Exploring Ex Ante Regulatory Mechanisms for Detecting Prescription Drug Misuse

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Prescription drug misuse affects several million people and results in direct medical costs for treatment of patients and indirect costs for society that total billions of dollars per year. Most prescription drug misuse is detected after it has occurred (ex post) by law enforcement agencies working with the medical provider community. The current method for enforcement is a litigation approach requiring casework and criminal prosecution. An alternative regulatory mechanism is to use health insurance claims data ex ante and expert systems/doctors/economists (specialist enforcers) to screen cases and prevent the prescription destined to be misused from being filled. This paper uses a large employer population's claims data to identify a regulatory approach that might work using existing algorithms to detect ex post misuse. This method shows that up to 1% of the covