantly reduced prescriptions for non-formulary drugs, and they infrequently substituted formulary drugs for non-formulary drugs (Texas Department of Insurance, 2015).<sup>10</sup> The response of North Carolina physicians to a Texas-like closed formulary may be similar to that of their Texas counterparts. However, that response might be more muted.
- To estimate the impact of adopting a Texas-like formulary in North Carolina, we made various alternative assumptions about how physician prescribing practices might change. This is not to say that these assumptions are realistic expectations of what might happen in the state. We provide these multiple scenarios to the reader to provide plausible ranges of potential cost savings and to illustrate how prescription cost savings may vary depending on North Carolina prescribers' responses to a closed drug formulary—specifically, (1) how often they seek preauthorization to prescribe non-formulary drugs, and (2) when they reduce the use of non-formulary drugs, how often they substitute with formulary drugs.<sup>11</sup> See Table A.

**Table A Impact of a Texas-Like Formulary for North Carolina State Employees**

	2012	2013	2014
% of all Rx that were for non-formulary drugs	22%	22%	23%
% of total Rx payments that were for non-formulary drugs	39%	40%	39%
<b>% of estimated reduction in total prescription payments</b>			
Scenario A (70% drop in non-formulary Rx/~0% substitution) (Texas-like experience)	-30%	-30%	-30%
Scenario B (70% drop/full substitution <sup>a</sup> )	-9%	-9%	-8%
Scenario C (25% drop/~0% substitution)	-12%	-12%	-12%
Scenario D (25% drop/full substitution <sup>a</sup> )	-5%	-5%	-4%

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

<sup>a</sup>To estimate the potential cost savings with full substitution, the price paid for each non-formulary prescription was substituted with the average price paid per prescription across all substitutes.

Key: Rx: prescriptions.

- **Scenario A (Texas experience).** Where physicians adjust to a closed formulary in ways that are similar to what we saw with Texas physicians, we estimate large effects of adopting such a formulary. We estimate reductions from 22–23 percent to 6–7 percent of all prescriptions that

<sup>10</sup> Consequently, there was a 30 percent reduction in total prescription costs in Texas between the first quarter of 2011 (pre-formulary) and the first quarter of 2014 (post full implementation of the formulary).

<sup>11</sup> Note that the Texas formulary does not exclude all drugs within a drug group, as shown in Table 3.3b. In each drug group, there are formulary drugs that do not require preauthorization that a physician may choose to substitute non-formulary drugs with. Chapter 1 and the technical appendix provide details about our approach to identifying potential substitutes for non-formulary drugs.

are for non-formulary drugs and a 30 percent reduction in total prescription costs or close to \$8.7 million dollars over the three-year period.

However, physicians in North Carolina may substitute with formulary drugs more frequently than did Texas physicians, due to other factors like patient's needs, prescribing norms, or financial incentives.

- **Scenario B** assumes that physicians in North Carolina reduce their use of non-formulary drugs to the same extent as their Texas counterparts, but that they fully substitute formulary drugs from the same drug group. In this scenario, we estimate a reduction in prescription costs of 8–9 percent.<sup>12,13</sup> This is smaller than Scenario A (30 percent) because Scenario A assumes that, as in the Texas experience, physicians do little substitution.
- **Scenario C.** Texas physicians reduced their use of non-formulary drugs by 70 percent. What if the behavior of Texas physicians was unique (for example, if physicians in North Carolina learn that adjudicators would override many denials of preauthorization by payors)? Scenario C contemplates a situation where physicians in North Carolina reduce use of non-formulary drugs by only 25 percent. But like physicians in Texas, little substitution of formulary drugs occurs. Under Scenario C, we estimate prescription cost reductions of 12 percent.
- **Scenario D** is the same as Scenario C except it assumes full substitution. Here we estimate prescription cost reductions of 4–5 percent. Under Scenarios C and D, we estimate that the percentage of all prescriptions that were for non-formulary drugs might drop from 22–23 percent to 16–17 percent.

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<sup>12</sup> To estimate the potential cost savings with substitution, the price paid for each non-formulary prescription is substituted with the average price paid per prescription across all substitutes. If we use the median price paid per prescription for substitutes, cost savings are estimated to be 13–15 percent in Scenario B and 6–7 percent in Scenario D.

<sup>13</sup> Note that for substitution scenarios, cost savings are slightly lower in 2014 than in earlier years because prices paid for several commonly prescribed formulary drugs that we are substituting non-formulary drugs with increased in 2014. This was a result of an increase in average wholesale price (AWP) of some commonly prescribed formulary drugs, such as ibuprofen, oxycodone-acetaminophen, pregabalin, etc.

## 1

**DATA AND METHODS**

Detailed prescription transaction data for all North Carolina state employee claims managed by the Office of State Human Resources (OSHR) and the Department of Public Instruction (DPI) were collected for this study. The data used in this analysis include more than 180,000 prescriptions filled between January 1, 2012, and December 31, 2014, by North Carolina state employees with or without indemnity benefits who received at least one prescription paid under the state workers' compensation program (Table 1.1).

**Table 1.1 Data Underlying the Study**

	2012	2013	2014	Total
Number of claims with prescription fills in calendar year	6,723	6,575	6,255	14,438
Number of claims with at least one non-formulary drug Rx	2,099	2,148	2,073	4,184
Number of claims with at least one formulary drug Rx	6,427	6,308	6,003	13,935
Total number of prescriptions filled in calendar year <sup>a</sup>	59,766	61,579	62,170	183,515
Number of Rx for non-formulary drugs	12,923	13,707	14,124	40,754
Number of Rx for formulary drugs	45,043	46,070	46,230	137,343
Total prescription costs in calendar year <sup>a</sup>	\$8,601,041	\$9,611,710	\$10,939,184	\$29,151,934
Total Rx cost for non-formulary drugs	\$3,397,247	\$3,819,438	\$4,255,950	\$11,472,635
Total Rx cost for formulary drugs	\$4,987,900	\$5,558,120	\$6,434,083	\$16,980,103

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

<sup>a</sup> Three percent of prescriptions filled in each calendar year were for drugs with "N" status for specific diagnoses under the Texas formulary. They are not considered non-formulary or formulary drugs in this study. Therefore, the total number of prescriptions and prescription costs do not add up to the sum of non-formulary and formulary drug components.

Key: Rx: prescriptions.

In this report, we included transactions for prescription strength and over-the-counter strength medications (referred to as *prescriptions* throughout the report). These prescriptions could be filled or refilled by the injured worker at a pharmacy or physician's office and were paid for under workers' compensation. We excluded prescription medications that were administered in a physician's office or a hospital (e.g., injections/infusions received at a physician's office), nutrition supplements, and medical supplies or devices that were billed using National Drug Codes (NDCs).<sup>1</sup> These excluded medications accounted for a small proportion of total prescriptions and prescription costs. For example, in calendar year 2014, only 1.2 percent

<sup>1</sup> To identify injectables, nutrition supplements, and medical supplies/equipment for exclusions, we mainly used Medi-Span® indicators that specified the types of products with NDCs as well as the route of administration.

of prescriptions and 1.4 percent of prescription costs were for the excluded categories of medications. We also excluded bulk chemicals and adjuvants that are used in preparing compound drugs from our definition of prescriptions because of a lack of detailed ingredient-level data for compound drugs.<sup>2</sup> These bulk powders accounted for 0.9 percent of prescriptions and 5.4 percent of prescription payments in 2014, an increase from 0.4 percent of prescriptions and 1.9 percent of prescription payments in 2012.<sup>3</sup> Under a Texas-like closed formulary, compound medications containing non-formulary ingredients would require preauthorization, and as the data do not include all bulk ingredients, we were unable to identify which compound drug prescriptions required preauthorization. Prescription transactions were linked to the Medi-Span® data by NDC to identify the type of medication (e.g., therapeutic class, narcotic, and federal-level narcotic schedule), brand/generic status, strength, and the manufacturer or repackaging firm for the medication.

This study focuses on identifying drugs that require preauthorization under the Texas closed formulary. Therefore, we categorized the drugs into two broad groups—(1) non-formulary drugs or drugs that require preauthorization, and (2) formulary drugs or drugs that do not require preauthorization. To flag these drugs, we merged the list of non-formulary drugs published by the Texas Department Insurance, Division of Workers' Compensation to our prescription drug data with permission from the Work Loss Data Institute (WLDI).<sup>4</sup> Drugs with “N” status in the formulary were considered non-formulary drugs; drugs with “Y” status and drugs without “N” or “Y” status were considered formulary drugs. Drugs where the “N” status is tied to a diagnosis are not considered formulary or non-formulary drugs in this study.<sup>5</sup> We used the classification scheme provided by Medi-Span®'s Generic Product Identifier (GPI) to assign drugs into therapeutic groups. We further divided two therapeutic groups of drugs into the following subgroups: opioids into long-acting and short-acting opioids,<sup>6</sup> and dermatologicals into topical analgesics and other topical drugs.

## KEY BENCHMARK METRICS AND ASSUMPTIONS

The key benchmark metrics we focus on for this study include the percentage of all prescriptions and prescription payments that were for non-formulary drugs. These measures are reported by therapeutic group, generic/brand status, and for the most common non-formulary drugs prescribed.

Additionally, we estimated the potential reduction in total prescription costs after the implementation of a Texas-like formulary using several alternative assumptions about physicians' responses to the formulary in North Carolina. We constructed four different scenarios with assumptions about physicians' likelihood of (1)

<sup>2</sup> Compound drugs are often billed using the NDC of the most expensive bulk ingredient if the state does not have explicit billing rules requiring the compounding pharmacies to list the NDCs and quantities of all the ingredients used in the compound drug. North Carolina's pharmacy fee schedule does not include specific language regarding the billing or reimbursement of compound drugs.

<sup>3</sup> Over the three-year period, over half of the prescription payments for bulk chemicals and adjuvants were for ketamine powder, one-third were for gabapentin powder, and another 10 percent were for cream base.

<sup>4</sup> The non-formulary drug list is available at <https://www.tdi.state.tx.us/WC/dm/documents/appendixa.xls>. Note that in this study we consider Duragesic® patches, MS Contin®, and Embeda® to be “N” drugs because, effective February 1, 2016, these long-acting opioids are going to be considered non-formulary drugs for first-line treatment of acute or chronic non-malignant pain.

<sup>5</sup> In 2014, 23 percent of all prescriptions were for drugs with “N” status, 3 percent of prescriptions were for drugs with “N” status for specific diagnoses, 66 percent were for drugs with “Y” status, and 8 percent of drugs were for drugs without “N” or “Y” status. Similar rates were seen in 2012 and 2013.

<sup>6</sup> Long-acting opioids are typically in extended-release formulations with a higher dosage or strength that lasts longer and provides stable drug plasma levels, while short-acting opioids are typically indicated for immediate relief of acute pain, or intermittent or breakthrough pain.

prescribing non-formulary drugs by seeking preauthorization and (2) substituting non-formulary drugs that are not prescribed because of the preauthorization requirement with other drugs that do not require preauthorization. Table 1.2 shows the four scenarios. The first scenario assumes that physicians in North Carolina respond to a Texas-like closed formulary as Texas doctors did, which is a 70 percent reduction in prescribing non-formulary drugs and 0 percent substitution with formulary drugs. We made an additional assumption that a similar 70 percent drop is seen across all non-formulary drug products and the price per prescription did not change, implying that the drug payments associated with non-formulary drugs would also drop by 70 percent.<sup>7</sup> The second scenario assumes a 70 percent reduction in prescribing of non-formulary drugs and 100 percent substitution with formulary drugs. In this case, we assume that the prescriber substitutes one non-formulary drug prescription with one formulary drug prescription, i.e., the total number of prescriptions remains the same. The other two scenarios assume that physicians in North Carolina seek preauthorization for non-formulary drugs more frequently than Texas doctors. In Scenarios C and D, we assume a smaller reduction in non-formulary prescriptions, a 25 percent drop. This is not to say that these assumptions are realistic expectations of what might happen in North Carolina. We provide a range of potential cost savings depending on North Carolina prescribers' reactions.

**Table 1.2 Key Assumptions about Physician Responses for Estimating Post-Formulary Impact in North Carolina**

	<b>Reduction in Prescribing of Non-Formulary Drugs That Require Preauthorization</b>	<b>Substitution of Non-Formulary Drugs with Drugs That Do Not Require Preauthorization</b>
Scenario A (Texas experience)	70%	0%
Scenario B	70%	100%
Scenario C	25%	0%
Scenario D	25%	100%

We used the prescribing patterns and prices paid for formulary drugs prescribed to North Carolina state employees in a given calendar year to estimate the cost savings in that year for the substitution scenarios in this study.<sup>8</sup> To identify the list of potential substitutes for non-formulary drugs in the majority of drug groups, we selected formulary drug prescriptions belonging to the same therapeutic group. For opioids, we assumed that physicians might substitute a non-formulary short-acting opioid with a formulary short-acting opioid prescription of the same morphine equivalent amount. For long-acting opioids, considering all long-acting opioids (except extended-release tramadol HCL) require preauthorization under the Texas formulary, we assumed that physicians may substitute with opioids that do not require preauthorization, like extended-release tramadol HCL and short-acting opioid prescriptions of the same morphine equivalent amount. We tested the sensitivity of estimates of cost savings in substitution scenarios using various other specifications to

<sup>7</sup> Contrary to this assumption, non-formulary drug prescriptions dropped by about 70 percent and non-formulary drug payments decreased by about 80 percent in Texas (TDI, 2015), which implies that larger drops were seen in the prescribing of more expensive non-formulary prescriptions. However, without more detailed data about the specific drug products that led to a larger drop in non-formulary drug payments compared with prescriptions, and whether those drug products are also prescribed to North Carolina state employees to the same extent, we cannot exactly replicate the Texas experience. Readers could, however, apply the 80 percent cost savings to the non-formulary prescription costs in Table 1.1 to estimate the cost savings in North Carolina if non-formulary drug payments dropped by about 80 percent like in Texas.

<sup>8</sup> Due to a small number of prescriptions for formulary drugs for topical lidocaine and antipsychotics in each calendar year, we pooled the prices paid for formulary drugs over the three years to estimate the cost savings in each calendar year.

identify potential substitutes and observed similar cost savings across the different specifications. Detailed explanations of our methodology to identify substitutes of non-formulary drugs, drug groups for which we had to make exceptions to the general rule of selecting substitutes, and alternative specifications for selecting substitutes are discussed in detail in the technical appendix.

As expected, there are wide variations in prices paid for formulary drug prescriptions selected as potential substitutes for non-formulary prescriptions. Therefore, to estimate the potential cost savings with substitution, the price paid for each non-formulary prescription was substituted with the average and median price paid per prescription for potential substitutes, and we report the cost savings in each case. Similarly for opioids, we used the average and median price per morphine equivalent amount of formulary drugs to estimate cost savings.

# 2

## BACKGROUND

### WORKERS' COMPENSATION FORMULARIES

In workers' compensation, only a few states (Ohio, Oklahoma, Texas, and Washington) have adopted drug formularies.<sup>1</sup> Our study focuses on the impact of Texas' formulary mainly because of the availability of detailed results on the impact of Texas' formulary on prescribing patterns and costs in the state. In this study, we made assumptions to estimate the cost savings with a formulary that relied on Texas' experience and we also present other scenarios illustrating deviations from the Texas experience. Oklahoma shares many characteristics with the Texas formulary. Most importantly, both states use the Official Disability Guidelines (ODG) formulary as the basis for selecting the drugs that require preauthorization, although there are some differences in implementation. For instance, formulary rules do not apply to injuries prior to February 2014 in Oklahoma, whereas the Texas formulary applies to all claims in the state. Ohio and Washington, both single payor workers' compensation jurisdictions, maintain their state formularies. Washington's formulary excludes more drugs than the Texas formulary, and the estimated cost savings could be higher under a Washington-like formulary for North Carolina state employees. Swedlow, Hayes, and David (2014) compared the potential cost savings with a more inclusive Texas formulary and a more exclusive Washington formulary and estimated a 12 percent reduction in drug payments with a Texas formulary and a 41 percent reduction with a Washington formulary in California, using the mean savings scenario. Ohio's formulary does not exclude more drug products than Texas but restricts the duration of use and maximum daily dose of several classes of medications, requires use of sustained-release morphine sulfate prior to trying other long-acting opioids, and ties the coverage of some drugs to specific diagnoses. For example, Ohio's formulary restricts the coverage of muscle relaxants to 90 days from first fill date per year and places daily dose limits on long-acting opioids and benzodiazepines. Ohio's formulary only allows lidocaine patches for post-herpetic neuralgia claims. Future studies should compare the differential impact of the various formularies on cost savings and outcomes achieved by injured workers.

### ABOUT THE TEXAS CLOSED FORMULARY

The adoption of treatment guidelines and an evidence-based closed formulary was a statutory requirement of House Bill (HB) 7, 79th Legislature, Regular Session.<sup>2</sup> The Texas Department of Insurance, Division of Workers' Compensation worked closely with several system stakeholders for several years after the bill was passed in 2005 to develop rules for the closed formulary. In December 2010, the commissioner adopted final

<sup>1</sup> Delaware has a preferred list of drugs for the following groups: NSAIDs, opioids, muscle relaxants, and anticonvulsants.

<sup>2</sup> See §§ 408.052 and 413.011 of the Texas Labor Code.

rules to implement the closed formulary. The formal rule adoption said:

“. . . the Division’s adopted treatment guidelines, required by statute, are evidence-based, scientifically valid, and outcome-focused. The evidence included in the Division’s adopted treatment guidelines is based on the AGREE Instrument and is described in detail in the hard copy and electronic version of *ODG Treatment in Workers’ Comp* and on the WLDI [Work Loss Data Institute] website.”<sup>3</sup>

The closed formulary was effective on September 1, 2011, for new injuries and on September 1, 2013, for *legacy* claims (i.e., injuries prior to September 1, 2011). Implementation of the closed formulary was done in two phases to ensure that the pharmaceutical care for injured workers being treated with medications to be excluded from the formulary would not be abruptly discontinued.

The Texas formulary includes all drugs approved by the Food and Drug Administration (FDA) except investigational and experimental drugs and drugs with “N” drug status in the current edition of ODG.<sup>4</sup> If a drug is included in the formulary, physicians may prescribe it without obtaining preauthorization. If the drug is excluded from the formulary, physicians may only prescribe it if they obtain preauthorization from the payor.

The most commonly prescribed medications to injured workers are included in the formulary and do not require preauthorization. These include Vicodin® (hydrocodone-acetaminophen), Percocet® (oxycodone-acetaminophen), Ultram® (tramadol HCL), Naprosyn® (naproxen), Motrin® (ibuprofen), and Flexeril® (cyclobenzaprine).<sup>5</sup> These drugs are referred to as *formulary drugs* in this study.

Preauthorization to substantiate medical necessity is required for the excluded drugs. We refer to such drugs as *non-formulary drugs* in this study. According to the developer of the formulary, some of these non-formulary drugs are not recommended as first-line therapy and others are not recommended at all due to the lack of therapeutic efficacy and/or safety concerns.<sup>6</sup> Examples of commonly prescribed drugs that require preauthorization:

- Several drugs with higher than normal abuse potential. All long-acting opioids, with the exception of extended-release tramadol HCL, like OxyContin®, Opana® ER, Exalgo®, Avinza®, Kadian®, and Zohydro®.
- Expensive brand name medications like Lidoderm®, Flector® Patch, and OxyContin®. OxyContin® and Lidoderm®<sup>7</sup> were reported to be the top two drugs in terms of prescription spending in the workers’ compensation system in 2011 (Lipton, Laws, and Li, 2013). Lidoderm® is approved for shingles pain and is used off-label to treat workers’ compensation injuries; Flector® Patch (diclofenac epolamine) and Voltaren® gel (diclofenac sodium) have an increased hepatic risk profile compared with other non-

<sup>3</sup> See the rule adoption at <http://www.tdi.texas.gov/wc/rules/adopted/documents/aorx1210.pdf>.

<sup>4</sup> The Texas closed formulary includes “all FDA approved drugs prescribed and dispensed for outpatient use with the following exclusions—(a) drugs with ‘N’ drug status in the current edition of ODG, (b) compounded drugs that contain an ‘N’ drug and (c) investigational or experimental drugs as defined in Texas Labor Code §413.014(a).”

<sup>5</sup> The Texas Department of Insurance posts monthly updates of the drug formulary on their website (<http://www.tdi.texas.gov/wc/pharmacy/>).

<sup>6</sup> For example, benzodiazepines are not recommended as first-line medications by ODG. ODG advises that benzodiazepines are “not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction.”

<sup>7</sup> Generics for Lidoderm® became available in September 2013.

steroidal anti-inflammatory drugs (NSAIDs).

- Generically available drugs that are not recommended for first-line therapy like Voltaren® (diclofenac sodium), an NSAID, and benzodiazepines like Xanax® and Valium®. Soma® (carisoprodol) is an example of a generically available drug that is not recommended at all because of safety concerns. The Substance Abuse and Mental Health Services Administration (SAMHSA) reported that emergency department visits related to the misuse or abuse of carisoprodol doubled between 2004 and 2009 (SAMHSA, 2011).

## IMPACT IN TEXAS

The impact of the selective preauthorization requirement on prescribing practices was very large. The Texas Department of Insurance (TDI) reported that the formulary resulted in cost savings and a reduction in unnecessary use of N-drugs, referred to as *non-formulary drugs* in our study. As the formulary is considered to be based on evidence-based guidelines, reduction in the use of non-formulary drugs may be perceived as an improvement in patient care. The 2015 update of the impact of the formulary by TDI<sup>8</sup> indicates that, for new injuries as of 24 months of maturity, fewer claims received N-drugs (a 65 percent decrease from 2010 to 2011 injuries), the percentage of prescriptions written for N-drugs decreased by about 73 percent, and the share of prescription drug costs accounted for by N-drugs decreased by 79 percent in the new claims (from 17 percent of total prescription costs to 3 percent). For legacy claims (i.e., injuries prior to September 2011, with a formulary effective date of September 2013), the cost share of N-drugs decreased from about 30 percent in the first quarter of 2011 to 19 percent in August 2013 to 6 percent of total costs in September 2014. Note that the drop in legacy claims is partly explained by claims closing over time.

Surprisingly, prescriptions for drugs included in the formulary, i.e., “other” drugs, referred to as *formulary drugs* in our study, did not increase—suggesting that many physicians chose not to write prescriptions for drugs that required preauthorization and, moreover, did not substitute other drugs that were not subject to preauthorization. For new injuries as of 24 months of maturity, the number of claims with other drugs dropped by 1 percent and the prescriptions for other drugs also decreased by 4 percent.<sup>9</sup> We do not have comparable numbers for legacy claims, but the 2015 update reported a drop in the total cost of N-drugs as well as other drugs. This suggests that even if substitution existed for some legacy claims, it may be to a smaller extent.

Overall, these changes resulted in a 30 percent reduction in total prescription costs in Texas from the first quarter of 2011 (pre-formulary) to the first quarter of 2014 (post full implementation of the formulary). If North Carolina were to have a similar implementation of a Texas-like formulary, there is strong potential for decreasing the utilization of drugs designated as non-formulary drugs, which may in turn lead to substantial prescription cost savings.

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<sup>8</sup> See TDI (2015).

<sup>9</sup> It is important to note that these results do not suggest that many injured workers who would have been prescribed N-drugs pre-formulary were not getting *any* prescriptions post-formulary. Before the implementation of the formulary, the majority of Texas workers with N-drugs also received other drugs; just 2 percent of claims only received N-drug prescriptions. Post-formulary, Texas workers who only received other drug prescriptions increased by 12 percent, suggesting that the formulary resulted in consolidation of prescriptions received by Texas injured workers.

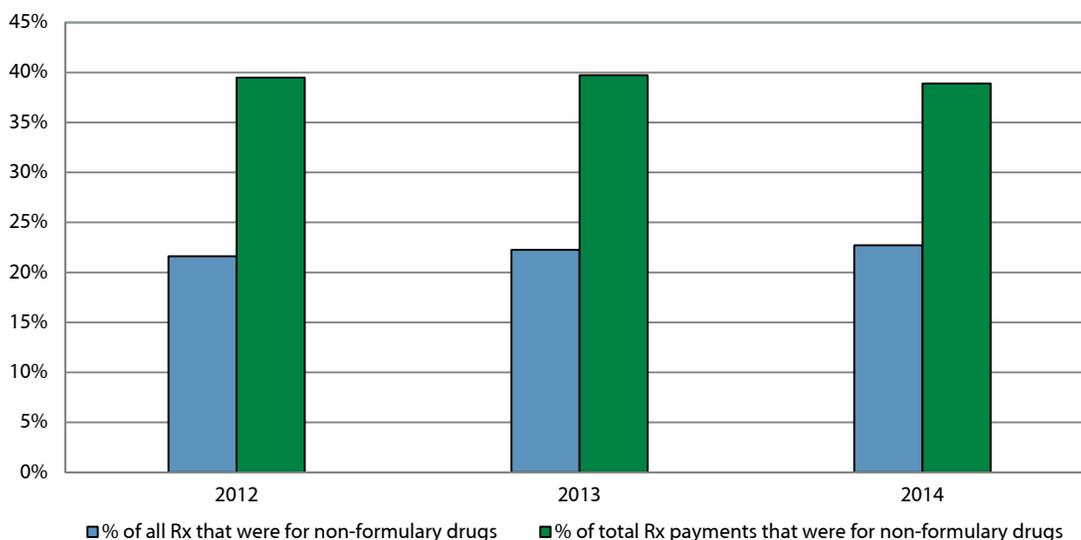
## 3

## MAJOR FINDINGS

### NON-FORMULARY DRUGS WERE FREQUENTLY PRESCRIBED FOR NORTH CAROLINA STATE EMPLOYEES

- We found that 22 to 23 percent of all prescriptions were written for non-formulary drugs across the three years, 2012 to 2014.<sup>1</sup> Figure 3.1 illustrates that non-formulary drugs accounted for a higher proportion of total prescription costs. For instance, in 2014, non-formulary drug prescriptions accounted for 39 percent of total prescription costs. Note that the prescriptions for non-formulary drugs accounted for a larger share of prescription spending than the share of all prescriptions filled. This occurred because several of the drugs listed as non-formulary drugs under the Texas formulary are expensive brand name medications like OxyContin® and Flector® Patch.

**Figure 3.1 Non-Formulary Drug Use and Costs among North Carolina State Employees**



Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

Key: Rx: prescriptions.

<sup>1</sup> Note that non-formulary drugs were rarely dispensed by physicians in North Carolina. Over the three-year period, 1–2 percent of non-formulary drug prescriptions filled by North Carolina state employees were physician dispensed. A similar rate (3 percent) was observed in an earlier WCRI study (Thumula and Liu, 2014), which examined the non-formulary drug use among North Carolina injured workers managed by private payors with at least seven days of lost time and at an average 12 months of maturity.

- Note that an additional 3 percent of prescriptions were written for drugs that require a preauthorization depending on the diagnosis. For example, fluoxetine (Prozac®) requires a preauthorization if the drug is being prescribed for pain relief but does not require a preauthorization for mental health conditions. It is difficult to reliably ascertain whether the drug is being prescribed for pain relief or not in each case using administrative claims data; therefore, we did not group these drugs as non-formulary drugs or formulary drugs in this study. These drugs accounted for 2–3 percent of total prescription payments across the three years.
- The use of non-formulary drugs was higher among older injuries. For instance, 10 percent of prescriptions filled in 2014 were for non-formulary drugs among claims that were less than a year old, and the same measure was 27 percent among claims that were more than a year old. In terms of prescription payments, 23 percent of prescription payments made in 2014 were for non-formulary drugs for workers with claims less than a year old, whereas the cost share of non-formulary drugs was 40 percent for claims more than a year old (Table 3.1).

**Table 3.1 Summary of Non-Formulary Drug Use and Costs**

	2012	2013	2014
<b>% of all prescriptions that were for non-formulary drugs</b>			
All claims	22%	22%	23%
Claims that were less than 1 year old	10%	11%	10%
Claims that were more than 1 year old	27%	27%	27%
<b>% of total prescription payments that were for non-formulary drugs</b>			
All claims	39%	40%	39%
Claims that were less than 1 year old	20%	23%	23%
Claims that were more than 1 year old	42%	41%	40%

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees in the following cohorts: (1) All claims include injuries that occurred between July 3, 1980, and December 30, 2014; (2) claims that are less than 1 year old include claims that occurred within 1 year prior to the prescription fill date; and (3) claims that are more than 1 year old include claims that occurred more than 1 year prior to the prescription fill date. Similar notation is used for other years.

## BRAND NAME NON-FORMULARY DRUG USE

- Several state workers’ compensation systems promote the use of generic drugs by enforcing generic mandate policies. Generic substitution is not mandated in North Carolina, but payors may be requiring the substitution of brand name drugs for which generic equivalents are available.<sup>2</sup> Generic mandates influence the use of brand name medications for which generic equivalents are available. For example, in a state with a generic mandate, pharmacists can substitute Motrin® with generic ibuprofen (generic equivalents). They cannot however substitute Motrin® with naproxen (generic alternatives), which is also

<sup>2</sup> For instance, only 2.5 percent of all prescriptions filled by North Carolina state employees in 2014 were for brand name medications for which generic equivalents were available. If all these prescriptions were substituted with the corresponding generic equivalents, total prescription costs could be reduced by about 3 percent or \$360,000. However, a generic substitution mandate may not entirely eliminate dispensing of brand name medications with generic equivalents for various reasons including “Dispense As Written” prescriptions or exceptions in state regulations for certain drugs with narrow therapeutic index.

an NSAID that can be used for relieving pain. Formularies can be used to encourage the use of generic alternative drugs prior to brand name medications. Other payors, like group health and Medicaid, use tiered formularies and encourage use of generics prior to the use of expensive brand name medications by charging lower co-payments for generic drugs. Workers’ compensation payors can use formularies to encourage generic use by requiring prior authorization for expensive brand name medications for which generic alternatives are available, like in Texas. In Texas, the TDI study (2015) reported that for newly injured workers, the generic use rate among non-formulary drugs increased after implementing the closed formulary, from 61 percent in 2010 to 74 percent in 2011.

- Over the three-year study period, the proportion of non-formulary drug prescriptions filled by North Carolina state employees that were for brand name medications ranged from 40 to 46 percent (Table 3.2). The most commonly dispensed brand name medication with non-formulary status in 2012 was Lidoderm®. Lidoderm® (lidocaine patch) is FDA approved for shingles pain and is used off label to treat workers’ compensation injuries involving low back pain. The prevalence of brand name non-formulary drug prescriptions decreased from 46 percent in 2012 to 40 percent in 2014 partly because generic equivalents of Lidoderm® became available in September 2013. Other common brand name non-formulary drugs include opioids like OxyContin® and Nucynta® (Schedule II narcotics not recommended as first-line therapy by ODG), NSAIDs like Flector® Patch (a topical version of the NSAID diclofenac, which is generically available as an oral product), and muscle relaxants like Amrix® (an extended-release version of generically available cyclobenzaprine).
- These brand name non-formulary drug medications accounted for 64–72 percent of non-formulary drug prescription payments (Table 3.2).
- Note that in 2014, only half of all brand name drug prescriptions filled were for non-formulary drugs (49 percent). A Texas-like formulary might decrease the use of brand name non-formulary drugs, but prescribing and dispensing of brand name formulary drugs may continue in the absence of other mechanisms to control their prescribing.

**Table 3.2 Brand Name Non-Formulary Drug Use and Costs**

	2012	2013	2014
<b>% of prescriptions for brand name drugs</b>			
Among non-formulary drugs	46%	44%	40%
Among formulary drugs	17%	17%	13%
<b>% of prescription payments for brand name drugs</b>			
Among non-formulary drugs	72%	70%	64%
Among formulary drugs	42%	45%	34%

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

## NON-FORMULARY DRUGS PRESCRIBED TO NORTH CAROLINA'S INJURED STATE EMPLOYEES

- This section describes the mix of non-formulary drugs prescribed to North Carolina's injured state employees.<sup>3</sup> More than three out of four non-formulary drug prescriptions were written for medications in the following therapeutic groups—long- and short-acting opioids, topical analgesics, benzodiazepines, anti-epilepsy drugs, and NSAIDs, as shown in [Table 3.3a](#).
  - Opioids accounted for 30 percent of all non-formulary drug prescriptions given to North Carolina state employees. Long-acting opioids, which include drugs like OxyContin®, MS Contin®, and Opana® ER, accounted for 23 percent of non-formulary prescriptions, and the other 7–8 percent was for short-acting opioids such as Nucynta®, Vicoprofen®, etc. Note that all long-acting opioids except extended-release tramadol HCL are considered non-formulary drugs under the Texas formulary, effective February 2016. As a result, 91 percent of all long-acting opioid prescriptions dispensed in 2014 were for non-formulary drugs. On the other hand, only 6 percent of all short-acting opioid prescriptions were for non-formulary drugs. The remaining 94 percent of short-acting opioids prescribed to North Carolina state employees were for drugs included in the Texas formulary ([Table 3.3b](#)).
  - Topical analgesics were a significant share of non-formulary drugs prescriptions in this population (16 percent). This class of medications predominantly included topical formulations of lidocaine (such as Lidoderm® and other generic products containing lidocaine) and topical NSAID formulations (like Flector® Patch and Pennsaid®).
  - Benzodiazepines were frequently prescribed, accounting for 13 percent of non-formulary drug prescriptions. All benzodiazepines are designated as non-formulary drugs under the Texas formulary and require preauthorization.<sup>4</sup> Examples of benzodiazepines include commonly abused controlled substances like Xanax® and Valium®.
  - Anti-epilepsy drugs or anticonvulsants, used for treating neuropathic pain in workers' compensation cases, accounted for 11 percent of all non-formulary prescriptions filled in 2014. They include drugs such as Gralise®, Vimpat®, and Topamax®, among others.
  - Eight percent of non-formulary drug prescriptions were for NSAIDs in 2014. Several commonly prescribed NSAIDs are considered formulary drugs under the Texas formulary. Of all NSAID prescriptions filled by injured state employees in North Carolina, 87 percent were for formulary drugs and 13 percent were for drugs that require preauthorization. Examples of NSAIDs that require preauthorization include Voltaren® and Naprelan® tablets.
- In terms of prescription cost share, long- and short-acting opioids, topical analgesics, anti-epilepsy drugs, antipsychotics, NSAIDs, and muscle relaxants accounted for about 90 percent of payments made for non-formulary drugs. Benzodiazepines and sedative-hypnotics, which were frequently dispensed, were not in the top therapeutic groups by prescription drug spending because generics are available for the majority of the commonly dispensed drugs in these therapeutic groups. On the other hand, 8 percent of

<sup>3</sup> Prescribing patterns of medications, specifically opioids are likely to be influenced by many factors in addition to the implementation of the closed formulary, including increasing use of the state prescription drug monitoring program, law enforcement efforts, new drug releases, and other legislative changes like up-scheduling of hydrocodone-acetaminophen.

<sup>4</sup> Clobazam (Onfi®) is a single-source benzodiazepine drug that is not included in the list of non-formulary drugs. Other anti-anxiety medications are also not included in the list of non-formulary drugs and do not require preauthorization.

non-formulary drug payments were for antipsychotics, predominantly for aripiprazole (Abilify®). Table 3.3a presents the percentage of prescription payments for non-formulary drugs by therapeutic group.

**Table 3.3a Percentage of Non-Formulary Drug Prescriptions and Non-Formulary Drug Payments by Therapeutic Group, 2012–2014**

	2012	2013	2014
% of all prescriptions that were for non-formulary drugs	22%	22%	23%
<b>% of non-formulary drug prescriptions that were for the therapeutic group</b>			
Long-acting opioids	23%	23%	23%
Topical analgesics	16%	16%	16%
Benzodiazepines/other anti-anxiety agents	13%	13%	13%
Anti-epilepsy drugs	8%	9%	11%
NSAIDs	9%	8%	8%
Short-acting opioids	8%	7%	7%
Sedative-hypnotics	7%	6%	6%
Muscle relaxants	6%	5%	5%
Antipsychotics	3%	3%	3%
Antidepressants	3%	2%	2%
All other therapeutic groups	6%	6%	5%
<b>% of non-formulary drug payments that were for the therapeutic group</b>			
Long-acting opioids	33%	34%	34%
Topical analgesics	21%	21%	18%
Benzodiazepines/other anti-anxiety agents	3%	2%	2%
Anti-epilepsy drugs	9%	11%	13%
NSAIDs	4%	4%	6%
Short-acting opioids	11%	9%	9%
Sedative-hypnotics	2%	2%	2%
Muscle relaxants	3%	4%	4%
Antipsychotics	7%	8%	8%
Antidepressants	1%	1%	1%
All other therapeutic groups	5%	4%	4%

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

Key: NSAIDs: non-steroidal anti-inflammatory drugs.

**Table 3.3b Percentage of Prescriptions in Therapeutic Groups for Non-Formulary and Formulary Drugs, 2014**

<b>These Drug Groups Accounted for 95% of Non-Formulary Drugs Prescriptions</b>	<b>% of Prescriptions in the Therapeutic Group That Were for Non-Formulary Drugs</b>	<b>% of Prescriptions in the Therapeutic Group That Were for Formulary Drugs</b>
Long-acting opioids	91%	9%
Topical analgesics	99%	1%
Benzodiazepines/other anti-anxiety agents	87%	13%
Anti-epilepsy drugs	25%	75%
NSAIDs	13%	87%
Short-acting opioids	6%	94%
Sedative-hypnotics	49%	51%
Muscle relaxants	10%	90%
Antipsychotics	81%	19%
Antidepressants	5%	69%

Notes: The underlying data includes all prescriptions filled between January 1, 2014 and December 31, 2014 by North Carolina state employees.

For antidepressants, 26 percent of prescriptions were for drugs with "N" status for pain and "Y" status for mental health condition, which are not considered formulary or non-formulary drugs in this study.

Key: NSAIDs: non-steroidal anti-inflammatory drugs.

### TOP NON-FORMULARY DRUGS

- [Table 3.4a](#) highlights the commonly prescribed non-formulary drugs by prescription share. Of these, generics were not available for Lidoderm<sup>5</sup>, OxyContin®, Nucynta®, Opana® ER, Gralise®, and Flector® Patch during the study period.
- Three out of every four dollars spent on non-formulary drugs were for one of the top 15 drugs in [Table 3.4b](#). The top non-formulary drugs by prescription drug spending included several opioids such as OxyContin®, Nucynta®, Duragesic® patches, Opana® ER, Exalgo®, and Kadian®. Lidoderm®, both brand name and generic drug products combined, was the top non-formulary drug in terms of prescription cost share. Note that the non-formulary cost share of lidocaine patches decreased from 14 percent in 2012 to 11 percent in 2014, whereas the prescription share was stable at 8 percent. This was because less expensive, generic versions of Lidoderm® became available in September 2013. Anticonvulsants (topiramate and extended-release gabapentin) accounted for nearly 10 percent of non-formulary prescription payments in 2014.

<sup>5</sup> Generics for Lidoderm® became available in September 2013.

**Table 3.4a Top 15 Non-Formulary Drugs by Prescription Share**

	2012	2013	2014
Diclofenac sodium (Voltaren®)	9%	10%	9%
Lidocaine patch (Lidoderm®)	8%	8%	8%
Oxycodone ER (OxyContin®)	7%	6%	6%
Tapentadol (Nucynta®)	5%	5%	5%
Topiramate (Topamax®)	4%	4%	5%
Trazodone (Desyrel®)	4%	4%	4%
Alprazolam (Xanax®)	4%	4%	4%
Fentanyl transdermal (Duragesic®)	4%	4%	4%
Morphine ER (Kadian®)	4%	4%	4%
Diazepam (Valium®)	4%	3%	4%
Clonazepam (Klonopin®)	4%	4%	3%
Oxymorphone ER (Opana® ER)	3%	4%	3%
Gabapentin ER (Gralise®)	1%	2%	3%
Carisoprodol (Soma®)	4%	3%	3%
Diclofenac epolamine (Flector Patch®)	3%	3%	3%
Total percentage	67%	67%	69%

**Table 3.4b Top 15 Non-Formulary Drugs by Prescription Cost Share**

	2012	2013	2014
Lidocaine patch (Lidoderm®)	14%	13%	11%
Oxycodone ER (OxyContin®)	9%	8%	8%
Tapentadol (Nucynta®)	5%	6%	6%
Fentanyl transdermal (Duragesic®)	6%	6%	6%
Oxymorphone ER (Opana® ER)	7%	7%	6%
Topiramate (Topamax®)	5%	5%	5%
Aripiprazole (Abilify®)	5%	5%	5%
Hydromorphone ER (Exalgo®)	4%	5%	5%
Gabapentin ER (Gralise®)	1%	2%	4%
Diclofenac sodium (Voltaren®)	4%	5%	4%
Diclofenac epolamine (Flector Patch®)	4%	4%	4%
Morphine ER (Kadian®)	4%	4%	4%
Cyclobenzaprine ER (Amrix®)	1%	3%	3%
Buprenorphine (transdermal) (Butrans®)	1%	2%	3%
Quetiapine (Seroquel®)	2%	2%	2%
Total percentage	73%	77%	76%

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

Key: ER: extended release.

**ESTIMATED REDUCTION IN NON-FORMULARY DRUG PRESCRIPTIONS AND COSTS IF A TEXAS-LIKE FORMULARY IS MANDATED FOR NORTH CAROLINA STATE EMPLOYEES**

This section presents estimates of the reduction in non-formulary drug prescriptions and overall prescription costs if a Texas-like formulary was adopted for North Carolina state employees under alternative assumptions about how physician prescribing practices change. The response of North Carolina physicians to a Texas-like closed formulary may be similar to that of their Texas counterparts. However, that response might be more muted. The multiple scenarios in this report provide plausible ranges of prescription cost savings depending on how North Carolina prescribers respond to a closed drug formulary—specifically, (1) how often they seek preauthorization to prescribe non-formulary drugs, and (2) when they reduce the use of non-formulary drugs, how often they substitute with formulary drugs. A summary of estimates of the impact on overall prescription costs based on these four scenarios is presented in Table 3.5.<sup>6</sup> The estimates of impact are based on the patterns of use of prescription drugs among North Carolina state employees, reported in earlier sections of this chapter, and the impact of the closed formulary observed in Texas, as published in the 2015 TDI study.

**Table 3.5 Estimated Reduction in Prescription Costs with a Texas-Like Formulary under Different Scenarios**

	Estimated Reduction in Total Rx Payments (substitution with the average formulary Rx)				Estimated Reduction in Total Rx Payments (substitution with the median formulary Rx)			
	2012	2013	2014	2012–2014	2012	2013	2014	2012–2014
Scenario A (70% drop in non-formulary Rx/~0% substitution) (Texas-like experience)	-30%	-30%	-30%	\$8,730,040	-30%	-30%	-30%	\$8,730,040
Scenario B (70% drop/full substitution)	-9%	-9%	-8%	\$2,570,337	-15%	-14%	-13%	\$4,052,840
Scenario C (25% drop/~0% substitution)	-12%	-12%	-12%	\$3,567,354	-12%	-12%	-12%	\$3,567,354
Scenario D (25% drop/full substitution)	-5%	-5%	-4%	\$1,367,460	-7%	-7%	-6%	\$1,896,926

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

Key: Rx: prescriptions.

**ESTIMATED REDUCTION IN NON-FORMULARY DRUG PRESCRIPTIONS**

In North Carolina, 22 to 23 percent of all prescriptions for injured state employees were written for non-formulary drugs.

**Scenarios A & B:** If we assume a drop in non-formulary drug prescriptions similar to Texas (i.e., a 70 percent reduction), non-formulary drug use in North Carolina is estimated to drop to 6–7 percent.

**Scenarios C & D:** Texas physicians reduced their use of non-formulary drugs by 70 percent. Scenarios C and D contemplate a situation where physicians in North Carolina reduce use of non-formulary drugs by only 25 percent. Based on this assumption, the percentage of prescriptions written for non-formulary drugs would be reduced to 16–17 percent.

<sup>6</sup> Data provided in Tables 1.1 and TA.2 can be used to estimate the cost savings by varying (1) how often prescribers seek preauthorization to prescribe non-formulary drugs, and (2) when they reduce the use of non-formulary drugs, how often they substitute with formulary drugs.

**ESTIMATED PRESCRIPTION COST SAVINGS**

**Scenario A:** To estimate the likely cost savings in North Carolina with a Texas-like formulary, let us first assume that the response of North Carolina physicians is similar to that of their Texas counterparts (i.e., 70 percent reduction in non-formulary drug prescriptions and 0 percent substitution of non-formulary drugs with formulary drugs). In Texas, non-formulary drug payments decreased by 80 percent, which implies that larger drops were seen in the prescribing of more expensive non-formulary medications. In this study, we assume that a similar 70 percent drop is seen across all non-formulary drugs (i.e., non-formulary drug payments also drop by 70 percent). In this scenario, the total prescription payments for formulary drugs should not change, the total prescriptions for non-formulary drugs should decrease by 70 percent, and the rest is potential cost savings. Total prescription payments under Scenario A could be reduced by 30 percent or close to \$8.7 million dollars over the three-year period. However, some physicians may choose to substitute with formulary drugs due to patients' needs and financial incentives, among other reasons.

**Scenario B:** The state may realize sizeable but lower cost savings if all non-formulary drugs are substituted with formulary drugs. To estimate the likely cost savings in this scenario, let us assume that (a) physicians discontinue prescribing non-formulary drugs as often as Texas prescribers, but (b) they substitute all non-formulary drugs that are not prescribed because of the preauthorization requirement with other drug prescriptions that do not require preauthorization from the same therapeutic class.

We estimated that within-class substitution of all non-formulary drugs with the average formulary drug prescription may reduce prescription costs by 8–9 percent ([Table 3.5](#)). Substitution with the median formulary drug prescription may result in cost savings of 13–15 percent. Non-formulary drugs include several expensive brand name medications; therefore, the average cost of prescriptions for non-formulary drugs is higher than the average cost of prescriptions for formulary drugs belonging to the same therapeutic group, in general.

**Scenario C:** Texas physicians reduced their use of non-formulary drugs by 70 percent. What if the behavior of Texas physicians was unique (for example, if physicians in North Carolina learn that adjudicators would override many denials of preauthorization by payors)? Scenario C contemplates a situation where North Carolina physicians reduce use of non-formulary drugs by only 25 percent. But like physicians in Texas, little substitution with formulary drugs occurs. As seen in [Table 3.5](#), prescription drug costs are estimated to drop by 12 percent in this scenario.

**Scenario D** is the same as Scenario C except it assumes full substitution. We estimate overall prescription costs to be reduced by 4–5 percent for substitution with the average formulary drug prescription and 6–7 percent for substitution with the median formulary drug prescription. See [Table 3.5](#).

# 4

## IMPLICATIONS

Pharmacy cost containment policies like drug formularies in the workers' compensation area were largely unexplored until recently. Washington was the first workers' compensation jurisdiction to mandate a drug formulary in 2004. Over the past five years, Texas, Ohio, and Oklahoma have implemented drug formularies, with a number of other states considering them.<sup>1</sup> Ohio, a single payor state like Washington, implemented a formulary effective September 1, 2011, and the state Bureau of Workers' Compensation reported that the formulary resulted in a 15 percent reduction in prescription drug costs, a 25 percent decrease in opioid prescriptions, and a 74 percent reduction in muscle relaxant prescriptions between fiscal years 2011 and 2014.<sup>2</sup> Texas is the first multi-payor state to adopt a closed formulary in the workers' compensation system. The formulary was also phased in on September 1, 2011, for new claims and on September 1, 2013, for legacy claims. The latest update of the formulary impact reported a decrease in non-formulary drug prescriptions, including high-risk opioids, as well as a 30 percent reduction in total prescription drug costs between the first quarters of 2011 and 2014 (TDI, 2015). More recently, Oklahoma implemented a closed formulary in two phases—the formulary was effective November 2014 for new injuries, and for those injured between February and November 2014, the formulary will be effective November 2016.<sup>3</sup> Tennessee also adopted a closed drug formulary and will be phasing in the formulary for new prescriptions (first fills after January 2016) starting in August 2016, and for refills of medications filled prior to January 2016, the formulary will be effective February 2017. California passed a bill in 2015 requiring the California Division of Workers' Compensation to establish a closed drug formulary by July 2017.

In North Carolina, Session Law 2015-241 directed the North Carolina Industrial Commission to study the implementation of a drug formulary for workers' compensation claims filed by state government employees. Our study provides some evidence of the potential impact of a Texas-like formulary on the North Carolina state employee workers' compensation program. First, drugs identified as non-formulary drugs were frequently prescribed to North Carolina state employees. In calendar year 2014, 23 percent of all prescriptions and 39 percent of total prescription payments were for drugs that would require preauthorization under a Texas-like closed drug formulary. The early impact of formularies in Texas and Ohio suggests that requiring preauthorization can significantly reduce the prescribing of non-formulary drugs (i.e., medications that are

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<sup>1</sup> Delaware has a preferred list of drugs for the following groups: NSAIDs, opioids, muscle relaxants, and anticonvulsants.

<sup>2</sup> Ohio Bureau of Workers' Compensation (2015).

<sup>3</sup> See <http://ok.gov/wcc/documents/Chapter%203-Medical%20Services.pdf>. Note that unlike Texas where all claims are governed by the same formulary rules as of September 2013, the closed formulary rules do not apply to claims with injuries prior to February 2014 in Oklahoma. It will be useful to monitor the impact of the formulary in states that only implement a closed formulary prospectively for injuries after a specified date of injury, like Oklahoma, compared with a state like Texas.

not recommended for workplace injuries based on existing evidence).<sup>4</sup> This suggests that there is significant potential for reducing the use of non-formulary drugs prescribed to North Carolina state employees and thereby achieving significant reduction in total prescription costs.

We found that one-third of the non-formulary drug spending was for long-acting opioids prescribed to North Carolina state employees. This category of medications includes high-risk drugs such as extended-release formulations of oxycodone (OxyContin®), morphine (MS Contin®), oxymorphone (Opana® ER), fentanyl patches (Duragesic®), etc. ODG specifies that long-acting opioids are not recommended as first-line treatment for acute or chronic pain. However, physicians can still prescribe these medications under a Texas-like formulary after seeking preauthorization by substantiating the medical necessity of these drugs. But evidence from other formulary states suggests that disincentives to prescribe non-formulary drugs, such as seeking preauthorization, reduce their utilization.

This study also provides estimates of potential cost savings if a Texas-like formulary was adopted for North Carolina state employees, based on certain assumptions about how frequently physicians in North Carolina are likely to seek preauthorization and continue to prescribe non-formulary drugs and how frequently they are likely to substitute non-formulary drugs that are not prescribed because of the preauthorization requirement with other drugs that do not require preauthorization. If North Carolina physicians' reactions to the formulary are similar to their Texas counterparts, the state could see a 30 percent reduction in prescription costs paid for state employees, which amounts to about \$8.7 million over a three-year period. One of the factors that differentiates North Carolina from Texas is that the formulary in Texas was adopted as a part of larger reforms in the state aimed at medical cost containment, including the adoption of ODG treatment guidelines. Texas has a requirement of preauthorization for various medical services such as physical and occupational therapy, outpatient surgical services, inpatient services, spinal surgery, and diagnostic imaging, among others.<sup>5</sup> Texas doctors had been seeking authorization prior to providing these medical services for many years before they were required to seek preauthorization for prescribing non-formulary medications.<sup>6</sup> Texas has a medical dispute resolution process in place wherein preauthorization requests that are denied are reviewed promptly by independent review organizations. It is possible that, in states without a well-defined utilization review process for pharmaceuticals, such as North Carolina, the full impact of the formulary may not be realized. Furthermore, the increased litigation costs might offset the formulary cost savings. Our study includes an alternate scenario that differs in the extent to which prescribers continue to prescribe non-formulary drugs (Scenario C, only a 25 percent reduction in non-formulary prescriptions). For instance, if in North Carolina denials of preauthorization by payors are overridden during the appeals process in favor of the prescribers, the cost savings are estimated to be about \$3.6 million over a three-year period instead of the \$8.7 million in Scenario A (Texas experience). We do not have information to know the extent of this behavior in North Carolina. But, the alternate scenarios provide a sense of the impact of a lenient appeals process.

The second factor we varied in our simulations of cost savings is the extent to which physicians might substitute non-formulary drugs with drugs that do not require preauthorization. Even if North Carolina

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<sup>4</sup> Texas (and Oklahoma) uses the Official Disability Guidelines (ODG) formulary, and in Ohio, the bureau's pharmacy and therapeutics (P&T) committee reviews the medical literature and best clinical practices to maintain the formulary.

<sup>5</sup> See <http://www.tdi.texas.gov/wc/rules/adopted/documents/2005911preauth.pdf> for more information on preauthorization of medical services in Texas.

<sup>6</sup> HB 2006, passed by the Texas legislature in 2001 and effective January 2002, required preauthorization for outpatient surgical services, inpatient services, spinal surgery, diagnostic imaging, and work hardening at certain facilities. HB 7, passed in May 2005 and effective September 2005, required preauthorization of physical and occupational therapy. Preauthorization for drugs excluded from the formulary was effective September 2011.

physicians substitute all non-formulary drugs that are not approved by the payor with formulary drugs, the state is still likely to have prescription cost savings, but to a lesser extent than reported under the non-substitution scenarios. So, are physicians in North Carolina likely to substitute with formulary drugs unlike Texas doctors? A previous Workers Compensation Research Institute (WCRI) study identified that physician dispensing is a factor that might have a muting effect on the impact a Texas-like closed formulary could have in other states as physician-dispensers may choose to substitute non-formulary drugs with formulary drugs more often because of financial incentives (Thumula and Liu, 2014). Physician dispensing of non-formulary drugs was infrequent among North Carolina state employees, only 1–2 percent of non-formulary prescriptions filled were physician dispensed. Therefore, substitution may not occur in North Carolina due to physician dispensing. However, physician dispensing is just one mechanism of financial incentives; there may also be other factors, such as patient needs and availability of physicians' preferred substitutes, that might influence North Carolina doctors to substitute.

# TECHNICAL APPENDIX

## ALTERNATE SPECIFICATIONS FOR FINDING SUBSTITUTES

The extent of cost savings with a formulary depends on the medication that the physician chooses to substitute the non-formulary drugs with. However, it is not easy to identify the likely substitutes that physicians may prescribe in place of non-formulary drugs. Physicians' choices could depend on the indication of the non-formulary drug, how long the patient was on the non-formulary medication, whether alternative medications were tried before the non-formulary drug in question, the physician's and patient's preferences, other medications prescribed to the injured worker, and other regulatory rules surrounding certain classes of medications like opioids, among other factors. While it is challenging to predict physicians' choices of whether or not to substitute and the type of drug to use for substitution, we examined the sensitivity of the choice of substitutes on estimated cost savings using various approaches to identify the potential substitutes for non-formulary drugs.

In a more specific approach, we could posit that physicians would choose to substitute the non-formulary drug with the closest possible alternative, an approach used by Swedlow, Hayes, and David (2014), i.e., if a brand name drug is off the formulary, physicians might switch the patient to the generic version of the drug; if both brand name and generic versions of a drug need preauthorization, they may consider prescribing a drug within the same class of medications; and if no alternatives are available on the formulary within the same class of medications, they may consider drugs in the same broader drug group. On the other hand, if we were to choose a more parsimonious approach, we could assume that physicians might substitute the non-formulary drug with drugs that do not require preauthorization from the same drug group. Or the choice could be somewhere in the middle of these two approaches. We estimated the cost savings by substituting non-formulary drugs with the matching formulary drug prescriptions using the various specifications starting from the most-specific to the least-specific approach and observed that the estimates were fairly similar across the various methods.

We used the classification scheme provided by Medi-Span®'s Generic Product Identifier (GPI) to identify the likely list of substitutes under the different specifications. GPI has 14 digits, with each two digits providing more specific information about the drug products. To illustrate, let us consider the drug product 40 milligrams tablet of citalopram hydrobromide (Celexa®), which is a non-formulary drug under the Texas formulary, with GPI of 58160020100340.

<b>58</b>	first 2 digits identifies the drug group, antidepressants
<b>5816</b>	next 2 digits identify the drug class, selective serotonin reuptake inhibitors (SSRIs)
<b>581600</b>	next 2 digits identify the drug subclass, there aren't any subclasses within SSRIs
<b>58160020</b>	next 2 digits identify the drug name, citalopram
<b>5816002010</b>	next 2 digits identify the drug name extension, citalopram hydrobromide
<b>581600201003</b>	next 2 digits identify the dosage form, tablets
<b>58160020100340</b>	last 2 digits identifies the strength, 40 milligrams

We tested the sensitivity of estimating cost savings for the substitution scenarios using seven different specifications. The specifications differ in terms of how the most likely substitutes were identified. In Specification 1, the most likely substitutes were identified by matching on all 14 digits of the GPI, and if we were not able to match on the 14 digits, we tried matching on the first 12 digits, then on the first 10 digits, and we continued the process until we found a match. For example, with the example of citalopram, considering all citalopram products are considered non-formulary drugs, we would not find any substitutes using 14, 12, 10, and 8 digits. And as there aren't any subclasses of SSRIs, we would try matching by 4-digit GPIs. However, all SSRIs are non-formulary drugs,<sup>1</sup> so the algorithm would proceed to match using 2 digits, i.e., other classes of antidepressants. In this case, tricyclic antidepressants and serotonin-norepinephrine reuptake inhibitors (SNRIs) are on the formulary and would be considered likely substitutes for citalopram (Celexa®). The subsequent specifications differed on the level at which we started matching formulary drugs to find likely substitutes. To identify the list of potential substitutes, we started the matching process using the first 12 digits (dosage form) in Specification 2, the first 10 digits (drug name extension) in Specification 3, the first 8 digits (drug name) in Specification 4, the first 6 digits (drug subclass) in Specification 5, the first 4 digits (drug class) in Specification 6, and the first 2 digits of the GPI (drug group) in Specification 7. In each specification, if possible substitutes were not available using the preferred level of matching then the next level of grouping of drugs was used in identifying possible substitutes.

The specifications described above using the GPI were useful in finding possible substitutes for non-formulary drugs in most drug groups, with some exceptions, either because all drugs within the drug group were considered non-formulary drugs or because the GPI classification did not appropriately capture likely substitutes. An example of the former is that all long-acting opioids require preauthorization under the Texas formulary (with the exception of long-acting tramadol HCL), effective February 1, 2016. In this case it is possible that physicians might either seek preauthorization for long-acting opioids or they may try to wean patients off of these medications instead of substituting them with alternatives. On the other hand, physicians may switch patients on long-acting opioids to short-acting opioid prescriptions of the same morphine equivalent amount,<sup>2</sup> which increases the concerns of adverse reactions, especially among patients receiving higher daily morphine equivalent doses. In this study, we made an assumption that short-acting opioids and long-acting tramadol HCL may be considered potential substitutes for long-acting opioids excluded from the formulary and that a non-formulary long-acting opioid prescription may be substituted with a formulary opioid prescription of the same morphine equivalent amount. Similarly, for short-acting opioids, we considered all short-acting opioids on the formulary as substitutes and substituted non-formulary prescriptions with formulary prescriptions of the same morphine equivalent amount.

Topical diclofenac products (Flector®, Voltaren®, and Pennsaid®) are an example where the GPI approach described earlier did not capture potential substitutes. There are no medications within the topical anti-inflammatory agents drug class among the formulary drugs; therefore, the specification matches the drugs on the first 2 digits, which is all dermatologicals including topical corticosteroids, antibiotics, etc. In this study, for the purpose of substitution, we split topical analgesics into two categories—topical diclofenac products and topical lidocaine products. We substituted diclofenac gels and patches with oral NSAIDs, and

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<sup>1</sup> Some SSRIs such as escitalopram (Lexapro®), fluoxetine (Prozac®), paroxetine (Paxil®), and sertraline (Zoloft®) require preauthorization if the drug is being prescribed for pain and do not require preauthorization if they are being prescribed for mental health conditions. In this study, we did not use such drugs with diagnosis dependent status for substitution.

<sup>2</sup> This approach might underestimate the potential cost savings under a Texas-like formulary in scenarios allowing for substitution.

lidocaine creams and patches with other topical analgesics containing capsaicin, menthol, and salicylates. For benzodiazepines, we estimated cost savings by assuming that other anti-anxiety medications like hydroxyzine HCL (Atarax®) or buspirone HCL (Buspar®) might be prescribed in their place. In the formulary, all benzodiazepines except clobazam (Onfi®) are listed under non-formulary drugs. Clobazam is not addressed in the Texas formulary. If physicians were to substitute non-formulary benzodiazepines with clobazam, which is an expensive single-source medication that was rarely prescribed, it may result in an increase in prescription payments for that class of medications.

Another challenge with our approach of estimation of cost savings was that for non-formulary drugs in two drug groups, topical lidocaine and antipsychotics, there were few prescriptions in each calendar year identified as substitutes (less than 50), and we observed large variation in prices across these prescriptions. As a result, the estimated cost savings in scenarios with substitution for these two drug groups were substantially different across years. For instance, the estimated cost savings by substituting topical lidocaine with formulary topical analgesics prescribed in the same year are shown in Table TA.1.

**Table TA.1 Estimated Reduction in Topical Lidocaine Prescription Costs If 100% of These Prescriptions Are Substituted with Formulary Drugs, Prior to Pooling**

	2012	2013	2014
Substitution with the average formulary prescriptions	-22%	-43%	-71%
Substitution with the median formulary prescriptions	-73%	-98%	-98%

*Notes:* The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

To minimize the impact of the small cell sizes and large variation in prices on our estimates, we pooled the formulary drug prescriptions across the three years and used this larger pool of substitutes to estimate the cost savings with substitution for topical lidocaine and antipsychotics. Note that this modification has a small impact on the overall cost savings we estimated for Scenarios B and D. To illustrate, in calendar year 2014, we estimated a 9 and 5 percent reduction in total prescription costs in Scenarios B and D using the average substitute without pooling (i.e., using substitute prescriptions in 2014), as opposed to the 8 and 4 percent reduction with pooling of substitutes across the three years.

[Table TA.2](#) presents the estimated cost savings if there is a 100 percent drop in non-formulary drug prescriptions and physicians substitute all non-formulary drugs with formulary drugs based on the seven specifications described above. The differences in cost savings were very small across the various specifications, so we reported the cost savings based on Specification 7 in the main body of this report. Note that the estimated cost savings were lower in calendar year 2014 compared with the other two years. This is because the average wholesale prices (AWPs) of several commonly prescribed formulary drugs increased in 2014, and as the prices paid for the substitutes increased, estimated cost savings decreased.

**Table TA.2 Estimated Reduction in Non-Formulary Drug Payments If 100% of Non-Formulary Drugs Are Substituted**

	Substitution with the Average Formulary Rx			Substitution with the Median Formulary Rx		
	2012	2013	2014	2012	2013	2014
<b>% of estimated reduction in non-formulary prescription payments</b>						
Specification 1 (match starting from 14-digit GPI)	-23%	-24%	-21%	-41%	-38%	-38%
Specification 2 (match starting from 12-digit GPI, dosage form)	-23%	-24%	-21%	-41%	-38%	-37%
Specification 3 (match starting from 10-digit GPI, drug name extension)	-23%	-25%	-22%	-41%	-39%	-39%
Specification 4 (match starting from 8-digit GPI, drug name)	-23%	-25%	-22%	-41%	-39%	-39%
Specification 5 (match starting from 6-digit GPI, drug subclass)	-22%	-24%	-20%	-41%	-38%	-37%
Specification 6 (match starting from 4-digit GPI, drug class)	-21%	-23%	-19%	-40%	-37%	-37%
Specification 7 (match starting from 2-digit GPI, drug group)	-24%	-25%	-21%	-43%	-42%	-40%

Notes: The underlying data include prescriptions for all North Carolina state employees who had prescriptions filled in the given calendar year. 2014 includes all prescriptions filled between January 1, 2014, and December 31, 2014, by North Carolina state employees. Similar notation is used for other years.

Key: GPI: Generic Product Identifier; Rx: prescriptions.

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The Workers Compensation Research Institute is a nonpartisan, not-for-profit research organization providing objective information about public policy issues involving workers' compensation systems.

The Institute does not take positions on the issues it researches; rather it provides information obtained through studies and data collection efforts that conform to recognized scientific methods, with objectivity further ensured through rigorous peer review procedures.

The Institute's work helps those interested in improving workers' compensation systems by providing new, objective, empirical information that bears on certain vital questions:

- How serious are the problems that policymakers want to address?
- What are the consequences of proposed solutions?
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The Institute's work takes several forms:

- Original research studies on major issues confronting workers' compensation systems
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- Benchmarking reports that identify key outcomes of state systems

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## **Appendix 2**

### **Comments on Drug Formularies from Other States' Workers' Compensation Officials**

**The North Carolina Industrial Commission requested that the Texas Bureau of Workers' Compensation provide comments on their experience with a drug formulary. Below are the four points the Commission asked Texas officials to consider along with Texas' comments.**

1) How the formulary has impacted the treatment of injured workers.

Texas has not seen an increase in complaints from injured employees or an increase in medical disputes since the implementation of the closed formulary.

As part of the implementation of the Texas formulary, the Division of Workers' Compensation worked very closely with health care provider organizations and insurance carriers to educate prescribing doctors, pharmacies and injured employees about the closed formulary.

As part of the rulemaking efforts to adopt a closed formulary in Texas, the Division of Workers' Compensation added requirements for insurance carriers to notify prescribing doctors, pharmacies and affected injured employees about the requirements of the formulary. Additionally, the Division, as part of these rules, allowed prescribing doctors and insurance carriers to engage in written pharmaceutical agreements for individual legacy claims that could supersede the formulary. These agreements could allow an injured employee to continue to receive certain excluded drugs for a specified period of time without preauthorization or accommodate a weaning plan if that was mutually agreed to by the prescribing doctor and the insurance carrier.

To account for any potentially dangerous discontinuation of previously prescribed drugs that were subsequently excluded from the formulary, the division adopted a provision for the issuance of medical interlocutory orders (MIO) so that injured employees facing an immediate risk of medical emergency could continue care while they appeal the insurance carrier's denial. To date, only 118 such orders have been requested and 62 have been approved. These relatively few requests are an additional indicator of the effectiveness of the division's education efforts, and are a testament to the cooperation among system participants to proactively address potential issues with continuity of care.

Texas continues to monitor the impact of the closed formulary on injured employees, including whether changes in prescription patterns have affected utilization of physical medicine and the impact of the closed formulary on return-to-work outcomes for injured employees.

2) How the formulary has impacted prescription drug costs.

For new claims, the implementation of the pharmacy closed formulary has resulted in a 15% reduction in total prescription costs in Texas and an 83% reduction in the costs associated with "N-drug" prescriptions.

Detailed information regarding the impact of the Texas pharmacy closed formulary on prescription costs and utilization can be found here (see <http://www.tdi.texas.gov//reports/wcreg/documents/pcformfinal.pdf>).

3) How the formulary has impacted opioid use.

It is important to note that not all opioids are excluded from the closed formulary in Texas. The Texas formulary has resulted in a 65% reduction in the number of “N-drug” opioid prescriptions for new claims and a 9% reduction in the number of “in-formulary” opioid prescriptions for new claims.

Detailed information regarding the impact of the Texas pharmacy closed formulary on opioid utilization can be found here (see <http://www.tdi.texas.gov//reports/wcreg/documents/pcformfinal.pdf>).

4) A comment on if the state had treatment guidelines in place before the formulary or if those were developed in conjunction with the formulary. Also, how important was it to have treatment guidelines in place to work with the formulary?

As part of the implementation of the 2005 legislative reforms in Texas (House Bill 7, 79<sup>th</sup> Legislature, Regular Session), the Division of Workers’ Compensation adopted evidence-based treatment guidelines, which took effect for health care provided on or after May 1, 2007. By rule, the Division of Workers’ Compensation adopted the *Official Disability Guidelines – Treatment in Workers’ Comp*, published by the Work Loss Data Institute (also known as ODG) as the evidence-based treatment guidelines to be used in the Texas workers’ compensation system for non-certified network claims. By statute, workers’ compensation certified networks may designate their own treatment guidelines, but they must be “evidence-based, scientifically valid and outcome-focused.” In practicality, most certified networks also use the ODG treatment guidelines for ease in administration of their claims.

Once Texas adopted and implemented evidence-based treatment guidelines, the Division of Workers’ Compensation began rulemaking efforts to adopt the closed formulary. The pharmacy closed formulary rules were adopted in January 2011 and took effect for new claims with dates of injury on or after September 1, 2011. The formulary took effect for older “legacy” claims (i.e., claims with dates of injury prior to September 1, 2011) on September 1, 2013.

Having evidence-based treatment guidelines implemented first was extremely helpful for Texas since the Texas formulary includes all FDA-approved drugs, except for “N-drugs” listed in Appendix A of the ODG treatment guidelines, compounds containing an “N-drug,” or drugs that are investigational or experimental. Essentially, Appendix A that lists the drugs excluded from the Texas formulary are a compilation of the ODG treatment guideline

recommendations for the use of these drugs in its procedure summary. This means that the Texas formulary is really an extension of the evidence-based treatment guidelines, which ensures that there will not be a conflict with pharmaceutical recommendations in the treatment guideline and the pharmacy closed formulary.

Additionally, implementing evidence-based treatment guidelines first allowed system participants to acclimate to those guidelines before the adoption of the Texas formulary, which helped reduce frictional costs and disputes. As a foundation for the adoption of the Texas formulary, Texas also ensured that there was an infrastructure in place to conduct utilization review (i.e., rules governing how the utilization review process works) and to resolve any medical necessity disputes that may arise after the implementation of the closed formulary. The treatment guidelines, utilization review requirements, data collection requirements and the process for handling medical necessity disputes were all in place before Texas adopted a closed formulary.

**The North Carolina Industrial Commission requested that the Ohio Bureau of Workers' Compensation provide comments on their experience with a drug formulary. Below are the four points the Commission asked Ohio officials to consider along with Ohio's comments.**

1) How the formulary has impacted the treatment of injured workers.

Prescription utilization and long term treatment of Ohio's injured workers has been improved by the formulary. This statement is most strongly demonstrated by the following data points:

In December 2010 there were 8,689 injured workers who met agency criteria for being physically dependent on opioids.

Criteria: Injured worker has received at least 60mg Morphine Equivalent Dose/Day of an opioid for at least 60 days, the equivalent of taking 12 Vicodin tablets per day for 60 days.

Of these injured workers 60 were receiving 1,000mg MED/Day or greater.

In December 2015 there were 6,020 injured workers in the physically dependent category of which 16 were at or greater than 1,000mg MED.

The number of opioid dependent injured workers covered by our program has been reduced by 30.7% over the past 5 years.

2) How the formulary has impacted prescription drug costs.

Drug costs declined by \$38.6M from CY2011 to CY2015.

Calendar year 2011 was BWC's highest year for drug costs at \$136.2M.

CY2015 drug costs were \$97.6M (-28.6%).

CY2015 was the first year since CY2000 that drug costs have been below \$100M.

3) How the formulary has impacted opioid use.

Total doses of narcotics declined by 16.4M from CY2011 to CY2015 (-41%).

The average daily opioid load (mg MED/Day) per injured worker has declined by 19.7% since it peaked in the first quarter of 2011.

The percentage of injured workers receiving opioid prescriptions in 2015 was below that of 2003.

After adjustment for overall claim volume decline, opioid prescriptions covered in new 2015 claims declined by 26% from new claims in 2011.

- 4) A comment on if the state had treatment guidelines in place before the formulary or if those were developed in conjunction with the formulary. Also, how important was it to have treatment guidelines in place to work with the formulary?

BWC utilizes ODG for treatment guidelines, however, there is no direct link between the formulary and the ODG treatment guidelines. They can be approached as independent tools for improving medical care for injured workers and driving best medical practices.

**The North Carolina Industrial Commission requested that the Washington State Department of Labor and Industries provide comments on their experience with a drug formulary. Below are the four points the Commission asked Washington officials to consider along with Washington's comments.**

- 1) How the formulary has impacted the treatment of injured workers.
- 2) How the formulary has impacted prescription drug costs.
- 3) How the formulary has impacted opioid use.
- 4) A comment on if the state had treatment guidelines in place before the formulary or if those were developed in conjunction with the formulary. Also, how important was it to have treatment guidelines in place to work with the formulary?

Thank you for the opportunity to provide comments on the Department of Labor & Industries' (L&I) experience with our drug formulary. L&I is the sixth largest workers' compensation insurer in the nation, covering 2.3 million workers and 161,000 employers. L&I pays out \$1.2 billion each year in benefits. As part of this function, the department strives to improve injured workers' access to appropriate and quality care while driving down the costs of prescription drugs.

The department's approach is to promote equally effective but less costly alternative drug treatment through the use of a formulary and preferred drug list. In conjunction with our formulary, we have established treatment guidelines and coverage criteria to ensure appropriate utilization of high risk drugs. Additionally, a competitive pharmacy fee schedule with 94% of statewide pharmacies participating results in easy access to pharmaceutical care for our injured workers. As a result of our efforts:

- L&I has saved millions through its industry-leading, high generic use rate. Of all prescriptions paid by L&I in fiscal year 2015, only 8% are for brand drugs.
- L&I has been recognized by WCRI as a leader in managing drug costs. ([http://www.wcrinet.org/new\\_electronic\\_rpts/rx\\_bnchmks\\_2/wcri\\_rx\\_bnchmk\\_2\\_WA.pdf](http://www.wcrinet.org/new_electronic_rpts/rx_bnchmks_2/wcri_rx_bnchmk_2_WA.pdf)).
- L&I's drug costs as a percentage of medical costs, is approximately 6%. This is significantly below the national average of 18%. (NCCI 2010 Prescription Drug Study <https://www.ncci.com/Documents/AIS-2010-Drug-Study-Lipton.pdf>).

It is important to recognize that a formulary can help control prescription drug cost but is not effective in managing the prescription benefit as a stand-alone effort. In particular, it does not ensure that opioids and other high risk drugs are prescribed appropriately. For this, treatment guidelines and coverage criteria play an important role. L&I has developed treatment guidelines since 1989 and the department's Guideline for Prescribing Opioids to Treat Pain in Injured Workers sets the standard for prescribing opioids in Washington workers' compensation.

**The North Carolina Industrial Commission requested that the Tennessee Bureau of Workers' Compensation provide comments on their experience with a drug formulary. Below are the four points the Commission asked Tennessee officials to consider along with Tennessee's comments.**

- 1) How the formulary will impact the treatment of injured workers.

It should provide safer patient care by monitoring of drug-drug interactions, potentially dangerous combinations and help with the epidemic of prescription drug abuse by encouraging more conversation between physician and patient.

- 2) How the formulary will impact prescription drug costs.

Reductions based upon the use of generic substitution.

- 3) How the formulary will impact opioid use.

Reductions based upon the use of generics. It is hoped that by the emphasis on physician education and public awareness of the limits and dangers of these drugs that we might be able to prevent the next generation in pills only for pain management.

- 4) A comment on if you had treatment guidelines in place before the formulary or if those were developed in conjunction with the formulary. Also, how important was it to have treatment guidelines in place to work with the formulary?

The drug formulary was adopted at the same time as part of a comprehensive set of treatment guidelines. The drug formulary is an important part of the treatment guidelines since 30% of the medical costs in Workers' Compensation are prescriptions. A comprehensive and inclusive approach was appropriate for us.

The Arkansas Workers' Compensation Commission provided the North Carolina Industrial Commission with the following response when the Commission inquired regarding their experience with a drug formulary. Note that the drug formulary utilized by Arkansas is only applicable to Arkansas public employee workers' compensation claims.

## **The Need for a Drug Formulary**

This overview is intended to advocate the need for a drug formulary to ensure cost containment for your program. In today's market, it is imperative to have such tools at your disposal to provide reasonable access to pharmaceuticals while preserving the limited financial resources of the plan. There are at least three areas where a drug formulary can add value to the health plan.

### **Current Drug Mix**

The entire scope of pharmaceuticals purchased by any health plan is comprised of drug categories made up of individual drug products. Within many drug categories, several drugs may exist with little to no difference in comparative clinical value but with significant variation in cost. Additionally, year-over-year inflation (i.e. drug price increases among existing products) can be significant and plan administrators need such a tool to limit the plan's exposure to such pricing practices. Therefore, significant savings for the plan exist by steering usage patterns toward the most cost-effective drug within a given category.

### **New Entries to the Market**

In addition to existing drug products, the new drug pipeline is dynamic with new drugs entering the market on a daily basis. While some new drugs are completely new entities, some products are simply new formulations of existing drugs (i.e. a new extended-release formulation of a drug that has been available for years in an immediate-release formulation). In most cases, new entries to the market can be significantly more costly than existing alternatives. Additionally, there is no correlation between newer and more expensive drugs to superior clinical effectiveness.

### **Better Care**

Several clinical management tools can be employed through the drug formulary that can further enhance patient care. For example, ***Quantity Limits*** (dispensing limits) can be applied to drugs prone to wastage or overdose. ***Step therapy*** can be employed to encourage adherence to clinical guidelines by requiring a "first-line" drug be used prior to a "second-line" drug. This can steer usage to safer, better or more cost-effective alternatives. ***Prior authorization*** can be incorporated into the formulary for agents associated with strict usage criteria and/or very expensive products.

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## Appendix 3

### Impact of a Texas-Like Formulary in Other States (June 2014)



# **IMPACT OF A TEXAS-LIKE FORMULARY IN OTHER STATES**

*Vennela Thumula*

*Te-Chun Liu*

WC-14-31

June 2014

WORKERS COMPENSATION RESEARCH INSTITUTE  
CAMBRIDGE, MASSACHUSETTS

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Of course, any errors or omissions that remain in the report are the responsibility of the authors.

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Cambridge, Massachusetts

June 2014

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## EXECUTIVE SUMMARY

This study examines how a Texas-like closed formulary might affect the prevalence and costs of drugs in 23 other state workers' compensation systems that do not currently have a drug formulary.<sup>1</sup>

### THE PREVALENCE OF NON-FORMULARY DRUGS

Among the major findings of the study are the following:<sup>2</sup>

- Non-formulary drugs were prevalent in the other 23 study states.<sup>3</sup> They accounted for 10–17 percent of all prescriptions and 18–37 percent of total prescription costs. The comparable numbers for pre-reform Texas were 11 percent and 22 percent, respectively. Non-formulary drugs were most common in New York<sup>4</sup> (17 percent) and Louisiana (16 percent). Even at the lower end of the states, the prevalence was similar to the prevalence in Texas prior to the formulary.
- Several non-formulary drugs were common in most or all states studied, but there were notable differences from state to state. Voltaren®, Soma®, Valium®, Lidoderm®, and OxyContin® were the most commonly prescribed non-formulary drugs in the majority of study states. They accounted for 35–60 percent of non-formulary drug prescriptions in most states. However, there were notable differences in the mix of drugs in some states. For example, in California, 11 percent of non-formulary drug prescriptions were for Banflex®. The drug accounted for less than 2 percent of non-formulary drug prescriptions in most other states.
- The costs of non-formulary drugs were higher in states with more frequent use of brand name drugs, despite the generic mandates that exist in most states.<sup>5</sup> In most states, brand name drugs comprised 30–40 percent of non-formulary prescriptions and 55–75 percent of payments for non-formulary drugs. States with relatively higher use of non-formulary brand name drugs include New York (57 percent of non-formulary prescriptions and 83 percent of costs), and New Jersey (49 percent of prescriptions and 80 percent of costs).

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<sup>1</sup> The 23 states are Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia, and Wisconsin.

<sup>2</sup> The underlying data include prescriptions for claims with injuries from October 1, 2010, to September 30, 2011, with more than seven days of lost time that had prescriptions filled through March 31, 2012.

<sup>3</sup> Non-formulary drugs are drugs that are excluded from the Texas closed formulary. They include drugs like OxyContin®, Lidoderm®, and Soma®.

<sup>4</sup> New York adopted major reforms addressing opioid use in recent years. In New York, the Internet System for Tracking Over-Prescribing (I-STOP) legislation was passed to mandate that physicians check the prescription drug monitoring program database prior to prescribing controlled substances. The New York State Workers' Compensation Board proposed non-acute pain medical treatment guidelines in April 2013 and has been working to coordinate its medical treatment guideline implementation with the I-STOP legislation and forthcoming regulations. The data presented in this report are prior to these reforms.

<sup>5</sup> States where generic substitution is not mandated include Connecticut, Illinois, Indiana, Iowa, Louisiana, Maryland, Missouri, New Jersey, North Carolina, and Pennsylvania.

## IMPACT OF ADOPTING A TEXAS-LIKE CLOSED FORMULARY

- In response to the closed formulary, Texas physicians adjusted prescribing patterns in two significant ways, on average (Texas Department of Insurance, 2013). First, physicians reduced prescriptions for non-formulary drugs by 70 percent. Second, physicians infrequently substituted formulary drugs for non-formulary drugs.
- The response of physicians in other states to a Texas-like closed formulary may be similar to that of their Texas counterparts. However, that response might be more muted. To estimate the impact of adopting a Texas-like formulary in other states, we made various alternative assumptions about how physician prescribing practices might change. This is not to say that these assumptions are realistic expectations of what might happen in the 23 states. We provide multiple scenarios to the reader in order to illustrate the sensitivity of the impact of the formulary to prescribers' reactions—specifically, (1) how often they seek preauthorization to prescribe non-formulary drugs and (2), when they reduce the use of non-formulary drugs, how often they substitute with formulary drugs.<sup>6</sup> See [Table A](#).

- **Scenario A.** Where physicians adjust to a closed formulary in ways that are similar to what we saw with Texas physicians, we estimate large effects of adopting such a formulary. We estimate reductions from 10–17 percent to 3–5 percent of all prescriptions that were for non-formulary drugs and a 14–29 percent reduction in total prescription costs. Larger effects are expected in New York, New Jersey, Virginia, Massachusetts,<sup>7</sup> Pennsylvania, Connecticut,<sup>8</sup> and Maryland. However, there are reasons to expect that physicians in some of these states may substitute formulary drugs more frequently than did Texas physicians.

For example, in states where physician dispensing is common, physicians may be more likely to substitute for non-formulary drugs due to the economic incentives incident to physician dispensing (a muting effect). An earlier Workers Compensation Research Institute (WCRI) study (Thumula, 2013) found high levels of substitution by Florida physician-dispensers when Florida banned physician dispensing of stronger opioids. By contrast, there was little substitution in Texas, where physician dispensing was not permitted in general. States where physician dispensing of non-formulary drugs was more common include California (42 percent of all non-formulary prescriptions), Maryland (36 percent), Florida (30 percent), Illinois (30 percent), Connecticut (25 percent), Georgia (16 percent), and Pennsylvania (15 percent).<sup>9</sup>

- **Scenario B** assumes that physicians in other states reduce their use of non-formulary drugs to the same extent as their Texas counterparts, but that they fully substitute formulary drugs. In this scenario, we estimate a reduction in prescription costs of 4 to 16 percent. This is smaller than

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<sup>6</sup> There is a third factor we do not analyze in this study. It pertains to the extent to which the closed formulary applies to legacy claims. We did not estimate the impact of a closed formulary on legacy claims in this study because this study benefits greatly from observing the results from Texas. At the time of this analysis, results of the impact of the Texas formulary on legacy claims were not available. The Texas formulary was implemented for new injuries on September 1, 2011, and for legacy claims on September 1, 2013.

<sup>7</sup> Massachusetts implemented chronic pain treatment guidelines, which went into effect in March 2013.

<sup>8</sup> In Connecticut, effective July 2012, the state Workers' Compensation Commission created new medical protocols for prescribing opioids for acute and chronic pain. In addition, Public Act 13-172, signed into law on June 21, 2013, requires all prescribers to register with the state prescription drug monitoring program (PDMP).

<sup>9</sup> Please refer to Appendix A of Wang, Liu, and Thumula (2013) for a comprehensive summary of state policies regarding pharmacy fee schedules and physician dispensing.

Scenario A (14–29 percent) because Scenario A assumes that, as in the Texas experience, physicians did little substitution.

- **Scenario C.** Texas physicians reduced their use of non-formulary drugs by 70 percent. What if the behavior of Texas physicians was unique (for example, if physicians in State X learn that adjudicators would override many denials of preauthorization by payors)? Scenario C contemplates a situation where physicians in State X reduce use of non-formulary drugs by only 25 percent. But like physicians in Texas, little substitution of formulary drugs occurs. Under Scenario C, we estimate prescription cost reductions of 4–9 percent.
- **Scenario D** is the same as Scenario C except it assumes full substitution. Here we estimate prescription cost reductions of 2–6 percent. Under Scenarios C and D, we estimate that the percentage of all prescriptions that were for non-formulary drugs might drop from 10–17 percent to 7–13 percent.
- States where brand name medications are commonly used are likely to see higher prescription cost savings with the adoption of a Texas-like formulary (a magnifying effect). These include New York and New Jersey.

**Table A Estimated Reduction in Prescription Costs with a Texas-Like Formulary under Different Scenarios, 2011/2012**

State	SCENARIO A: % Reduction in Rx Costs	SCENARIO B: % Reduction in Rx Costs	SCENARIO C: % Reduction in Rx Costs	SCENARIO D: % Reduction in Rx Costs	% Non-Formulary Drug Rx That Were Brand Name (key factor magnifying effect)	% Non-Formulary Drug Rx That Were Dispensed by Physicians (key factor muting effect)
Arkansas	19%	7%	6%	3%	40%	2%
California <sup>a</sup>	14%	4%	4%	2%	32%	42%
Connecticut <sup>b,c,d</sup>	21%	10%	7%	4%	38%	25%
Florida <sup>c</sup>	19%	8%	6%	3%	35%	30%
Georgia <sup>a</sup>	15%	5%	5%	2%	30%	16%
Illinois <sup>b,c</sup>	17%	8%	5%	3%	31%	30%
Indiana <sup>b,c</sup>	16%	8%	5%	3%	33%	6%
Iowa <sup>b</sup>	15%	7%	5%	3%	35%	3%
Kansas	16%	8%	5%	3%	32%	4%
Louisiana <sup>b</sup>	18%	5%	6%	2%	30%	5%
Maryland <sup>b</sup>	20%	10%	6%	3%	30%	36%
Massachusetts <sup>d</sup>	23%	12%	7%	4%	33%	0%
Michigan <sup>c</sup>	19%	11%	6%	4%	24%	6%
Minnesota	17%	9%	6%	3%	32%	0%
Missouri <sup>b</sup>	14%	6%	4%	2%	26%	11%
New Jersey <sup>b</sup>	25%	14%	8%	5%	49%	3%
New York <sup>d</sup>	29%	16%	9%	6%	57%	0%
North Carolina <sup>b</sup>	18%	8%	6%	3%	35%	3%
Pennsylvania <sup>b</sup>	22%	12%	7%	4%	41%	15%
South Carolina <sup>c</sup>	17%	5%	5%	2%	26%	9%
Tennessee <sup>c,d</sup>	18%	7%	5%	3%	31%	11%
Texas	17%	8%	5%	3%	34%	2%
Virginia	24%	12%	7%	4%	34%	5%
Wisconsin	19%	9%	6%	3%	40%	6%

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> Two states included in the study (California and Georgia) made rule changes for physician-dispensed prescriptions, effective March 2007 and April 2011, respectively. The data are post-reform for California and partially post-reform for Georgia.

<sup>b</sup> States where generic substitution is not mandated (Connecticut, Illinois, Indiana, Iowa, Louisiana, Maryland, Missouri, New Jersey, North Carolina, and Pennsylvania).

<sup>c</sup> Seven states (Connecticut, Florida, Illinois, Indiana, Michigan, South Carolina, and Tennessee) recently adopted reforms aimed at reducing the costs of physician-dispensed prescriptions. The data presented here are pre-reform for these states. Note that we grouped South Carolina and Tennessee with the pre-reform states because the data for the two states are predominantly pre-reform.

<sup>d</sup> Some study states had major reforms addressing the use of controlled substances and pain medications, specifically opioids, after our study period, and these reforms may have affected prescription utilization in the states. Massachusetts, New York, and Tennessee passed laws in 2012 requiring registration and use of a prescription drug monitoring program by prescribers. Connecticut (in 2012) and Massachusetts (in 2013) adopted chronic pain treatment guidelines. New York also proposed non-acute pain medical treatment guidelines in 2013.

Key: Rx: prescriptions.

## SCOPE OF STUDY

This study examines the utilization and costs of non-formulary drugs among newly injured workers in Texas and 23 other states. The focus of this study is on the potential impact of a Texas-like formulary on prescription use and costs and not on the patient outcomes. We chose to report the data for new injuries because, to estimate the likely impact of a formulary in other states, we made assumptions that rely on the impact of the closed formulary in Texas, and the evidence available so far pertains to the impact the closed formulary had on new injuries in Texas. In this study, we look at prescription utilization for injuries arising from October 1, 2010, to September 30, 2011, with prescriptions filled through March 31, 2012, and paid for by workers' compensation payors. The data reflect an average 12 months of experience for claims included in the analysis. Some non-formulary drugs, like long-acting narcotics, are typically used more often at a later stage of medical treatment. So, it is possible that the impact could be larger than the estimates reported in this study at longer maturities. It is important to note that some states had reforms after the time period of these data and those reforms may have affected the prescription utilization in the state. We note which states had such material reforms.<sup>10</sup>

## LIMITATIONS

Two limitations of this study should be noted. The claims used for this study may not be representative of all claims in a few states. This may occur because the reporting of pharmacy data, although improving, was less complete for several data sources, resulting in additional exclusions.<sup>11</sup> For a few states, we were missing data from some large regional insurers.<sup>12</sup> Lastly, the interstate comparisons in this study were not adjusted for interstate differences in the mix of cases. However, the differences in these factors are unlikely to be large enough to affect the results, based on other WCRI studies that adjusted for these factors (see Yang et al., 2009).

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<sup>10</sup> Non-formulary drugs include several controlled substances and pain medications. Therefore, major reforms that impact the prescribing of such medications, like mandatory use of a prescription drug monitoring program (PDMP) by physicians prior to prescribing controlled substances and adoption of chronic pain treatment guidelines, may affect the utilization of non-formulary drugs in those states. Readers interested in legislative or regulatory changes related to PDMPs and other reforms addressing opioid misuse should refer to Technical Appendix A in Thumula, Wang, and Liu (2014) for a detailed discussion of the reforms.

<sup>11</sup> Although we made sure that the claims included for this study represented all claims from the same data sources, the additional exclusions (of data sources in some states) may affect the representativeness if the claims from those data sources were different or had different experience. The percentage of claims in the population of each state that were represented by the claims included in our study ranged from 22 to 58 percent, depending on the state.

<sup>12</sup> We do not provide more details because of confidentiality concerns.

# 1

## INTRODUCTION

As policymakers seek to contain medical costs, part of the focus is on pharmacy costs. A common tool used by commercial insurers and some government programs for this purpose is a closed drug formulary—a limited list of medications covered by a health plan. A closed formulary typically limits access to some drugs by requiring prior-authorization for drugs not included in the formulary.

In workers' compensation, only a few states have adopted drug formularies. The most recent was Texas.<sup>1</sup> Among the objectives of the Texas closed formulary, which is an evidence-based formulary, are (1) to encourage pharmaceutical care provided to injured workers to be evidence-based, and (2) to help contain pharmaceutical costs, since use of drugs excluded from the formulary is likely to be reduced and also because some of the drugs that fall outside of the closed formulary are expensive brand name drugs while less expensive therapeutic alternatives are within the closed formulary.

This study examines how a Texas-like closed formulary might affect the use and costs of drugs in 23 other states.<sup>2</sup> The states to be analyzed were selected because they are larger, geographically diverse, and represent over 70 percent of workers' compensation benefits in the United States.

### ABOUT THE TEXAS CLOSED FORMULARY

The adoption of treatment guidelines and an evidence-based closed formulary is a statutory requirement of House Bill (HB) 7, 79th Legislature, Regular Session.<sup>3</sup> The Texas Department of Insurance, Division of Workers' Compensation worked closely with several system stakeholders for several years after the bill was passed in 2005 to develop rules for the closed formulary. In December 2010, the commissioner adopted final rules to implement the closed formulary. The formal rule adoption said:

“. . . the Division's adopted treatment guidelines, required by statute, are evidence-based, scientifically valid, and outcome-focused. The evidence included in the Division's adopted treatment guidelines is based on the AGREE Instrument and is described in detail in the hard copy and

---

<sup>1</sup> Oklahoma has recently adopted a closed formulary, which will be implemented for injuries occurring on or after February 1, 2014. See <http://ok.gov/wcc/documents/Chapter%203-Medical%20Services.pdf>.

<sup>2</sup> The 23 states are Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, Tennessee, Virginia, and Wisconsin.

<sup>3</sup> See §§ 408.052 and 413.011 of the Texas Labor Code.

electronic version of *ODG Treatment in Workers' Comp* and on the WLDI [Work Loss Data Institute] website.”<sup>4</sup>

The closed formulary was effective on September 1, 2011, for new injuries and on September 1, 2013, for *legacy* claims (i.e., injuries prior to September 1, 2011). Implementation of the closed formulary was done in two phases to ensure that the pharmaceutical care for injured workers being treated with medications to be excluded from the formulary would not be abruptly discontinued.

The Texas formulary includes all drugs approved by the Food and Drug Administration (FDA) except investigational and experimental drugs and drugs with “N” drug status in the current edition of the Official Disability Guidelines (ODG).<sup>5</sup> If a drug is included in the formulary, physicians may prescribe it without obtaining preauthorization. If the drug is excluded from the formulary, physicians may only prescribe it if they obtain preauthorization from the payor.

The most commonly prescribed medications to injured workers are included in the formulary and do not require preauthorization. This includes Vicodin® (hydrocodone-acetaminophen), Percocet® (oxycodone-acetaminophen), Ultram® (tramadol), Naprosyn® (naproxen), Motrin® (ibuprofen), and Flexeril® (cyclobenzaprine).<sup>6</sup> These drugs are referred to as *formulary drugs* in this study.

Preauthorization to substantiate medical necessity is required for the excluded drugs. We refer to such drugs as *non-formulary drugs* in this study. According to the developer of the formulary, some of these non-formulary drugs are not recommended as first-line therapy and others are not recommended at all due to the lack of therapeutic efficacy and/or safety concerns.<sup>7</sup> The guidelines for the formulary also encourage physicians to avoid prescribing more expensive brand name medications when less expensive alternatives are available.<sup>8</sup>

Examples of commonly prescribed drugs that require preauthorization:

- Several drugs with higher than normal abuse potential. Most long-acting Schedule II narcotics, like OxyContin®, Opana®, Exalgo®, Avinza®, Kadian®, and Zohydro®, require authorization.<sup>9</sup> MS-Contin® is the only long-acting Schedule II narcotic in the formulary.
- Expensive brand name medications like Lidoderm®, Flector® Patch, and OxyContin®. OxyContin® and

<sup>4</sup> See the rule adoption at <http://www.tdi.texas.gov/wc/rules/adopted/documents/aorx1210.pdf>.

<sup>5</sup> The Texas closed formulary includes “all FDA approved drugs prescribed and dispensed for outpatient use with the following exclusions—(a) drugs with ‘N’ drug status in the current edition of ODG, (b) compounded drugs that contain an ‘N’ drug and (c) investigational or experimental drugs as defined in Texas Labor Code §413.014(a).”

<sup>6</sup> TDI posts monthly updates of the drug formulary on their website (<http://www.tdi.texas.gov/wc/pharmacy/>).

<sup>7</sup> For example, benzodiazepines are not recommended as first-line medications by ODG. ODG advises that benzodiazepines are “not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction.”

<sup>8</sup> For instance, ODG recommends that brand name extended-release morphine (Kadian® and Avinza®) should be prescribed only after a trial of generic extended-release morphine (equivalent to MS Contin®). ODG cites research which shows that there are no significant differences between these brand name medications and MS-Contin® in terms of clinical efficacy or safety.

<sup>9</sup> *Schedule II narcotics* are narcotics that are classified as Schedule II controlled substances, which are of the highest abuse potential among the controlled substances for medical use. There are five schedules of controlled substances, classified by the Drug Enforcement Administration under federal law, which are based on a drug’s medical usefulness and abuse potential. Long-acting Schedule II narcotics are typically in the form of sustained or controlled release with a higher dosage or strength that lasts longer for consistent pain relief, while short-acting Schedule II narcotics are indicated for immediate relief of acute pain or intermittent or breakthrough pain.

Lidoderm<sup>®10</sup> were reported to be the top two drugs in terms of prescription spending in the workers' compensation system in 2011 (Lipton, Laws, and Li, 2013). Lidoderm<sup>®</sup> is approved for shingles pain and is used off-label to treat workers' compensation injuries; Flector<sup>®</sup> Patch (diclofenac epolamine) has an increased cardiovascular risk profile compared with other non-steroidal anti-inflammatory drugs (NSAIDs).

- Generically available drugs that are not recommended for first-line therapy like Voltaren<sup>®</sup> (diclofenac sodium), an NSAID, and benzodiazepines like Xanax<sup>®</sup> and Valium<sup>®</sup>. Soma<sup>®</sup> (carisoprodol) is an example of a generically available drug that is not recommended at all because of safety concerns. The Substance Abuse and Mental Health Services Administration (SAMHSA) reported that emergency department visits related to the misuse or abuse of carisoprodol doubled between 2004 and 2009 (SAMHSA, 2011).

## INITIAL IMPACT IN TEXAS

The initial impact of the selective preauthorization requirement on prescribing practices was very large.<sup>11</sup> The Texas Department of Insurance (TDI) reported that the formulary resulted in cost savings and a reduction in unnecessary use of non-formulary drugs. As the formulary is based on evidence-based guidelines, reduction in use of non-formulary drugs could be perceived as an improvement in patient care. The 2013 report by TDI<sup>12</sup> indicates the following:

- The number of new claims with non-formulary drugs that required preauthorization decreased by 67 percent from 2010 to 2011.
- The percentage of prescriptions written for non-formulary drugs decreased by about 70 percent for these new claims.
- The share of prescription drug costs accounted for by non-formulary drugs decreased by over 80 percent in the new claims.
- Surprisingly, prescriptions for drugs included in the formulary did not increase—suggesting that many physicians chose not to write the prescription for the drug that required preauthorization and, moreover, did not substitute another drug that was not subject to preauthorization.
  - Prescriptions for formulary drugs decreased by 4 percent.
  - The number of claims with formulary drugs dropped by 4 percent. Among those receiving formulary drugs, the number of formulary drug prescriptions per claim decreased by 2 percent.
- The study also reported a decrease in total opioid prescriptions by 10 percent after the closed formulary was implemented.<sup>13</sup>

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<sup>10</sup> Generics for Lidoderm<sup>®</sup> became available in September 2013.

<sup>11</sup> Texas doctors were used to seeking preauthorization for other medical services, such as physical and occupational therapy, outpatient surgical services, inpatient services, spinal surgery, diagnostic imaging, etc., for several years before they were required to seek authorization prior to prescribing non-formulary medications.

<sup>12</sup> See TDI (2013). An update of the study was recently published covering 12 months of injuries and 12 months of services, and the findings did not change materially.

<sup>13</sup> Prescribing patterns of opioids are likely to be influenced by many factors in addition to the implementation of the closed formulary, including law enforcement efforts, new drug releases, and other legislative changes like mandatory registration of pain management clinics.

Given these large effects, policymakers and stakeholders in other states may wonder about the effect of a Texas-like formulary in their states.

- Would adoption of a Texas-like formulary have a large effect in my state?
- Is the use of drugs that require preauthorization in Texas common in my state?
- If a Texas-like closed formulary is implemented, what are the potential prescription cost savings in my state?

This study addresses these questions for 23 states.

## **ORGANIZATION OF REPORT**

Chapter 2 describes the data and methods used in this study. Chapter 3 presents, for the 23 states plus Texas, how common the drugs that require preauthorization under the Texas closed formulary are and what proportion of prescription payments are for these drugs. Also reported are the most common non-formulary drugs prescribed in each state. In Chapter 4, we analyze the impact of adopting a Texas-like formulary in each of the 23 states. We examine the impact on both prevalence and costs under alternative assumptions about how physician prescribing practices change. The assumptions range from (A) physicians in State X respond as their Texas counterparts did to (B) physicians in State X are much less responsive. We also identify factors that influence whether the impacts are likely to be larger or smaller. Chapter 5 discusses the implications of the findings.

# 2

## DATA AND METHODS

This section describes the data and methods used for this study. For readers interested in more detailed information about the Workers Compensation Research Institute (WCRI) prescription benchmarking metrics and a discussion of certain data and methodological issues, we recommend a previous WCRI report (Wang and Liu, 2011).

### DATA AND REPRESENTATIVENESS

In this study, our data include more than 138,000 claims with more than seven days of lost time that received at least one prescription paid under workers' compensation and 1.1 million prescriptions associated with those claims in Texas and 23 other states.<sup>1</sup>

The claims cover work-related injuries arising from October 1, 2010, to September 30, 2011, with prescriptions filled through March 31, 2012. The data were extracted from the WCRI Detailed Benchmark/Evaluation (DBE) database, in which we have detailed prescription transaction data that were collected from the medical bill review and payment systems of payors and their pharmacy benefit managers. [Table 2.1](#) provides the number of prescriptions and claims by state that are included in this study. The claims included in the study represent 22–58 percent of the claims in each state's workers' compensation system. The unit of analysis for this study is the state. The data reflect an average 12 months of experience for claims included in the analysis.

Unlike in other WCRI benchmarking reports, the data included in this study may not necessarily be representative of the total population of claims in some states for two reasons. First, for a few states, we did not have data from some large regional insurers. If a large regional insurer in a state is different in terms of practice and the book of business they underwrite, data used without the large regional insurer may be less representative of the whole market experience for the state. Second, compared with data on other medical services, the data provided to WCRI on workers' compensation prescriptions, although improving, were less complete for a few data sources. We excluded the data sources from all analyses where our tests suggested that the data provided were not complete and were likely to bias the study results. The additional exclusions of

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<sup>1</sup> We chose to use claims with more than seven days of lost time for the analysis for several reasons. First, because these claims provided a similar set of cases across states in terms of disability for work-related injuries, they helped to make the interstate comparisons of prescribing patterns more meaningful. Second, these claims received more prescriptions and experienced a wider range of medication therapy, compared with those that had only seven or fewer days of lost time. Focusing on these claims helped identify more meaningful interstate variations. Third, the claims with more than seven days of lost time also accounted for the majority of workers' compensation medical costs, an area of greater policy implications. We also tested whether the characterization of states as higher or lower in terms of frequency of non-formulary drug use and costs is different if we use all claims instead of seven days of lost time claims and found no substantial differences.

some data sources may have affected the representativeness of the data to the extent that the claims from those excluded data sources may have been different or had different experiences from those that were included. To maximize the representativeness, we applied a threshold of a minimum three data sources so that we did not report the results for a state if fewer than three data sources were included in the data underlying any given prescription benchmark measure.

**Table 2.1 Actual Number of Claims and Prescriptions Included in the Analysis and Percentage Representation, 2011/2012**

State	Number of Claims Included	Number of Claims with at Least One Rx Included	Number of Rx Included	Number of Claims Included as a Percentage of All Claims in the Population
Arkansas	1,505	944	8,381	25%
California	34,417	27,139	249,135	32%
Connecticut	6,392	3,525	22,278	46%
Florida	12,785	9,677	77,428	28%
Georgia	5,368	3,918	35,959	31%
Illinois	12,735	7,776	60,076	37%
Indiana	4,562	3,156	24,773	30%
Iowa	3,814	2,197	14,707	37%
Kansas	2,862	1,828	14,339	24%
Louisiana	2,856	1,909	22,166	30%
Maryland	6,578	4,002	28,455	38%
Massachusetts	9,610	3,439	22,131	48%
Michigan	6,456	4,314	29,551	32%
Minnesota	5,523	2,835	18,743	37%
Missouri	4,455	2,897	19,154	22%
New Jersey	13,649	7,370	41,969	58%
New York	17,755	8,429	57,070	31%
North Carolina	5,917	3,849	34,215	31%
Pennsylvania	14,552	9,254	68,699	38%
South Carolina	3,304	2,204	19,544	31%
Tennessee	5,733	4,116	32,834	38%
Texas	24,041	17,397	145,468	49%
Virginia	4,552	2,580	20,220	38%
Wisconsin	7,772	3,751	22,481	41%

Notes: The claims include those that had more than seven days of lost time for injuries occurring from October 1, 2010, to September 30, 2011. The prescription transaction data are for those prescriptions filled through March 31, 2012, and paid under workers' compensation.

Key: Rx: prescriptions.

## IDENTIFYING AND GROUPING PRESCRIPTION DRUGS

In this report, we included transactions for prescription strength and over-the-counter strength medications (referred to as *prescriptions* throughout the report). These prescriptions could be filled or refilled by the injured worker at a pharmacy or physician's office, and paid for under workers' compensation. We excluded prescription medications that were billed by a hospital or administered in a physician's office (e.g., injections

received at a physician's office). We also excluded nutrition supplements and medical supplies or devices that were billed using National Drug Codes (NDCs).<sup>2</sup>

The data for each prescription typically contained the amounts charged and paid, the number of pills (for orally-administered drugs in pill form) or quantity,<sup>3</sup> the date on which the prescription was filled, and a code that identified the transaction as a prescription. The codes used for identifying prescriptions could be an NDC, a Current Procedural Terminology (CPT) code, a Healthcare Common Procedure Coding System (HCPCS) code, or a code for prescription medications specific to a data source.

The NDCs were linked to the Medi-Span<sup>®</sup> data that identify the type of medication (e.g., therapeutic class, narcotic, and federal-level narcotic schedule), brand/generic status, strength, and the manufacturer or repackaging firm for the medication.

## **IDENTIFYING NON-FORMULARY DRUGS**

This study focuses on identifying drugs that require preauthorization under the Texas closed formulary. Therefore, we categorized the drugs into two groups—(1) non-formulary drugs or drugs that require preauthorization, and (2) formulary drugs or drugs that do not require preauthorization. We merged the list of non-formulary drugs published by the Texas Department Insurance, Division of Workers' Compensation to our prescription drug data to flag these drugs. We classified the drugs into ten therapeutic groups based on the therapeutic groupings provided in the Texas formulary: NSAIDs (e.g., Voltaren<sup>®</sup>), benzodiazepines (e.g., Xanax<sup>®</sup>), opioids (e.g., OxyContin<sup>®</sup>), muscle relaxants (e.g., Soma<sup>®</sup>), sedative-hypnotics (e.g., Phenergan<sup>®</sup>), topical analgesics (e.g., Lidoderm<sup>®</sup>), antidepressants (e.g., Prozac<sup>®</sup>), anti-epilepsy drugs (e.g., Topamax<sup>®</sup>), proton pump inhibitors (e.g., Nexium<sup>®</sup>), and other therapeutic groups. We used the classification scheme provided by Medi-Span<sup>®</sup> to assign drugs into a therapeutic group.

## **IDENTIFYING DISPENSING POINTS**

This study categorizes prescriptions that were dispensed either at pharmacies or at the office of the prescribing physician. By our definition, a prescription is considered a physician-dispensed prescription if it was filled at and billed for by an independent practitioner, a physician group, or a multispecialty medical center.<sup>4</sup>

In order to group prescriptions into physician- and pharmacy-dispensed categories, we used two variables in the data—the provider group, a field that indicates whether the prescription was billed by a physician or non-physician, and the Medi-Span<sup>®</sup> indicator that identifies repackaged drugs based on the

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<sup>2</sup> To identify the injectables, nutrition supplements, and medical supplies/equipment for exclusions, we mainly used Medi-Span<sup>®</sup> indicators that specified the types of products with NDCs as well as the route of administration.

<sup>3</sup> A vast majority of the prescription medications included in this study were in oral dosage form. The non-oral medications may have been in the form of a pad, patch, cream, or lotion.

<sup>4</sup> Conceivably, physicians who are affiliated with physician groups and multispecialty clinics can dispense repackaged and non-repackaged drugs. If a practice group or medical center owns an on-site pharmacy (i.e., a vertical integration between a physician practice and a pharmacy as a financial entity), the pharmacy may dispense drugs like a retail pharmacy but bill the drugs under the same financial entity as the physician group or medical center. When this happens, the reimbursement rule may be different from that for pharmacies. We observed this trend in our data.

NDCs assigned for repackaged drugs by the U.S. Food and Drug Administration.<sup>5</sup> Since we excluded prescriptions billed by hospitals, we classified a prescription as physician dispensed if the prescription was billed by a physician or if the Medi-Span® indicator labeled the prescription as one for a repackaged drug (even when the provider group was a non-physician). Note that we included mail-order prescriptions in the definition of pharmacy-dispensed prescriptions.

**KEY BENCHMARK METRICS AND ASSUMPTIONS**

The key benchmark metrics we focus on for this study include the percentage of all prescriptions and prescription payments that were for non-formulary drug prescriptions. These measures are reported by dispensing point, therapeutic group, generic/brand status, and for the most common non-formulary drugs prescribed across states.

Additionally, we estimated the percentage of all prescriptions that were for non-formulary drugs and the reduction in total prescription costs after the implementation of a Texas-like formulary using several plausible assumptions about physicians’ responses to the formulary in other states. We constructed four different scenarios with assumptions about physicians’ likelihood of (1) prescribing non-formulary drugs by seeking preauthorization and (2) substituting non-formulary drugs that are not prescribed because of the preauthorization requirement with other drugs that do not require preauthorization. Table 2.2 shows the four scenarios. The first scenario assumes that physicians in other states respond to a Texas-like closed formulary as Texas doctors did, i.e., a 70 percent reduction in prescribing non-formulary drugs and very little substitution with formulary drugs. The second scenario assumes a 70 percent reduction in prescribing of non-formulary drugs and 100 percent substitution with formulary drugs. The other two scenarios assume a smaller reduction in non-formulary prescriptions, i.e., we assume that physicians in other states seek preauthorization for non-formulary drugs more frequently than Texas doctors. We assumed a 25 percent drop. This is not to say that these assumptions are realistic expectations of what might happen in the 23 other states. We provide multiple scenarios to the readers in order to illustrate the sensitivity of the impact of a Texas-like formulary to prescribers’ reactions.

**Table 2.2 Key Assumptions About Physician Responses for Estimating Post-Formulary Impact in Other States**

	<b>Reduction in Prescribing Non-Formulary Drugs by Seeking Preauthorization</b>	<b>Substitution of Non-Formulary Drugs with Drugs That Do Not Require Preauthorization</b>
Scenario A (Texas experience)	70%	0%
Scenario B	70%	100%
Scenario C	25%	0%
Scenario D	25%	100%

<sup>5</sup> Repackaged drugs are rarely dispensed by pharmacies, which was consistent with what we saw in a more detailed data review.

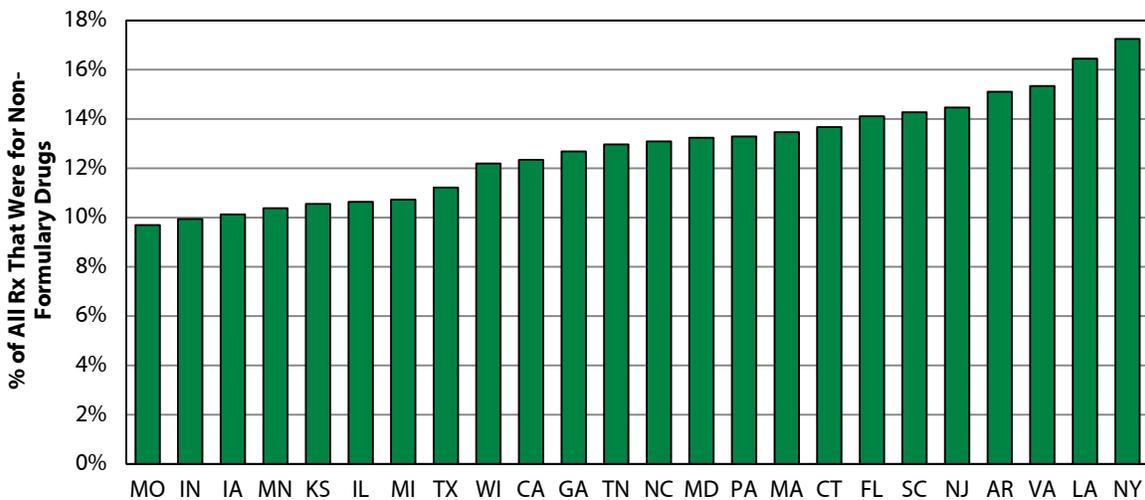
# 3

## PREVALENCE AND COSTS OF NON-FORMULARY DRUGS

### NON-FORMULARY DRUGS WERE AT LEAST AS PREVALENT IN MOST STUDY STATES AS IN PRE-FORMULARY TEXAS

We found that 10 to 17 percent of all prescriptions were written for non-formulary drugs across the 24 states in 2011/2012. Figure 3.1 illustrates that a slightly higher proportion of prescriptions were written for these drugs in New York and Louisiana—1 in 6 prescriptions were for non-formulary drugs in the two states. The prevalence of non-formulary drugs was also noteworthy in states on the lower end, with 1 in 10 prescriptions being written for these drugs in most of the Midwest states included in this study. In Texas, 11 percent of the prescriptions were written for these non-formulary drugs prior to the formulary.<sup>1</sup>

**Figure 3.1 Percentage of All Prescriptions That Were for Non-Formulary Drugs, 2011/2012**



*Notes:* The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

*Key:* Rx: prescriptions.

<sup>1</sup> The data included in this study are predominantly prior to the implementation of the closed formulary. Injuries included are from October 1, 2010, to September 30, 2011, and the closed formulary was effective for injuries on or after September 1, 2011.

## PRESCRIPTION PAYMENTS FOR NON-FORMULARY DRUGS

Non-formulary drug prescriptions accounted for 18 to 37 percent of prescription payments across the 24 states in 2011/2012. Note that the prescriptions for non-formulary drugs accounted for a larger share of prescription spending than the share of all prescriptions filled. This occurred because several of the drugs listed as non-formulary drugs in the Texas formulary are expensive brand name medications like OxyContin®, Lidoderm®, and Flector® Patch. Another reason for the prescription cost share for non-formulary drugs to be higher than the share for number of prescriptions in some states is the higher price of physician-dispensed prescriptions. In states like Florida, Connecticut, and Maryland, where physician dispensing is prevalent, 13–14 percent of prescriptions were written for non-formulary drugs but the prescription cost share was 24–26 percent.<sup>2</sup> Frequency of brand name and physician-dispensed, non-formulary drugs will be discussed in more detail later in this chapter.

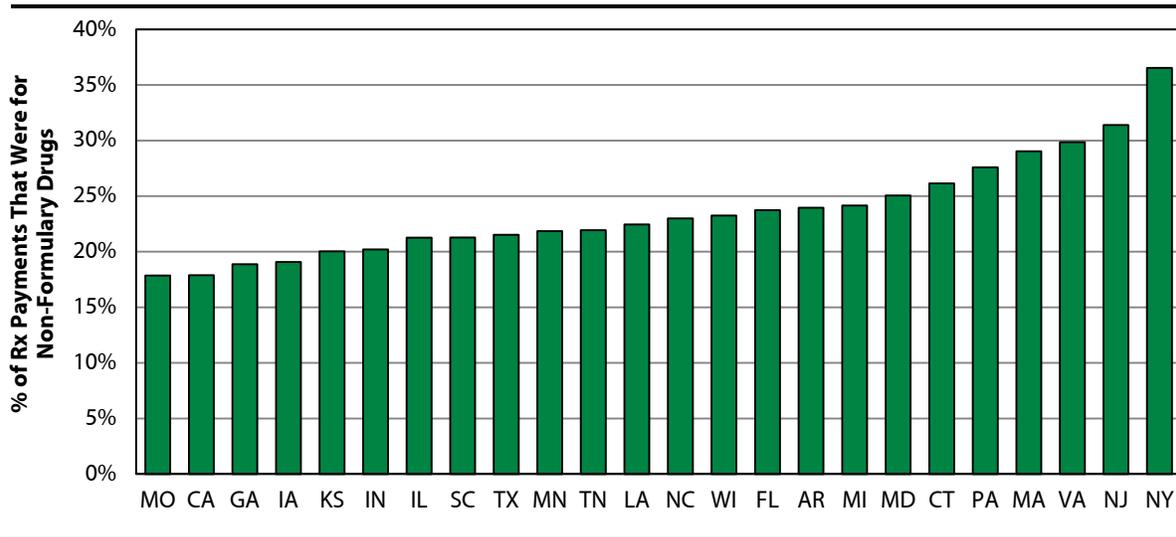
As indicated in [Figure 3.2](#), there is substantial interstate variation in the prescription cost share of non-formulary drugs. In New York, prescriptions for non-formulary drugs accounted for 37 percent of total prescription payments. More than a quarter of prescription payments were for these drugs in six other states—New Jersey, Virginia, Massachusetts, Pennsylvania, Connecticut, and Maryland. Even at the lower end, a significant proportion of the prescription cost share was for non-formulary drugs in California and Missouri, at 18 percent. Twenty-two percent of the prescription cost share was for non-formulary drugs in Texas prior to the formulary.

The TDI study results indicate that implementing the formulary resulted in about an 80 percent drop in payments made for non-formulary drug prescriptions (TDI, 2013). This implies that the post-formulary cost share of non-formulary drugs is likely to be as low as 4 percent. Compared with post-reform Texas, the percentage of prescription payments for non-formulary drug prescriptions was 14–33 percentage points higher in all other study states. If other states are able to successfully implement a Texas-like formulary, there is huge potential for decreasing the utilization of the drugs designated as non-formulary drugs by Texas, which may in turn lead to substantial prescription cost savings in all states, particularly New York.

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<sup>2</sup> The average prices paid to physician-dispensers were often much higher than what was paid if the same drugs were dispensed at a pharmacy because physician-dispensers typically dispense repackaged drugs. The average wholesale price of a repackaged drug is typically higher than that of the original drug from the manufacturer. Florida and Connecticut adopted reforms aimed at reducing the costs of physician-dispensed prescriptions after the study period. The issue was actively debated but no legislative changes were made in Maryland.

**Figure 3.2 Percentage of Total Prescription Payments That Were for Non-Formulary Drugs, 2011/2012**



Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

Key: Rx: prescriptions.

### USE AND COSTS OF NON-FORMULARY DRUGS IN CALENDAR YEAR 2011

Throughout this study, we report the prevalence of non-formulary drugs and estimate the impact of a Texas-like formulary using newly injured workers in 2011 with 12 months of experience (i.e., 2011/2012). An alternate approach to provide these metrics is by examining prescription patterns in a calendar year. For readers interested in this approach we provide the prevalence metrics based on prescription use in calendar year 2011 in [Table 3.1](#).

We chose to report the data for new injuries because, to estimate the likely impact of a formulary in other states, we made assumptions that rely on the impact of the closed formulary in Texas. The evidence available so far pertains to the impact the closed formulary had on new injuries (see TDI, 2013). The formulary was effective for new injuries on September 1, 2011, and for workers injured prior to September 1, 2011, the closed formulary was effective September 1, 2013. It is possible that the drop in non-formulary drugs among existing users might be lower than among newly injured workers and physicians may substitute with formulary drugs more frequently than in the case of newly injured workers.

**Table 3.1 Prevalence and Costs of Non-Formulary Drugs**

State	Percentage of All Rx That Were for Non-Formulary Drugs		Percentage of Total Rx Payments That Were for Non-Formulary Drugs	
	2011/2012	2011	2011/2012	2011
Arkansas	15%	18%	24%	28%
California	12%	17%	18%	26%
Connecticut	14%	20%	26%	36%
Florida	14%	18%	24%	30%
Georgia	13%	18%	19%	28%
Illinois	11%	15%	21%	29%
Indiana	10%	10%	20%	25%
Iowa	10%	14%	19%	26%
Kansas	11%	14%	20%	27%
Louisiana	16%	23%	22%	31%
Maryland	13%	21%	25%	39%
Massachusetts	13%	19%	29%	36%
Michigan	11%	14%	24%	33%
Minnesota	10%	15%	22%	30%
Missouri	10%	12%	18%	24%
New Jersey	14%	21%	31%	40%
New York	17%	25%	37%	44%
North Carolina	13%	19%	23%	34%
Pennsylvania	13%	20%	28%	36%
South Carolina	14%	22%	21%	34%
Tennessee	13%	20%	22%	33%
Texas	11%	15%	22%	27%
Virginia	15%	21%	30%	38%
Wisconsin	12%	16%	23%	32%

Notes: 2011/2012: The underlying data include claims with injuries occurring from October 1, 2010, to September 30, 2011, with more than seven days of lost time that had prescriptions filled through March 31, 2012, and paid for by a workers' compensation payor. Texas data are predominantly pre-formulary.

2011: The underlying data include prescriptions that were paid for by a workers' compensation payor in calendar year 2011 for claims with more than seven days of lost time and with injuries occurring from October 1, 2005, to September 30, 2011. Texas data are predominantly pre-formulary.

Key: Rx: prescriptions.

## BRAND NAME NON-FORMULARY DRUG USE

Several state workers' compensation systems promote the use of generic drugs by enforcing generic mandate policies. The majority of the study states have generic mandates in place. States where generic substitution is not mandated include Connecticut, Illinois, Indiana, Iowa, Louisiana, Maryland, Missouri, New Jersey, North Carolina, and Pennsylvania (see Tanabe, 2013). Generic mandates influence the use of brand name medications for which generic equivalents are available. For example, in a state with a generic mandate, pharmacists can substitute Motrin® with generic ibuprofen (generic equivalents). They cannot however substitute Motrin® with naproxen (generic alternatives), which is also an NSAID that can be used for relieving pain. Formularies can be used to encourage the use of generic alternative drugs prior to brand name medications. Other payors, like group health and Medicaid, use tiered formularies and encourage use of generics prior to the use of expensive brand name medications by charging lower co-payments for generic drugs. Workers' compensation payors can use formularies to encourage generic use by requiring prior authorization for expensive brand name medications for which generic alternatives are available, like in Texas. In Texas, the TDI study (2013) reported that the generic substitution rate for non-formulary drugs improved after implementing the closed formulary. Prior to the formulary, 41 percent of non-formulary drugs were for brand name medications. The number dropped to 28 percent after the formulary came into effect. States with higher use of brand name non-formulary medications can benefit from the adoption of a Texas-like formulary.

[Figure 3.3](#) provides the interstate comparisons of the frequency of use of brand name non-formulary drugs in 2011/2012. [Figure 3.4](#) shows the percentage of non-formulary drug payments that were for brand name medications in 2011/2012.<sup>3</sup>

There was substantial variation in the proportion of non-formulary drug prescriptions that were for brand name medications—24 to 57 percent. The most commonly dispensed brand name medication with non-formulary status in the Texas formulary was Lidoderm®. Lidoderm® (lidocaine patch) is FDA approved for shingles pain and is used off label to treat workers' compensation injuries involving low back pain.<sup>4</sup> Other common brand name non-formulary drugs include opioids like OxyContin® and Nucynta® (Schedule II narcotics not recommended as first-line therapy by ODG), NSAIDs like Flector® Patch (a topical version of the NSAID diclofenac which is generically available as an oral product), and Naprelan® (an extended-release version of generically available naproxen), and muscle relaxants like Amrix® (an extended-release version of generically available cyclobenzaprine). These branded non-formulary drug medications accounted for 53–83 percent of non-formulary drug prescription payments.

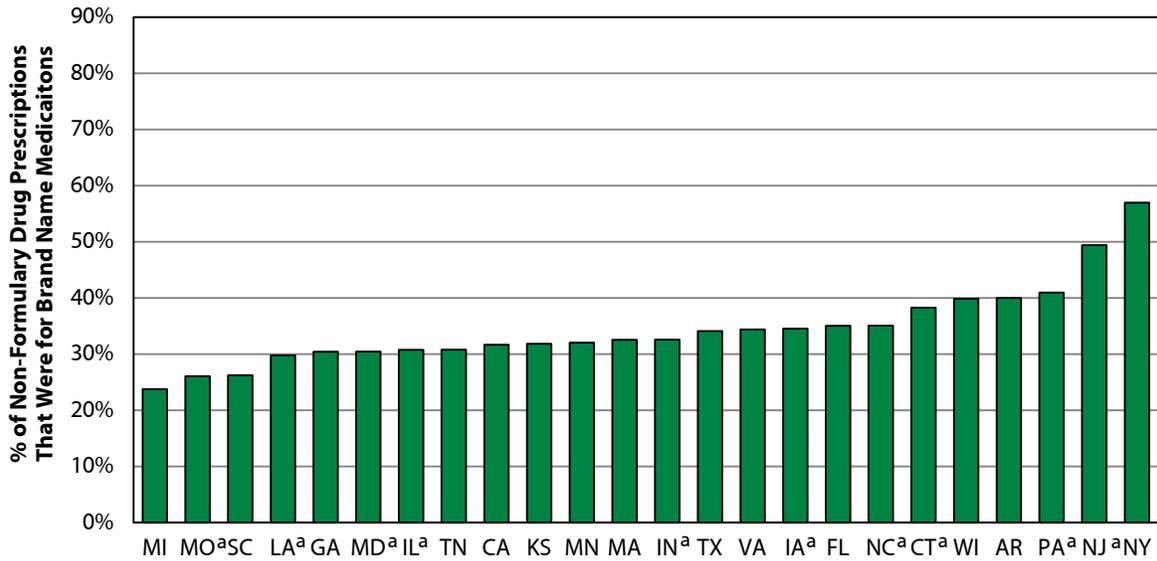
New York and New Jersey had higher brand name non-formulary drug use with 57 percent and 49 percent of non-formulary drug prescriptions written for branded drugs. In these two states, at least 80 percent of non-formulary drug prescription payments were for brand name drugs. Even at the lower end, in states like Michigan, Missouri, and South Carolina, about 25 percent of non-formulary drug prescriptions were for brand name medications, but these medications accounted for 50–70 percent of payments made for non-formulary drugs. As seen in Texas, other states can realize substantial cost savings if the generic substitution rate can be increased with the adoption of a Texas-like formulary.

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<sup>3</sup> [Table SA.1](#) presents the data underlying [Figures 3.3](#) and [3.4](#).

<sup>4</sup> Generic equivalents of Lidoderm® became available after the study period in September 2013.

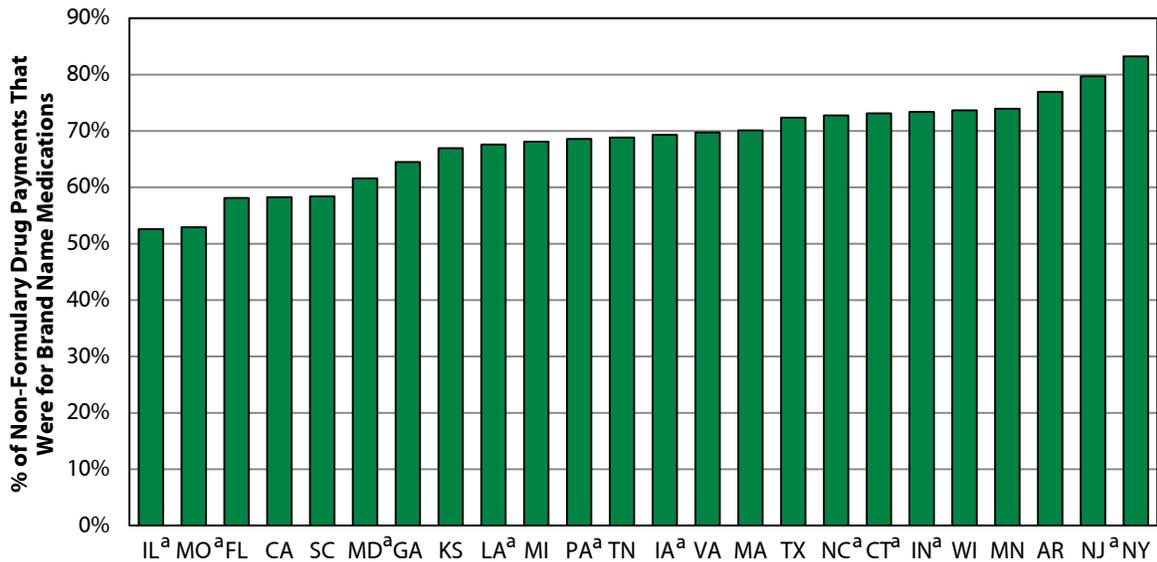
**Figure 3.3 Percentage of Non-Formulary Drug Prescriptions That Were for Brand Name Medications, 2011/2012**



Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> States where generic substitution is not mandated.

**Figure 3.4 Percentage of Non-Formulary Drug Payments That Were for Brand Name Medications, 2011/2012**



Notes: The underlying data included prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> States where generic substitution is not mandated.

## PHYSICIAN DISPENSING OF NON-FORMULARY DRUGS

This section describes the prevalence of physician-dispensed, non-formulary drugs in the 24 study states. Of these states, three (Massachusetts, New York, and Texas) prohibit physicians from dispensing prescription drugs in general. Nine of the other 21 states in this study where physician dispensing is permitted have adopted reforms aimed at reducing the costs associated with physician-dispensed prescriptions.<sup>5</sup> We footnoted, in the figures and tables related to physician dispensing, if the data we included for the states were post-reform (California), partially post-reform (Georgia), or pre-reform (Connecticut, Florida,<sup>6</sup> Illinois, Indiana, Michigan, South Carolina, and Tennessee).

[Figures 3.5](#) and [3.6](#) show the percentage of non-formulary drug prescriptions and the percentage of non-formulary drug prescription payments that were for physician-dispensed prescriptions, in 2011/2012.<sup>7</sup> Physicians dispensed a significant proportion of non-formulary drugs in states where physician dispensing is common in general, like California, Connecticut, Florida, Illinois, and Maryland.<sup>8</sup>

Physician-dispensers filled 42 percent and 36 percent of non-formulary drug prescriptions in California and Maryland, respectively. Other states where physician dispensing accounted for at least one in four non-formulary drug prescriptions are Florida, Illinois, and Connecticut. Physician-dispensed, non-formulary drugs accounted for 31–53 percent of non-formulary drug prescription costs in the top five states. Eleven to sixteen percent of non-formulary drug prescriptions were physician-dispensed in Georgia, Pennsylvania, Missouri, and Tennessee. Physicians dispensed less than 10 percent of prescriptions in all other study states. It is interesting to note that in California, physician-dispensed drugs accounted for 42 percent of the non-formulary prescription share but only 31 percent of the non-formulary prescription cost share. The underlying reason is that the California data included in this study are after the reform aimed at equalizing pharmacy- and physician-dispensed drug prices. In other states, the data are partially or completely pre-reform.

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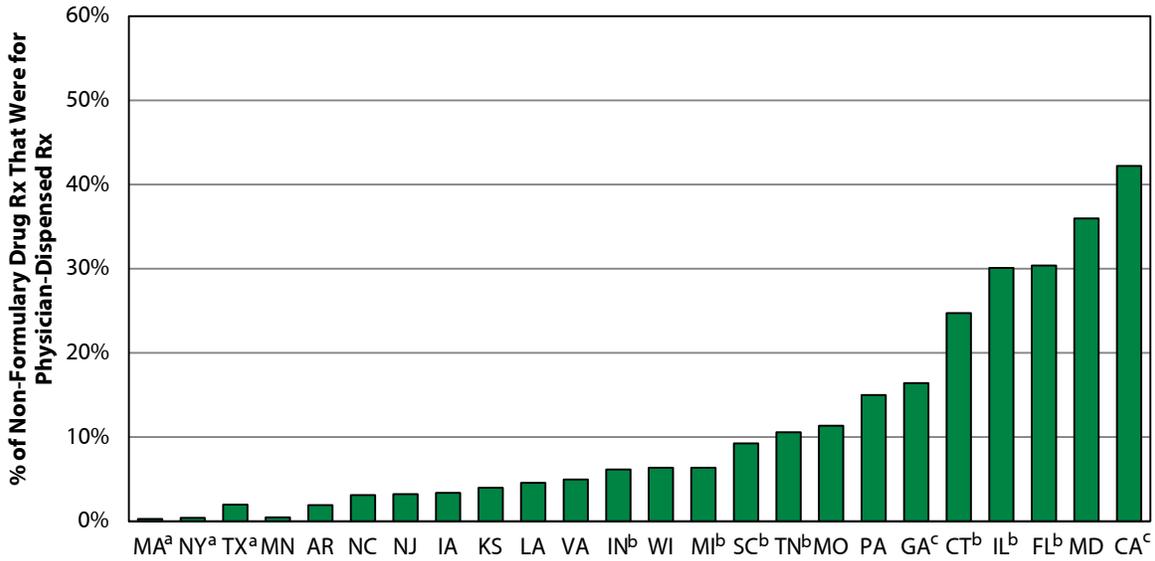
<sup>5</sup> Readers interested in the prevalence of physician dispensing in the 24 study states may refer to Wang, Liu, and Thumula (2013). See Chapter 1 and Appendix A for a summary of state policies regarding pharmacy fee schedules and physician dispensing in the same report.

<sup>6</sup> For Florida, the pre-reform baseline refers to the experience of physician dispensing before the changes in reimbursement rules for physician-dispensed prescriptions, effective July 2013. An analysis of the 2011 law change banning physicians from dispensing Schedule II and III narcotics was discussed in Thumula (2013).

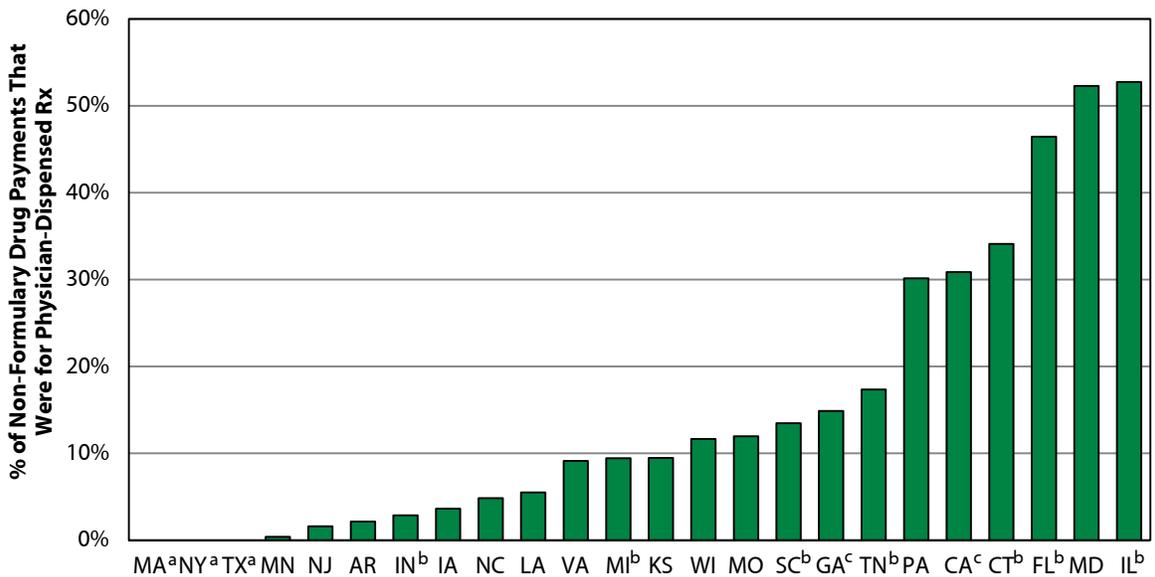
<sup>7</sup> [Table SA.2](#) presents the data underlying [Figures 3.5](#) and [3.6](#).

<sup>8</sup> Wang et al. (2013) reported that more than a quarter of all prescriptions were physician dispensed in California, Connecticut, Florida, Georgia, Illinois, and Maryland.

**Figure 3.5 Percentage of Non-Formulary Drug Prescriptions That Were for Physician-Dispensed Prescriptions, 2011/2012**



**Figure 3.6 Percentage of Non-Formulary Drug Payments That Were for Physician-Dispensed Prescriptions, 2011/2012**



Notes: The underlying data included prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> In Massachusetts, New York, and Texas, physician dispensing is not allowed in general. See Appendix A of Wang, Liu, and Thumula (2013) for more details.

<sup>b</sup> Seven states (Connecticut, Florida, Illinois, Indiana, Michigan, South Carolina, and Tennessee) recently adopted reforms aimed at reducing the costs of physician-dispensed prescriptions. The data presented here are pre-reform for these states. Note that we grouped South Carolina and Tennessee with the pre-reform states because the data for the two states are predominantly pre-reform.

<sup>c</sup> Two states included in the study (California and Georgia) made rule changes for physician-dispensed prescriptions, effective March 2007 and April 2011, respectively. The data are post-reform for California and partially post-reform for Georgia.

Key: Rx: prescriptions.

## THERAPEUTIC CLASSES OF NON-FORMULARY DRUGS PRESCRIBED IN THE 24 STUDY STATES

This section describes the mix of non-formulary drugs prescribed to injured workers across the 24 study states. Over 70 percent of non-formulary drug prescriptions were written for four therapeutic groups of medications—NSAIDs, opioids, benzodiazepines, and muscle relaxants. Most states had a similar mix of drugs, barring a few exceptions, as shown in [Table 3.2](#). It is important to note that several states adopted major reforms addressing the use of controlled substances and pain medications, specifically opioids, after our study period.<sup>9</sup>

- NSAIDs, which include drugs like naproxen, were the most common therapeutic group of non-formulary medications. Twenty to thirty percent of non-formulary drug prescriptions were for NSAIDs in most states. The frequency was slightly higher in Georgia (35 percent) and lower in Michigan (12 percent). Non-formulary NSAIDs accounted for 2–5 percent of all prescriptions in the majority of study states. Examples of common NSAIDs prescribed in most study states are oral formulations (Voltaren®, Naprelan®) and topical formulations (Flector® Patch).
- Opioids accounted for 10–20 percent of all non-formulary drug prescriptions in most states. The percentage was relatively higher in Arkansas, Minnesota, New Jersey, New York, and Pennsylvania (25–26 percent). Non-formulary opioids, which include drugs like OxyContin®, Nucynta®, and Opana®, accounted for 2–4 percent of all prescriptions in most states.
- Benzodiazepines were the most frequently prescribed non-formulary drug class in Michigan (30 percent of all non-formulary drug prescriptions), Massachusetts (26 percent), and Connecticut (24 percent). In these three states, benzodiazepines accounted for 3–4 percent of all prescriptions filled. All benzodiazepines are designated as non-formulary drugs in the Texas formulary and require preauthorization. Examples of benzodiazepines include commonly abused controlled substances like Xanax® and Valium®.
- Non-formulary drugs belonging to the therapeutic category of muscle relaxants, like Soma®, Amrix®, and Banflex®, were prescribed more often in states where physician dispensing is common. In Maryland (33 percent), California (27 percent), Florida (25 percent), and Illinois (23 percent), nearly a quarter or more of non-formulary drug prescriptions were for muscle relaxants. Compare this with about 10 percent in states like Massachusetts and New York, where physician dispensing is not permitted in general.
- Sedative-hypnotics (e.g., Phenergan®) and topical analgesics (e.g., Lidoderm®) are the two other therapeutic classes of medications which accounted for a significant share of non-formulary drugs prescriptions in some of the study states. Topical NSAID formulations, like Flector® Patch and Pennsaid®, were considered NSAIDs and not topical analgesics in this section.
- Antidepressants, anti-epilepsy drugs, proton pump inhibitors, and other therapeutic groups together accounted for less than 15 percent of non-formulary drugs.

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<sup>9</sup> Massachusetts, New York, and Tennessee passed laws in 2012 requiring registration and use of a prescription drug monitoring program (PDMP) by prescribers (Clark et al., 2012). PDMP use is not as regulated in other study states. Connecticut (in 2012) and Massachusetts (in 2013) adopted chronic pain treatment guidelines after the study period. New York also proposed non-acute pain medical treatment guidelines in 2013. These reforms may affect prescription utilization in the states. Readers interested in a detailed discussion of legislative or regulatory changes addressing opioid prescribing should refer to Technical Appendix A in Thumula, Wang, and Liu (2014).

**Table 3.2 Percentage of Non-Formulary Drug Prescriptions by Therapeutic Group, 2011/2012**

	AR	CA	CT <sup>a</sup>	FL	GA	IA	IL	IN	KS	LA	MA <sup>a</sup>	MD	MI	MN	MO	NC	NJ	NY <sup>a</sup>	PA	SC	TN <sup>a</sup>	TX	VA	WI
% of all prescriptions that were for non-formulary drugs	15%	12%	14%	14%	13%	10%	11%	10%	11%	16%	13%	13%	11%	10%	10%	13%	14%	17%	13%	14%	13%	11%	15%	12%
<b>% of non-formulary drug prescriptions that were for the therapeutic group</b>																								
NSAIDs (e.g., Voltaren®)	22%	23%	23%	28%	35%	26%	25%	25%	26%	17%	17%	16%	12%	23%	26%	27%	25%	30%	23%	23%	24%	29%	31%	27%
Opioids (e.g., OxyContin®)	26%	11%	18%	16%	16%	20%	14%	19%	20%	16%	20%	21%	20%	26%	16%	20%	25%	25%	25%	21%	18%	16%	22%	22%
Benzodiazepines (e.g., Xanax®)	14%	11%	24%	10%	10%	21%	18%	18%	12%	19%	26%	11%	30%	20%	18%	17%	16%	9%	17%	19%	13%	13%	15%	22%
Muscle relaxants (e.g., Soma®)	17%	27%	16%	25%	15%	8%	23%	-	15%	19%	10%	33%	10%	9%	17%	9%	12%	12%	16%	12%	13%	18%	9%	-
Sedative-hypnotics (e.g., Phenergan®)	13%	-	-	-	10%	-	-	13%	10%	11%	-	-	-	-	-	12%	-	-	-	12%	15%	10%	-	-
Topical analgesics (e.g., Lidoderm®)	-	14%	11%	8%	-	-	-	-	-	-	13%	-	-	-	-	-	8%	11%	-	-	-	-	-	12%
Antidepressants (e.g., Prozac®)	-	-	-	-	-	-	-	-	-	-	-	-	10%	-	-	-	-	-	-	-	-	-	-	-
Anti-epilepsy drugs (e.g., Topamax®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proton pump inhibitors (e.g., Nexium®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other therapeutic groups	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> Some study states had major reforms addressing the use of controlled substances and pain medications, specifically opioids, after our study period, and these reforms may have affected prescription utilization in these states. Massachusetts, New York, and Tennessee passed laws in 2012 requiring registration and use of a prescription drug monitoring program by prescribers. Connecticut (in 2012) and Massachusetts (in 2013) adopted chronic pain treatment guidelines. New York also proposed non-acute pain medical treatment guidelines in 2013.

Key: - percentage of non-formulary drug prescriptions that were for the therapeutic group was less than 8 percent; NSAIDs: non-steroidal anti-inflammatory drugs.

**Table 3.3 Percentage of Non-Formulary Payments by Therapeutic Group, 2011/2012**

	AR	CA	CT <sup>a</sup>	FL	GA	IA	IL	IN	KS	LA	MA <sup>a</sup>	MD	MI	MN	MO	NC	NJ	NY <sup>a</sup>	PA	SC	TN <sup>a</sup>	TX	VA	WI
% of total prescription payments that were for non-formulary drugs	24%	18%	26%	24%	19%	19%	21%	20%	20%	22%	29%	25%	24%	22%	18%	23%	31%	37%	28%	21%	22%	22%	30%	23%
<b>% of non-formulary drug payments that were for the therapeutic group</b>																								
Opioids (e.g., OxyContin®)	29%	19%	19%	14%	18%	26%	13%	26%	33%	25%	28%	25%	35%	42%	19%	31%	26%	29%	29%	29%	23%	17%	30%	33%
NSAIDs (e.g., Voltaren®)	31%	28%	23%	27%	36%	24%	25%	25%	22%	23%	11%	16%	13%	18%	24%	34%	28%	32%	22%	23%	28%	36%	25%	25%
Topical analgesics (e.g., Lidoderm®)	-	20%	29%	19%	15%	17%	15%	17%	12%	9%	35%	19%	16%	19%	16%	11%	18%	20%	17%	-	13%	13%	15%	27%
Muscle relaxants (e.g., Soma®)	17%	13%	16%	27%	8%	-	35%	-	-	9%	-	27%	10%	-	11%	8%	11%	8%	19%	15%	9%	13%	11%	-
Antidepressants (e.g., Prozac®)	-	-	-	-	-	-	-	-	-	8%	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Benzodiazepines (e.g., Xanax®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Anti-epilepsy drugs (e.g., Topamax®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	15%	-	-	-	-	-	-	-	-	-
Sedative-hypnotics (e.g., Phenergan®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Proton pump inhibitors (e.g., Nexium®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other therapeutic groups	-	-	-	-	-	10%	-	11%	-	-	-	-	10%	-	-	-	-	-	-	-	-	-	-	-

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> Some study states had major reforms addressing the use of controlled substances and pain medications, specifically opioids, after our study period, and these reforms may have affected prescription utilization in these states. Massachusetts, New York, and Tennessee passed laws in 2012 requiring registration and use of a prescription drug monitoring program by prescribers. Connecticut (in 2012) and Massachusetts (in 2013) adopted chronic pain treatment guidelines. New York also proposed non-acute pain medical treatment guidelines in 2013.

Key: - percentage of non-formulary drug prescriptions that were for the therapeutic group was less than 8 percent; NSAIDs: non-steroidal anti-inflammatory drugs.

In terms of prescription cost share, four classes of medications (opioids, NSAIDs, topical analgesics, and muscle relaxants) accounted for more than three-fourths of payments made for non-formulary drugs in the majority of the states. Of these, NSAIDs, opioids, and muscle relaxants were in the top four drug classes by both prescription share and cost share. Benzodiazepines, which were frequently dispensed in many states, were not in the top four therapeutic classes by prescription drug spending because these drugs are generically available. On the other hand, 15–20 percent of non-formulary drug payments were for topical analgesics in the majority of study states. It is noteworthy that 35 percent of prescription payments made for non-formulary drugs were for topical analgesics (predominantly Lidoderm®) in Massachusetts. The percentage was also high in Connecticut (29 percent) and Wisconsin (27 percent). Topical analgesics accounted for 4–10 percent of total prescription costs in most states included in this study. [Table 3.3](#) presents the percentage of prescription payments for non-formulary drugs by therapeutic group.

### COMMONLY PRESCRIBED NON-FORMULARY DRUGS IN THE 24 STUDY STATES

Commonly prescribed non-formulary drugs varied to a small extent across the 24 study states. In most states, five drugs (Voltaren®, Soma®, Valium®, Lidoderm®, and OxyContin®) were the most commonly prescribed non-formulary drugs, accounting for 35–60 percent of the non-formulary drug prescriptions. Other drugs were more frequently prescribed than the five drugs listed above in a few states: for example, Phenergan®, Nucynta®, Xanax®, Flector® Patch, and Banflex®. [Table 3.4](#) highlights the commonly prescribed non-formulary drugs in the 24 study states. Of these, generics were not available for Lidoderm®<sup>10</sup>, OxyContin®, Nucynta®, and Flector® Patch during the study period.

[Table 3.5](#) presents the commonly prescribed non-formulary drugs by prescription payments. The top five non-formulary drugs by prescription drug spending were Lidoderm®, Flector® Patch, Voltaren®, OxyContin®, and Nucynta® in the majority of the study states. In some states where physician dispensing is prevalent, like Florida, Illinois, Maryland, and Pennsylvania, Soma® accounted for a significant share of prescription payments.<sup>11</sup> Amrix® and Voltaren-XR® were the other top drugs by cost share in some of the study states. Generic equivalents were available only for Voltaren® at the time of this study.

[Table 3.6](#) provides a summary of the top five common drugs in each state by prescription share and cost share. As shown in the table, the utilization of non-formulary drugs is highly concentrated in a few drugs. The top five non-formulary drugs by prescription share accounted for 42–60 percent of all non-formulary prescriptions. The top five non-formulary drugs by cost share accounted for 38–73 percent of all non-formulary prescription payments.

<sup>10</sup> Generics for Lidoderm® became available in September 2013.

<sup>11</sup> Florida and Illinois adopted reforms aimed at reducing the costs of physician-dispensed prescriptions after the study period. The data included in this study for these two states are pre-reform. Reforms to limit physician dispensing and/or control prices of physician-dispensed medications were actively debated in Pennsylvania and Maryland, but the bills did not pass.

**Table 3.4 Commonly Prescribed Non-Formulary Drugs by Prescription Share Varied by State, 2011/2012**

	AR	CA	CT <sup>a</sup>	FL	GA	IA	IL	IN	KS	LA	MA <sup>a</sup>	MD	MI	MN	MO	NC	NJ	NY <sup>a</sup>	PA	SC	TN <sup>a</sup>	TX	VA	WI	
% of all prescriptions that were for non-formulary drugs	15%	12%	14%	14%	13%	10%	11%	10%	11%	16%	13%	13%	11%	10%	10%	13%	14%	17%	13%	14%	13%	11%	15%	12%	
<b>% of non-formulary drug prescriptions that were for the drug listed</b>																									
Diclofenac sodium (Voltaren®)	*	*	**	**	***	**	**	**	**	*	*	*	*	*	**	**	*	**	**	**	**	**	**	**	**
Carisoprodol (Soma®)	**	**	**	**	**	*	***	-	**	**	-	***	*	*	**	*	*	*	**	**	**	**	**	-	-
Diazepam (Valium®)	*	-	**	-	-	**	**	**	*	*	**	*	**	**	**	*	*	-	*	*	*	-	*	**	**
Lidocaine patch (Lidoderm®)	-	**	**	*	-	*	*	*	-	-	**	*	*	*	*	-	*	**	*	-	-	-	*	*	**
Oxycodone ER (OxyContin®)	*	-	*	-	*	*	-	*	*	-	*	*	-	**	*	-	*	-	*	*	-	-	-	-	**
Tapentadol (Nucynta®)	*	-	-	*	*	*	-	-	-	-	-	*	-	-	-	*	*	*	*	*	*	-	*	-	-
Promethazine (Phenergan®)	**	-	-	-	*	-	-	*	*	*	-	-	-	-	-	*	-	-	-	**	**	*	-	-	-
Alprazolam (Xanax®)	-	-	-	-	-	-	-	-	-	*	-	-	*	-	-	-	-	-	-	-	-	-	-	-	-
Diclofenac epolamine (Flector® Patch)	-	-	*	-	-	-	*	-	-	-	-	-	-	-	-	-	-	*	-	-	-	-	-	-	-
Ketorolac (Toradol®)	-	-	-	-	-	-	-	-	-	-	-	-	-	*	*	-	-	-	-	-	-	-	-	-	-
Diclofenac potassium (Cataflam®)	-	-	-	*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*	-	-
Lorazepam (Ativan®)	-	-	-	-	-	-	-	-	-	-	*	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Orphenadrine (Banflex®)	-	**	-	-	-	-	-	-	-	-	-	*	-	-	-	-	-	-	-	-	-	-	-	-	-
Diclofenac sodium ER (Voltaren-XR®)	-	*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> Some study states had major reforms addressing the use of controlled substances and pain medications, specifically opioids, after our study period, and these reforms may have affected prescription utilization in the states. Massachusetts, New York, and Tennessee passed laws in 2012 requiring registration and use of a prescription drug monitoring program by prescribers. Connecticut (2012) and Massachusetts (2013) adopted chronic pain treatment guidelines. New York also proposed non-acute pain medical treatment guidelines in 2013.

Key: \*\*\* ≥20% non-formulary drug prescriptions were for that drug; \*\* ≥10% to 20%; \* ≥5% to 10%; - <5%.

**Table 3.5 Commonly Prescribed Non-Formulary Drugs by Cost Share Varied by State, 2011/2012**

	AR	CA	CT <sup>a</sup>	FL	GA	IA	IL	IN	KS	LA	MA <sup>a</sup>	MD	MI	MN	MO	NC	NJ	NY <sup>a</sup>	PA	SC	TN <sup>a</sup>	TX	VA	WI
% of total prescription payments that were for non-formulary drugs	24%	18%	26%	24%	19%	19%	21%	20%	20%	22%	29%	25%	24%	22%	18%	23%	31%	37%	28%	21%	22%	22%	30%	23%
<b>% of non-formulary drug payments that were for the drug listed</b>																								
Lidocaine patch (Lidoderm®)	*	***	***	**	**	**	**	**	**	*	***	**	**	**	**	**	**	**	**	*	**	**	**	***
Diclofenac epolamine (Flector® Patch)	**	*	**	**	*	*	**	*	-	-	-	*	*	-	-	**	*	**	**	-	*	*	*	*
Diclofenac sodium (Voltaren®)	*	*	*	*	**	*	*	**	*	*	-	-	-	*	*	**	*	*	*	*	**	*	**	**
Oxycodone ER (OxyContin®)	**	*	**	-	-	*	-	**	***	-	**	*	*	***	*	*	**	*	**	*	*	*	-	**
Tapentadol (Nucynta®)	**	-	-	*	*	*	-	-	*	*	-	*	*	*	*	**	*	*	*	**	*	*	**	-
Carisoprodol (Soma®)	*	-	*	***	*	-	***	-	-	-	-	***	*	-	*	-	-	-	**	*	*	-	-	-
Cyclobenzaprine ER (Amrix®)	**	-	*	-	-	-	-	-	-	-	-	-	-	-	-	-	*	-	-	*	-	*	*	-
Oxymorphone (Opana®)	-	-	-	-	-	*	-	-	-	-	-	-	-	-	-	*	-	*	-	-	*	-	-	*
Topiramate (Topamax®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*	-	-	-	-	-	-	-	-	-
Diclofenac potassium (Cataflam®)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	*	-	*	-	-
Naproxen ER (Naprelan®)	*	-	-	-	-	-	-	-	-	*	-	-	-	-	-	-	*	*	-	-	-	*	-	-
Orphenadrine (Banflex®)	-	*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Morphine ER (Kadian®)	-	-	-	-	-	-	-	-	-	-	*	-	*	-	-	-	-	-	-	-	-	-	-	-
Buprenorphine (Suboxone®)	-	-	-	-	-	-	-	-	-	-	*	-	-	-	-	-	-	-	-	-	-	-	-	-
Diclofenac sodium ER (Voltaren-XR®)	-	**	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> Some study states had major reforms addressing the use of controlled substances and pain medications, specifically opioids, after our study period, and these reforms may have affected prescription utilization in the states. Massachusetts, New York, and Tennessee passed laws in 2012 requiring registration and use of a prescription drug monitoring program by prescribers. Connecticut (2012) and Massachusetts (2013) adopted chronic pain treatment guidelines. New York also proposed non-acute pain medical treatment guidelines in 2013.

Key: \*\*\* ≥20% non-formulary drug prescription payments were for that drug; \*\* ≥10% to 20%; \* ≥5% to 10%; - <5%.

**Table 3.6 Top Five Commonly Prescribed Non-Formulary Drugs by Prescription Share and Cost Share, 2011/2012**

AR	CA	CT <sup>a</sup>	FL	GA	IA	IL	IN	KS	LA	MA <sup>a</sup>	MD
<b>% of all prescriptions that were for non-formulary drugs</b>											
15%	12%	14%	14%	13%	10%	11%	10%	11%	16%	13%	13%
<b>% of non-formulary drug prescriptions that were for the drug listed</b>											
Soma® (13%)	Soma® (15%)	Valium® (16%)	Soma® (19%)	Voltaren® (23%)	Voltaren® (14%)	Soma® (21%)	Voltaren® (13%)	Voltaren® (16%)	Voltaren® (7%)	Valium® (16%)	Soma® (28%)
Phenergan® (10%)	Lidoderm® (14%)	Voltaren® (12%)	Voltaren® (13%)	Soma® (14%)	Valium® (11%)	Voltaren® (11%)	Valium® (11%)	Soma® (13%)	Soma® (17%)	Lidoderm® (13%)	Voltaren® (8%)
Voltaren® (9%)	Banflex (11%)	Soma® (12%)	Lidoderm® (8%)	Phenergan® (8%)	Lidoderm® (6%)	Valium® (10%)	Phenergan® (9%)	OxyContin® (9%)	Valium® (7%)	Voltaren® (10%)	Valium® (7%)
Nucynta® (9%)	Voltaren® (9%)	Lidoderm® (11%)	Nucynta® (7%)	Nucynta® (5%)	OxyContin® (6%)	Lidoderm® (6%)	OxyContin® (7%)	Valium® (6%)	Xanax® (6%)	OxyContin® (6%)	Lidoderm® (7%)
OxyContin® (6%)	Voltaren-XR® (9%)	OxyContin® (9%)	Cataflam (6%)	Lidoderm® (5%)	Nucynta® (6%)	Flector® (5%)	Lidoderm® (6%)	Phenergan® (6%)	Phenergan® (6%)	Ativan (5%)	OxyContin® (5%)
<b>Total percentage of non-formulary drugs that were for the top five drugs in the state</b>											
47%	58%	60%	53%	55%	43%	53%	46%	50%	43%	50%	54%
<b>% of total prescription payments that were for non-formulary drugs</b>											
24%	18%	26%	24%	19%	19%	21%	20%	20%	22%	29%	25%
<b>% of non-formulary drug payments that were for the drug listed</b>											
Nucynta® (13%)	Lidoderm® (20%)	Lidoderm® (29%)	Soma® (22%)	Voltaren® (19%)	Lidoderm® (17%)	Soma® (32%)	Lidoderm® (17%)	OxyContin® (21%)	Lidoderm® (9%)	Lidoderm® (35%)	Soma® (24%)
Amrix® (12%)	Voltaren-XR® (11%)	Flector® (13%)	Lidoderm® (19%)	Lidoderm® (15%)	Voltaren® (9%)	Lidoderm® (15%)	OxyContin® (12%)	Voltaren® (13%)	Naprelan® (9%)	OxyContin® (12%)	Lidoderm® (19%)
OxyContin® (11%)	Flector® (9%)	OxyContin® (12%)	Flector® (10%)	Nucynta® (9%)	Nucynta® (9%)	Flector® (13%)	Flector® (9%)	Lidoderm® (12%)	Nucynta® (8%)	Kadian® (5%)	Flector® (9%)
Flector® (11%)	Banflex (7%)	Soma® (10%)	Voltaren® (9%)	Flector® (8%)	OxyContin® (7%)	Voltaren® (5%)	Voltaren® (9%)	Nucynta® (6%)	Voltaren® (7%)	Amrix® (5%)	OxyContin® (6%)
Naprelan® (8%)	OxyContin® (6%)	Voltaren® (7%)	Nucynta® (7%)	Soma® (6%)	Opana® (7%)	OxyContin® (5%)	Nucynta® (5%)	Flector® (5%)	Soma® (5%)	Voltaren® (5%)	Nucynta® (6%)
<b>Total percentage of non-formulary drug payments that were for the top five drugs in the state</b>											
54%	54%	71%	66%	57%	50%	70%	52%	57%	38%	61%	64%

*continued*

**Table 3.6 Top Five Commonly Prescribed Non-Formulary Drugs by Prescription Share and Cost Share, 2011/2012 (continued)**

MI	MN	MO	NC	NJ	NY <sup>a</sup>	PA	SC	TN <sup>a</sup>	TX	VA	WI
<b>% of all prescriptions that were for non-formulary drugs</b>											
11%	10%	10%	13%	14%	17%	13%	14%	13%	11%	15%	12%
<b>% of non-formulary drug prescriptions that were for the drug listed</b>											
Valium® (16%)	OxyContin® (16%)	Voltaren® (10%)	Voltaren® (15%)	Voltaren® (9%)	Voltaren® (13%)	Voltaren® (12%)	Voltaren® (11%)	Voltaren® (13%)	Soma® (13%)	Voltaren® (19%)	Voltaren® (16%)
Xanax® (8%)	Valium® (11%)	Soma® (14%)	Phenergan® (10%)	OxyContin® (9%)	Lidoderm® (11%)	Soma® (12%)	Phenergan® (11%)	Phenergan® (13%)	Voltaren® (12%)	Valium® (8%)	Valium® (15%)
Voltaren® (6%)	Voltaren® (9%)	Valium® (12%)	Valium® (10%)	Nucynta® (9%)	Nucynta® (8%)	Valium® (8%)	Soma® (10%)	Soma® (11%)	Phenergan® (7%)	Lidoderm® (6%)	OxyContin® (13%)
Soma® (6%)	Toradol® (7%)	OxyContin® (6%)	Nucynta® (6%)	Lidoderm® (8%)	Soma® (8%)	Lidoderm® (8%)	Valium® (8%)	Valium® (7%)	Cataflam® (6%)	Nucynta® (7%)	Lidoderm® (12%)
Lidoderm® (5%)	Lidoderm® (6%)	Toradol® (6%)	Soma® (6%)	Valium® (8%)	Flector® (7%)	OxyContin® (7%)	Nucynta® (8%)	Nucynta® (5%)	Vicoprofen® (5%)	Soma® (5%)	Kadian® (4%)
<b>Total percentage of non-formulary drugs that were for the top five drugs in the state</b>											
42%	50%	48%	47%	43%	47%	47%	48%	48%	43%	44%	59%
<b>% of total prescription payments that were for non-formulary drugs</b>											
24%	22%	18%	23%	31%	37%	28%	21%	22%	22%	30%	23%
<b>% of non-formulary drug payments that were for the drug listed</b>											
Lidoderm® (16%)	OxyContin® (32%)	Lidoderm® (16%)	Voltaren® (13%)	Lidoderm® (18%)	Lidoderm® (20%)	Lidoderm® (17%)	Nucynta® (12%)	Lidoderm® (13%)	Lidoderm® (13%)	Lidoderm® (15%)	Lidoderm® (27%)
OxyContin® (10%)	Lidoderm® (19%)	Topamax® (10%)	Lidoderm® (11%)	OxyContin® (12%)	Flector® (13%)	Soma® (14%)	OxyContin® (9%)	Voltaren® (13%)	Voltaren® (10%)	Nucynta® (12%)	OxyContin® (18%)
Nucynta® (6%)	Voltaren® (7%)	Voltaren® (8%)	Flector® (11%)	Nucynta® (8%)	Nucynta® (9%)	Flector® (12%)	Voltaren® (9%)	Flector® (10%)	Cataflam® (8%)	Voltaren® (10%)	Voltaren® (11%)
Kadian® (6%)	Nucynta® (6%)	OxyContin® (7%)	Nucynta® (11%)	Flector® (8%)	Voltaren® (9%)	OxyContin® (10%)	Soma® (9%)	Soma® (6%)	Naprelan® (8%)	Flector® (8%)	Flector® (10%)
Soma® (6%)	Flector® (5%)	Soma® (7%)	Opana® (9%)	Naprelan® (8%)	Naprelan® (6%)	Nucynta® (7%)	Lidoderm® (7%)	Opana® (6%)	Amrix® (7%)	Amrix® (7%)	Opana® (8%)
<b>Total percentage of non-formulary drug payments that were for the top five drugs in the state</b>											
43%	69%	48%	55%	54%	56%	61%	46%	45%	47%	52%	73%

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> Some study states had major reforms addressing the use of controlled substances and pain medications, specifically opioids, after our study period, and these reforms may have affected prescription utilization in the states. Massachusetts, New York, and Tennessee passed laws in 2012 requiring registration and use of a prescription drug monitoring program by prescribers. Connecticut (2012) and Massachusetts (2013) adopted chronic pain treatment guidelines. New York also proposed non-acute pain medical treatment guidelines in 2013.

# 4

## ESTIMATED IMPACT ON PREVALENCE AND COSTS IF A TEXAS-LIKE FORMULARY IS ADOPTED IN OTHER STATES

This chapter presents estimates of the reduction in non-formulary drug prescriptions and overall prescription costs if a Texas-like formulary were adopted by other states under alternative assumptions about how physician prescribing practices change. In response to a closed formulary, Texas physicians adjusted prescribing patterns in two significant ways, on average. First, physicians reduced prescriptions for non-formulary drugs by 70 percent. Second, physicians infrequently substituted formulary drugs for the non-formulary drugs that they were prescribing much less often post-reform (see TDI, 2013). The response of physicians in other states to a Texas-like closed formulary may be similar to that of their Texas counterparts. However, that response might be more muted. We present four scenarios by making alternative assumptions about how physician prescribing practices change. This is not to say that these assumptions are realistic expectations of what might happen in the other 23 states. We provide multiple scenarios to the readers in order to illustrate the sensitivity of the impact of the formulary to prescribers' reactions—specifically, (1) how often they seek preauthorization to prescribe non-formulary drugs and (2), when they reduce the use of non-formulary drugs, how often they substitute formulary drugs. A summary of estimates of the impact on non-formulary drug prescriptions and overall prescription costs based on these four scenarios is presented in [Figure 4.1](#) and [Table A](#), respectively. The estimates of impact are based on the limited evidence from Chapter 3 in this report and results published in the 2013 TDI study regarding the impact of the Texas closed formulary on new injuries.

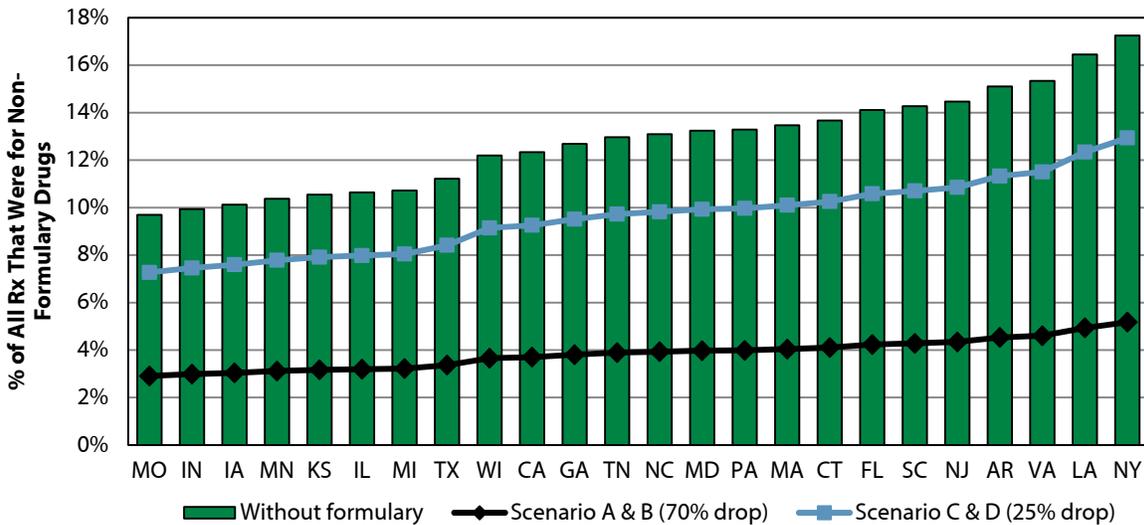
### ESTIMATED REDUCTION IN NON-FORMULARY DRUG PRESCRIPTIONS WITH A TEXAS-LIKE FORMULARY

Ten to seventeen percent of all prescriptions were written for non-formulary drugs in other states prior to the formulary.

**Scenarios A & B:** If we assume that other states have a drop in non-formulary drug prescriptions similar to Texas with the adoption of a formulary (i.e., a 70 percent reduction), non-formulary drug use in other states is estimated to drop to 3–5 percent. See [Figure 4.1](#). While it appears that states with a relatively higher prevalence of non-formulary drugs, like New York and Louisiana, are likely to have a larger effect if a Texas-like formulary is adopted, states with a relatively lower prevalence of these drugs could also reduce the utilization of non-formulary drugs by at least 7 percentage points (from 10 percent to 3 percent).

**Scenarios C & D:** Texas physicians reduced their use of non-formulary drugs by 70 percent. What if the behavior of Texas physicians was unique (for example, if physicians in State X learn that adjudicators would override many denials of preauthorization by payors)? Scenarios C & D contemplate a situation where physicians in State X reduce use of non-formulary drugs by only 25 percent. Based on this assumption, the percentage of prescriptions written for non-formulary drugs would be reduced to 7–13 percent from 10–17 percent across the study states (Figure 4.1).

**Figure 4.1 Estimated Percentage of All Prescriptions That Were for Non-Formulary Drugs under Different Scenarios, 2011/2012**



*Notes:* The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

Key: Rx: prescriptions.

**ESTIMATED PRESCRIPTION COST SAVINGS IF A TEXAS-LIKE FORMULARY IS MANDATED IN OTHER STATES**

**Scenario A:** To estimate the likely cost savings in other states with a Texas-like formulary, let us assume that the response of physicians in other states to a Texas-like closed formulary is similar to that of their Texas counterparts. In this scenario, the percentage of total prescription payments for formulary drugs should not change, the percentage of total prescription payments for non-formulary drugs should decrease by 80 percent, and the rest is potential cost savings. Please see the cost savings in study states with the adoption of a Texas-like formulary based on these assumptions in [Figure 4.2](#).

Total prescription payments could be reduced by 14–29 percent across the study states. Prescription costs in New York could be reduced by as much as 29 percent. Other states that could realize potential prescription cost savings of 20 percent and higher are New Jersey, Virginia, Massachusetts, Pennsylvania, Connecticut, and Maryland. Even at the lower end, states like California and Missouri might reduce their prescription drug spending by 14 percent with the adoption of a Texas-like formulary. However, there are reasons to expect that

physicians in some of these states may substitute with formulary drugs more frequently than did Texas physicians.

**Scenario B:** States may realize sizeable but lower cost savings if all non-formulary drugs are substituted with other drugs. To estimate the likely cost savings in other states in this scenario, let us assume that (a) physicians prescribed non-formulary drugs as often as Texas prescribers, but (b) they substituted all non-formulary drugs that were not prescribed because of the preauthorization requirement with other drug prescriptions that do not require preauthorization from the same therapeutic class.

We estimated that within-class substitution of all non-formulary drugs with formulary drugs may reduce prescription costs by 4 to 16 percent in other study states ([Figure 4.2](#)). Non-formulary drugs include several expensive brand name medications; therefore, the average cost of prescriptions for non-formulary drugs is higher than the average cost of prescription for formulary drugs belonging to the same therapeutic group.<sup>1</sup> States that stand to have higher prescription cost savings are New York and New Jersey (about a 15 percent drop in prescription costs). At least a 10 percent reduction in prescription drug spending is estimated in Pennsylvania, Massachusetts, Virginia, Michigan, and Connecticut. On the other hand, states like California, Georgia, Louisiana, and South Carolina are estimated to have lower prescription cost savings (5 percent or lower).

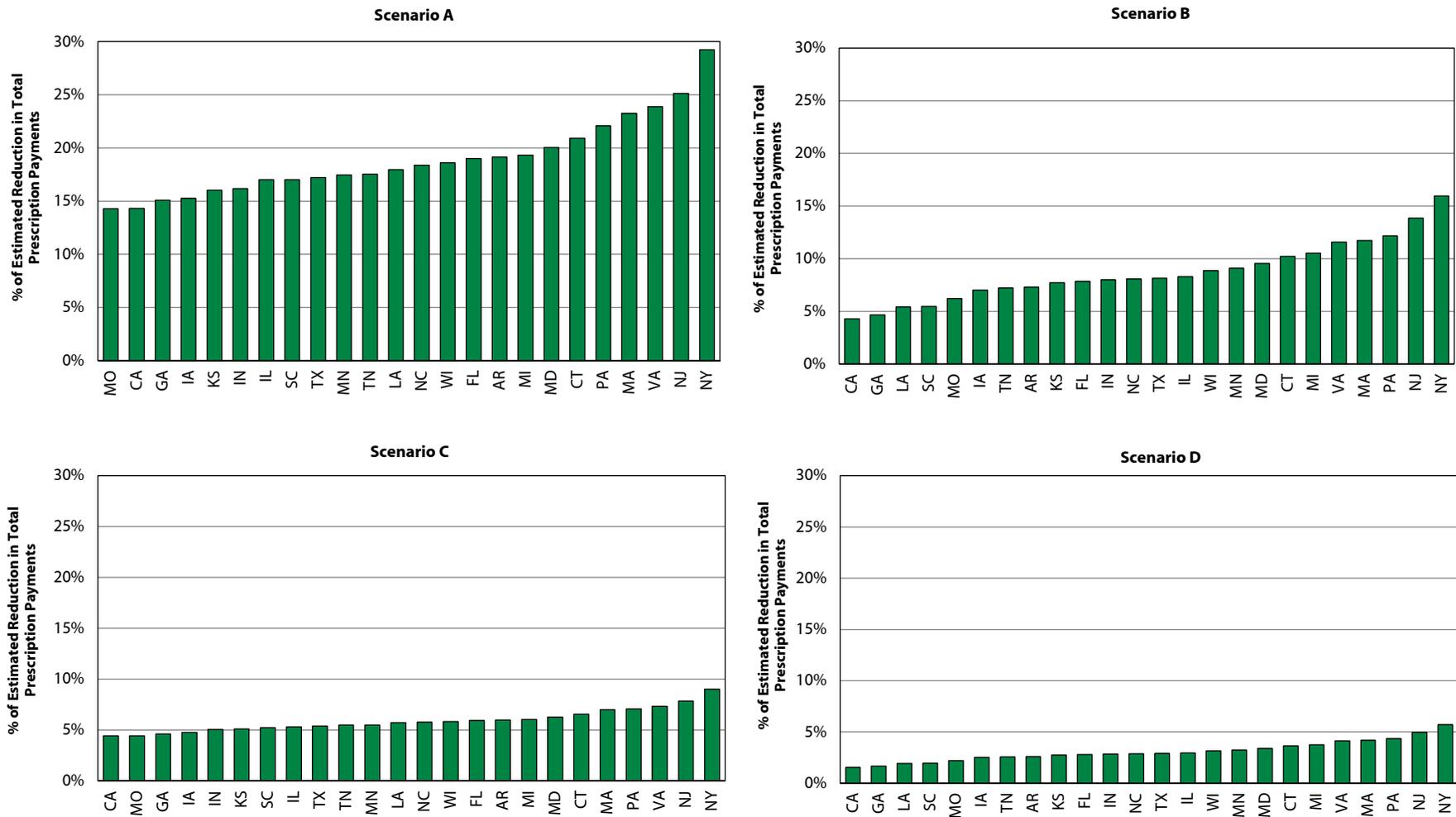
**Scenario C:** Texas physicians reduced their use of non-formulary drugs by 70 percent. What if the behavior of Texas physicians was unique (for example, if physicians in State X learn that adjudicators would override many denials of preauthorization by payors)? Scenario C contemplates a situation where physicians in State X reduce use of non-formulary drugs by only 25 percent. But like physicians in Texas, little substitution with formulary drugs occurs. As seen in [Figure 4.2](#), prescription drug costs are estimated to drop by 4–9 percent in other states in this scenario.

**Scenario D** is the same as Scenario C except it assumes full substitution. We estimated overall prescription costs to be reduced by 2–6 percent in this scenario. See [Figure 4.2](#).

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<sup>1</sup> Underlying data for average prescription payments of non-formulary drugs and formulary drugs by therapeutic group used for estimating prescription cost savings are included in [Table SA.3](#). We estimated the prescription cost savings assuming that a prescriber substitutes one non-formulary drug prescription with one formulary drug prescription of the same therapeutic group.

**Figure 4.2 Percentage of Estimated Reduction in Total Prescription Payments under Different Scenarios, 2011/2012**



Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

Scenario A: 70 percent reduction in non-formulary drug prescriptions and 0 percent substitution of non-formulary drugs with formulary drugs.

Scenario B: 70 percent reduction in non-formulary drug prescriptions and 100 percent substitution of non-formulary drugs with formulary drugs.

Scenario C: 25 percent reduction in non-formulary drug prescriptions and 0 percent substitution of non-formulary drugs with formulary drugs.

Scenario D: 25 percent reduction in non-formulary drug prescriptions and 100 percent substitution of non-formulary drugs with formulary drugs.

### **ESTIMATED PRESCRIPTION COST SAVINGS IN STATES WHERE PHYSICIAN DISPENSING IS COMMON**

It is possible that states where physician dispensing is common may realize lower cost savings than states without physician dispensing, because physicians may be more likely to substitute for non-formulary drugs due to the economic incentives incident to physician dispensing. Physician-dispensers can easily request their suppliers to customize the in-office formulary to include drugs that are not on the list of non-formulary drugs. An earlier WCRI study found high levels of substitution by Florida physician-dispensers when Florida banned physician-dispensing of stronger opioids. Physician-dispensers substituted Schedule II and III narcotics with NSAIDs they are allowed to dispense in their offices after the reform (Thumula, 2013). By contrast, there was little substitution in Texas,<sup>2</sup> where physician dispensing was not permitted in general. It is possible that physician-dispensers may substitute all non-formulary drugs with other drugs in order to maintain their revenues. For example, 9 percent of all non-formulary drug prescriptions were written for Banflex® by physician-dispensers in California. Physician-dispensers could easily substitute Banflex® with a muscle relaxant that doesn't require preauthorization, and prescribe it at the same rate.

To estimate the likely cost savings in this scenario, let us assume, like Scenario A, (a) a 70 percent drop in non-formulary drugs like in Texas, (b) no substitution by physicians who do not dispense, and (c) full substitution by dispensing physicians. [Figure 4.3](#) shows the potential cost savings based on these assumptions. Total prescription payments could be reduced by 15–29 percent in states where physician dispensing is not common. The cost savings are lower in states where physician dispensing is common, 8–15 percent.

### **ESTIMATED PRESCRIPTION COST SAVINGS IN STATES WHERE BRAND NAME MEDICATIONS ARE COMMON**

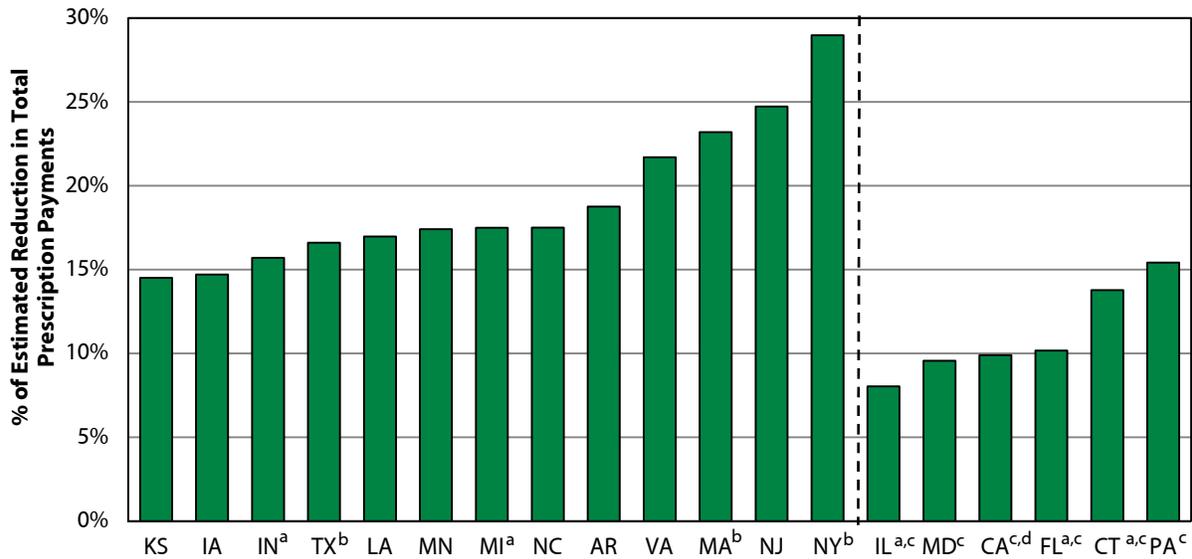
States where brand name medications are common are likely to see higher prescription cost savings with the adoption of a Texas-like formulary. There is substantial interstate variation in the proportion of non-formulary drug prescriptions that were for brand name medications—24 to 57 percent. In states with higher brand name medication use, even if physicians substituted all non-formulary drugs with cheaper generic alternatives, the potential cost savings could be substantial.

For example, New York (17 percent) and Louisiana (16 percent) have similar prevalence of non-formulary drugs ([Figure 3.1](#)). More than half (57 percent) of non-formulary drug prescriptions were for brand name medications in New York, highest among the study states. Only 30 percent were for brand name medications in Louisiana ([Figure 3.3](#)). Under Scenario B, which assumes a 70 percent drop in non-formulary prescriptions and full substitution, we estimate that prescription costs could be reduced by 16 percent in New York and only 5 percent in Louisiana ([Figure 4.2](#)).

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<sup>2</sup> See TDI (2013).

**Figure 4.3 Estimated Reduction in Total Prescription Payments Grouped by Prevalence of Physician Dispensing, 2011/2012**



*Notes:* The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

*Key assumptions:* 70 percent reduction in non-formulary drug prescriptions and 0 percent substitution of non-formulary drugs with formulary drugs by non-dispensers and 100 percent substitution of non-formulary drugs with formulary drugs by physician-dispensers.

For illustrative purposes, we only include states where physician dispensing is very common (more than 30 percent of non-recommended drugs are physician dispensed) and states where physician dispensing is infrequent (less than 10 percent).

<sup>a</sup> Connecticut, Florida, Illinois, Indiana, and Michigan recently adopted reforms aimed at reducing the costs of physician-dispensed prescriptions. The data presented here are pre-reform for these states.

<sup>b</sup> In Massachusetts, New York, and Texas, physician dispensing is not allowed in general. See Appendix A of Wang, Liu, and Thumula (2013) for more details.

<sup>c</sup> States where physician dispensing is common.

<sup>d</sup> California made rule changes for physician-dispensed prescriptions, effective March 2007. The data are post-reform for California.

# 5

## IMPLICATIONS

Pharmacy cost containment policies like drug formularies in the workers' compensation area remain largely unexplored. There is evidence from other payors that drug formularies are effective in reducing prescription drug spending. Huskamp, Epstein, and Blumenthal (2003) assessed the effect of a closed formulary implemented by the Veterans Health Administration (VHA), in 1997, on drug spending and estimated the total savings resulting from the formulary. They reported that the VHA formulary was effective in shifting prescribing behavior toward preferred drugs on the formulary and resulted in a decrease in average prescription spending per patient of 7–41 percent (depending on the drug class) following the adoption of the formulary.

In the workers' compensation system, two single payor states, Washington and Ohio, have mandated drug formularies.<sup>1,2</sup> Texas is the first multi-payor state to adopt a closed formulary in the workers' compensation system. The formulary was effective on September 1, 2011, for new claims and on September 1, 2013, for legacy claims (i.e., claims with injuries prior to September 1, 2011). Oklahoma is also implementing a closed formulary in two phases. The formulary is effective November 2014 for new injuries, and for those injured between February and November 2014, the formulary will be effective November 2016.<sup>3</sup> But unlike Texas where all claims are governed by the same formulary rules as of September 2013, the closed formulary rules do not apply to claims with injuries prior to February 2014 in Oklahoma. It will be interesting to monitor the impact of the formulary in states that only implement a closed formulary prospectively for injuries after a specified date of injury, like Oklahoma, compared with a state like Texas.

Early results from the Texas closed formulary indicate an experience similar to that of the VHA national formulary—there was a change in prescribing patterns for treating new injuries and there was a decrease in overall prescription drug spending. The formulary reduced the use of non-formulary medications in Texas. Because the formulary is based on evidence-based guidelines, reduction in use of non-formulary drugs could be perceived as an improvement in medical care provided to injured workers. As an example, the formulary resulted in a decrease in the use of high-risk medications like opioids in the state (TDI, 2013).

For other states considering whether they should adopt a Texas-like closed formulary, our study provides some evidence of the potential impact of a Texas-like formulary in other states based on certain assumptions. We identified several factors that could influence the effect a Texas-like closed formulary may have in other states. The first factor is the prevalence of non-formulary drugs that require preauthorization under the Texas closed formulary in a state. We observed that non-formulary drugs were prevalent in 23 other study states and they were at least as prevalent as in pre-formulary Texas. States with higher prevalence, like New York

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<sup>1</sup> See the Washington drug formulary (<http://www.lni.wa.gov/ClaimsIns/Files/Providers/DrugFormulary.pdf>).

<sup>2</sup> See the Ohio drug formulary (<https://www.bwc.ohio.gov/downloads/blankpdf/OAC4123-6-21.3Appendix.pdf>).

<sup>3</sup> See <http://ok.gov/wcc/documents/Chapter%203-Medical%20Services.pdf>.

and Louisiana, have a larger scope for reducing the use of non-formulary drugs. In these states, workers' compensation payors have an opportunity for more active management of prescribing patterns.

Considering that the prevalence of non-formulary drugs was similar to or higher than Texas in other study states, the potential impact of a formulary could be at least as large as Texas if physicians in these other states respond to the formulary as Texas doctors did. However, two other factors may influence the impact of a formulary in other states—how frequently physicians in other states are likely to seek preauthorization and continue to prescribe non-formulary drugs and how frequently they are likely to substitute non-formulary drugs that are not written because of the preauthorization requirement with other drugs that do not require preauthorization.

It is important to note that Texas has a requirement of preauthorization for various medical services such as physical and occupational therapy, outpatient surgical services, inpatient services, spinal surgery, diagnostic imaging, among others.<sup>4</sup> Texas doctors had been seeking authorization prior to providing these medical services for many years before they were required to seek preauthorization for prescribing non-formulary medications.<sup>5</sup> Texas has a medical dispute resolution process in place wherein preauthorization requests that are denied are reviewed by independent review organizations. It is possible that in states without a well-defined utilization review process the increased litigation costs might offset the formulary cost savings.

Our study identified two other factors that could have a muting or magnifying effect on the impact of the formulary. Physician dispensing is a factor that might have a muting effect on the impact a Texas-like closed formulary could have in other states. Physician-dispensers may choose to substitute non-formulary drugs with formulary drugs more often because of financial incentives. An earlier WCRI study found that Florida physician-dispensers substituted Schedule II and III narcotics with NSAIDs after a reform banned in-office dispensing of stronger opioids (Thumula, 2013). For this reason, states like California, Maryland, Florida, Illinois, and Connecticut, where a sizeable proportion of non-formulary drug prescriptions are physician-dispensed (greater than 25 percent), may have a larger substitution effect and lower prescription cost savings. Lastly, the prevalence of brand name non-formulary drugs might magnify the impact of a Texas-like closed formulary. We estimated that states where brand name medications are common, like New York, would have higher prescription cost savings with the adoption of a Texas-like formulary compared with states, like Louisiana, with relatively lower brand name non-formulary medications.

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<sup>4</sup> See <http://www.tdi.texas.gov/wc/rules/adopted/documents/2005911preauth.pdf> for more information on preauthorization of medical services in Texas.

<sup>5</sup> HB 2006, passed by the Texas legislature in 2001 and effective January 2002, required preauthorization for outpatient surgical services, inpatient services, spinal surgery, diagnostic imaging, and work hardening at certain facilities. HB 7, passed in May 2005 and effective September 2005, required preauthorization of physical and occupational therapy. Preauthorization for drugs excluded from the formulary was effective September 2011.

## STATISTICAL APPENDIX

**Table SA.1 Prevalence and Costs of Brand Name Medications among Non-Formulary Drugs, 2011/2012**

State	Percentage of All Prescriptions That Were for Non-Formulary Drugs	Percentage of Non-Formulary Drug Prescriptions That Were for Brand Name Medications	Percentage of Total Prescription Payments That Were for Non-Formulary Drugs	Percentage of Non-Formulary Drug Payments That Were for Brand Name Medications
Arkansas	15%	40%	24%	77%
California	12%	32%	18%	58%
Connecticut <sup>a</sup>	14%	38%	26%	73%
Florida	14%	35%	24%	58%
Georgia	13%	30%	19%	64%
Illinois <sup>a</sup>	11%	31%	21%	53%
Indiana <sup>a</sup>	10%	33%	20%	73%
Iowa <sup>a</sup>	10%	35%	19%	69%
Kansas	11%	32%	20%	67%
Louisiana <sup>a</sup>	16%	30%	22%	68%
Maryland <sup>a</sup>	13%	30%	25%	62%
Massachusetts	13%	33%	29%	70%
Michigan	11%	24%	24%	68%
Minnesota	10%	32%	22%	74%
Missouri <sup>a</sup>	10%	26%	18%	53%
New Jersey <sup>a</sup>	14%	49%	31%	80%
New York	17%	57%	37%	83%
North Carolina <sup>a</sup>	13%	35%	23%	73%
Pennsylvania <sup>a</sup>	13%	41%	28%	69%
South Carolina	14%	26%	21%	58%
Tennessee	13%	31%	22%	69%
Texas	11%	34%	22%	72%
Virginia	15%	34%	30%	70%
Wisconsin	12%	40%	23%	74%

*Notes:* The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Texas data are predominantly pre-formulary.

<sup>a</sup> States where generic substitution is not mandated.

**Table SA.2 Prevalence and Costs of Physician-Dispensed Prescriptions among Non-Formulary Drugs, 2011/2012**

State	Percentage of All Prescriptions That Were for Non-Formulary Drugs	Percentage of Non-Formulary Drug Prescriptions That Were for Physician-Dispensed Prescriptions	Percentage of Total Prescription Payments That Were for Non-Formulary Drugs	Percentage of Non-Formulary Drug Payments That Were for Physician-Dispensed Prescriptions
Arkansas	15%	2%	24%	2%
California <sup>a</sup>	12%	42%	18%	31%
Connecticut <sup>b</sup>	14%	25%	26%	34%
Florida <sup>b</sup>	14%	30%	24%	46%
Georgia <sup>a</sup>	13%	16%	19%	15%
Illinois <sup>b</sup>	11%	30%	21%	53%
Indiana <sup>b</sup>	10%	6%	20%	3%
Iowa	10%	3%	19%	4%
Kansas	11%	4%	20%	9%
Louisiana	16%	5%	22%	5%
Maryland	13%	36%	25%	52%
Michigan <sup>b</sup>	11%	6%	24%	9%
Minnesota	10%	0%	22%	0%
Missouri	10%	11%	18%	12%
New Jersey	14%	3%	31%	2%
North Carolina	13%	3%	23%	5%
Pennsylvania	13%	15%	28%	30%
South Carolina <sup>b</sup>	14%	9%	21%	13%
Tennessee <sup>b</sup>	13%	11%	22%	17%
Virginia	15%	5%	30%	9%
Wisconsin	12%	6%	23%	12%

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012. Three states (Massachusetts, New York, and Texas) where physician dispensing is not allowed in general were not included in this table.

<sup>a</sup> Two states included in the study (California and Georgia) made rule changes for physician-dispensed prescriptions, effective March 2007 and April 2011, respectively. The data are post-reform for California and partially post-reform for Georgia.

<sup>b</sup> Seven states (Connecticut, Florida, Illinois, Indiana, Michigan, South Carolina, and Tennessee) recently adopted reforms aimed at reducing the costs of physician-dispensed prescriptions. The data presented here are pre-reform for these states. Note that we grouped South Carolina and Tennessee with the pre-reform states because the data for the two states are predominantly pre-reform.

**Table SA.3 Utilization and Price of Non-Formulary and Formulary Drugs by Therapeutic Group, 2011/2012**

	AR	CA	CT	FL	GA	IA	IL	IN	KS	LA	MA	MD	MI	MN	MO	NC	NJ	NY	PA	SC	TN	TX	VA	WI
<b>% of all prescriptions that were for non-formulary drugs</b>	15%	12%	14%	14%	13%	10%	11%	10%	11%	16%	13%	13%	11%	10%	10%	13%	14%	17%	13%	14%	13%	11%	15%	12%
<b>Anticonvulsants</b>																								
% of NF drugs that were for the therapeutic group	3%	3%	3%	3%	4%	4%	3%	4%	3%	5%	4%	4%	4%	4%	6%	4%	5%	4%	3%	5%	4%	4%	4%	2%
% of formulary drugs that were for the therapeutic group	5%	2%	4%	2%	4%	4%	4%	4%	3%	5%	5%	4%	4%	5%	3%	5%	4%	7%	5%	5%	4%	4%	5%	6%
Price per Rx for NF drugs by therapeutic group (mean)	\$35	\$39	\$84	\$151	\$108	\$100	\$147	\$125	\$126	\$114	\$144	\$167	\$82	\$55	\$212	\$118	\$121	\$163	\$149	\$109	\$136	\$93	\$171	\$109
Price per Rx for formulary drugs by therapeutic group (mean)	\$149	\$74	\$146	\$150	\$126	\$146	\$170	\$141	\$138	\$137	\$115	\$206	\$105	\$113	\$114	\$134	\$144	\$134	\$155	\$135	\$135	\$136	\$142	\$140
<b>Antidepressants</b>																								
% of NF drugs that were for the therapeutic group	5%	6%	4%	4%	5%	9%	6%	9%	9%	11%	8%	5%	13%	9%	6%	5%	4%	5%	4%	6%	7%	6%	6%	7%
% of formulary drugs that were for the therapeutic group	2%	1%	1%	1%	1%	1%	1%	1%	1%	2%	2%	1%	2%	2%	1%	1%	1%	2%	1%	2%	1%	2%	3%	2%
Price per Rx for NF drugs by therapeutic group (mean)	\$71	\$50	\$96	\$84	\$68	\$74	\$79	\$78	\$87	\$91	\$61	\$69	\$38	\$50	\$94	\$79	\$85	\$83	\$85	\$66	\$100	\$87	\$95	\$88
Price per Rx for formulary drugs by therapeutic group (mean)	\$122	\$77	\$70	\$112	\$95	\$92	\$96	\$118	\$94	\$107	\$67	\$75	\$110	\$77	\$86	\$97	\$111	\$100	\$128	\$126	\$125	\$121	\$107	\$80
<b>Dermatologicals</b>																								
% of NF drugs that were for the therapeutic group	10%	23%	20%	18%	15%	13%	16%	14%	13%	8%	16%	12%	8%	11%	10%	14%	17%	25%	17%	6%	12%	14%	12%	20%
% of formulary drugs that were for the therapeutic group	1%	6%	0%	2%	2%	1%	3%	1%	1%	2%	1%	3%	1%	0%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Price per Rx for NF drugs by therapeutic group (mean)	\$196	\$103	\$274	\$258	\$190	\$198	\$311	\$252	\$174	\$231	\$239	\$428	\$267	\$226	\$225	\$225	\$234	\$261	\$311	\$220	\$235	\$199	\$279	\$214
Price per Rx for formulary drugs by therapeutic group (mean)	\$65	\$123	\$28	\$173	\$156	\$82	\$42	\$33	\$34	\$365	\$76	\$233	\$48	\$35	\$20	\$30	\$61	\$91	\$208	\$59	\$207	\$65	\$133	\$37
<b>Muscle relaxants</b>																								
% of NF drugs that were for the therapeutic group	17%	27%	16%	25%	15%	8%	23%	7%	15%	19%	10%	33%	10%	9%	17%	9%	12%	12%	16%	12%	13%	18%	9%	5%
% of formulary drugs that were for the therapeutic group	11%	9%	12%	13%	12%	10%	8%	10%	11%	13%	11%	12%	12%	11%	10%	12%	10%	12%	10%	11%	10%	14%	11%	10%
Price per Rx for NF drugs by therapeutic group (mean)	\$94	\$34	\$130	\$144	\$52	\$70	\$232	\$62	\$43	\$54	\$86	\$137	\$91	\$40	\$61	\$95	\$121	\$127	\$179	\$105	\$67	\$76	\$144	\$57
Price per Rx for formulary drugs by therapeutic group (mean)	\$58	\$30	\$58	\$59	\$57	\$47	\$58	\$54	\$51	\$66	\$59	\$70	\$50	\$42	\$57	\$55	\$71	\$68	\$59	\$54	\$50	\$69	\$69	\$56
<b>NSAIDs</b>																								
% of NF drugs that were for the therapeutic group	15%	15%	14%	19%	26%	19%	16%	18%	18%	14%	14%	11%	10%	19%	22%	19%	18%	17%	14%	20%	17%	20%	25%	20%
% of formulary drugs that were for the therapeutic group	13%	29%	23%	27%	21%	18%	22%	17%	17%	14%	18%	25%	22%	13%	19%	17%	25%	20%	22%	17%	18%	21%	16%	15%
Price per Rx for NF drugs by therapeutic group (mean)	\$99	\$76	\$70	\$86	\$76	\$68	\$93	\$74	\$60	\$131	\$66	\$69	\$62	\$43	\$68	\$88	\$123	\$135	\$77	\$72	\$87	\$115	\$83	\$61
Price per Rx for formulary drugs by therapeutic group (mean)	\$79	\$36	\$68	\$92	\$77	\$59	\$93	\$60	\$60	\$112	\$40	\$81	\$35	\$45	\$57	\$77	\$49	\$72	\$72	\$77	\$91	\$55	\$69	\$64
<b>Opioids</b>																								
% of NF drugs that were for the therapeutic group	26%	8%	18%	14%	14%	19%	14%	18%	19%	15%	18%	19%	18%	25%	16%	19%	24%	22%	24%	19%	17%	13%	19%	21%
% of formulary drugs that were for the therapeutic group	56%	35%	50%	39%	47%	52%	46%	55%	56%	52%	52%	42%	47%	53%	53%	52%	46%	47%	48%	53%	53%	48%	51%	54%
Price per Rx for NF drugs by therapeutic group (mean)	\$92	\$147	\$132	\$126	\$116	\$132	\$152	\$165	\$169	\$188	\$153	\$224	\$187	\$144	\$117	\$170	\$142	\$228	\$204	\$124	\$137	\$127	\$185	\$155
Price per Rx for formulary drugs by therapeutic group (mean)	\$27	\$30	\$39	\$39	\$34	\$28	\$45	\$35	\$31	\$38	\$27	\$50	\$24	\$19	\$32	\$33	\$32	\$44	\$38	\$32	\$32	\$30	\$33	\$29
<b>All other pain medications</b>																								
% of NF drugs that were for the therapeutic group	0%	3%	1%	2%	2%	1%	1%	1%	1%	2%	2%	1%	2%	1%	1%	1%	2%	3%	2%	2%	1%	3%	4%	0%
% of formulary drugs that were for the therapeutic group	1%	3%	2%	3%	3%	2%	3%	3%	2%	2%	1%	2%	3%	3%	2%	2%	2%	2%	3%	1%	2%	2%	2%	2%
Price per Rx for NF drugs by therapeutic group (mean)	\$52	\$56	\$28	\$54	\$25	\$26	\$37	\$21	\$44	\$30	\$26	\$37	\$23	\$19	\$30	\$24	\$33	\$71	\$32	\$25	\$28	\$29	\$50	\$62
Price per Rx for formulary drugs by therapeutic group (mean)	\$24	\$17	\$32	\$31	\$28	\$28	\$24	\$28	\$20	\$46	\$44	\$26	\$15	\$29	\$25	\$43	\$29	\$65	\$40	\$60	\$22	\$31	\$56	\$29
<b>Sedative-hypnotics</b>																								
% of NF drugs that were for the therapeutic group	0%	2%	1%	2%	2%	1%	1%	1%	2%	2%	0%	1%	2%	1%	1%	1%	2%	1%	2%	2%	2%	2%	1%	1%
% of formulary drugs that were for the therapeutic group	1%	1%	1%	1%	1%	1%	1%	0%	2%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	2%	1%	1%	1%	1%
Price per Rx for NF drugs by therapeutic group (mean)	\$30	\$55	\$46	\$82	\$47	\$54	\$119	\$81	\$97	\$69	\$87	\$376	\$41	\$80	\$49	\$62	\$78	\$91	\$76	\$51	\$69	\$57	\$64	\$37
Price per Rx for formulary drugs by therapeutic group (mean)	\$136	\$31	\$107	\$140	\$149	\$105	\$141	\$119	\$124	\$108	\$95	\$143	\$83	\$106	\$99	\$121	\$115	\$116	\$144	\$107	\$121	\$114	\$125	\$112
<b>Ulcer drugs</b>																								
% of NF drugs that were for the therapeutic group	0%	2%	1%	1%	1%	2%	2%	1%	1%	1%	1%	1%	2%	1%	0%	1%	1%	1%	1%	1%	1%	1%	0%	1%
% of formulary drugs that were for the therapeutic group	0%	7%	1%	4%	2%	1%	4%	0%	1%	0%	1%	3%	1%	1%	0%	1%	0%	1%	1%	0%	1%	0%	1%	1%
Price per Rx for NF drugs by therapeutic group (mean)	\$63	\$153	\$58	\$179	\$175	\$153	\$161	\$118	\$149	\$164	\$97	\$77	\$166	\$135	\$108	\$149	\$150	\$168	\$131	\$173	\$221	\$174	\$153	\$141
Price per Rx for formulary drugs by therapeutic group (mean)	\$109	\$130	\$147	\$162	\$145	\$102	\$230	\$87	\$97	\$172	\$91	\$192	\$77	\$66	\$101	\$132	\$102	\$151	\$195	\$107	\$159	\$96	\$103	\$139
<b>All other therapeutic groups</b>																								
% of NF drugs that were for the therapeutic group	23%	12%	23%	14%	16%	25%	19%	26%	18%	23%	26%	12%	31%	21%	22%	26%	17%	10%	17%	27%	25%	19%	19%	23%
% of formulary drugs that were for the therapeutic group	9%	6%	6%	8%	7%	11%	8%	9%	9%	7%	8%	6%	8%	11%	10%	9%	9%	7%	8%	7%	9%	8%	9%	10%
Price per Rx for NF drugs by therapeutic group (mean)	\$39	\$40	\$25	\$50	\$61	\$55	\$41	\$63	\$55	\$57	\$32	\$53	\$45	\$31	\$31	\$23	\$52	\$58	\$41	\$31	\$50	\$45	\$49	\$23
Price per Rx for formulary drugs by therapeutic group (mean)	\$58	\$47	\$43	\$65	\$70	\$62	\$73	\$61	\$65	\$110	\$51	\$62	\$45	\$50	\$66	\$63	\$68	\$72	\$55	\$50	\$56	\$57	\$62	\$63

Notes: The underlying data include prescriptions for claims with more than seven days of lost time that had prescriptions filled over the defined period and paid for by a workers' compensation payor. 2011/2012 refers to claims with injuries occurring from October 1, 2010, to September 30, 2011, and prescriptions filled through March 31, 2012.

Key: NF drug: non-formulary drug; NSAID: non-steroidal anti-inflammatory drug; Rx: prescriptions.

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The Workers Compensation Research Institute is a nonpartisan, not-for-profit research organization providing objective information about public policy issues involving workers' compensation systems.

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The Institute's work helps those interested in improving workers' compensation systems by providing new, objective, empirical information that bears on certain vital questions:

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- Periodic research briefs that report on significant new research, data, and issues in the field
- Benchmarking reports that identify key outcomes of state systems

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## Appendix 4

### Table of Procedures in States with Drug Formularies

	<b>TEXAS</b>	<b>TENNESSEE</b>	<b>OHIO</b> (The state is the only insurer for workers' compensation.)	<b>WASHINGTON</b> (Employers self-insure or buy insurance from the state.)	<b>OKLAHOMA</b>
<b>Drug Formulary Adopted</b>	ODG	ODG	Developed internally	Developed internally	ODG
<b>Treatment Guidelines</b>	Yes	Yes	Yes	Yes	Yes
<b>First Fill Program</b>	Yes, 7-day initial supply.	Yes, 7-day supply within 7 days of injury.	Yes, prior to decision on claim, from specific list only.	Yes, 10-day emergency supply of non-preferred drug if outside business hours.	Uncertain
<b>Preauthorization Procedure</b>	Any provider or pharmacist can request. Carrier has 3 days for review.	Carrier may approve or send to UR within 3 days of request.	A physician may file a form for prior authorization of a non-formulary drug with the Bureau of Workers' Compensation.	Pharmacist calls Dept. of Labor & Industries if non-formulary drug prescribed. Claims Director and pharmacists on staff review requests and speak directly with provider.	Carriers must make preauthorization decisions within 3 days.
<b>Internal/Carrier Utilization Review (UR)</b>	If preauthorization is denied, UR must have a peer-to-peer discussion with provider within 24 hours. Provider can request reconsideration by another physician.	UR must approve or deny within 7 days. Only a physician can deny a prescription at UR level.	No	No	No

	<b>TEXAS</b>	<b>TENNESSEE</b>	<b>OHIO</b> (The state is the only insurer for workers' compensation.)	<b>WASHINGTON</b> (Employers self-insure or buy insurance from the state.)	<b>OKLAHOMA</b>
<b>External/Legal Review</b>	If denied at UR, provider can appeal to independent medical review (IMR) which must be completed within 30 days. Further appeal by injured worker/provider is legal appeal to Div. of Workers' Compensation.	UR denial can be appealed to Bureau of Workers' Compensation within 31 days. If carrier does not rescind denial within 5 days, Bureau's medical director issues decision within 30 days.	Denial of a request for a non-formulary drug may be appealed to the Bureau of Workers' Compensation, which takes 4-6 weeks.	Provider can appeal denial to the Board of Industrial Insurance Appeals.	If preauthorization is denied, the injured worker can request a hearing before an Administrative Law Judge.
<b>Emergency Appeal Procedure</b>	Interlocutory medical order (IMO) can be sought from Div. of Workers' Compensation.	Requests for expedited determination made to Bureau of Workers' Compensation are decided within 3 days.	No	No	Medical interlocutory order (MIO) can be sought from Workers' Compensation Commission.

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## **Appendix 5**

### **Sample Flowchart of Basic Steps in a Drug Formulary Review and Appeal Procedure**

*(This is a basic procedural flowchart included for illustrative purposes only. The North Carolina Industrial Commission recommends further study of a potential drug formulary and related procedures.)*

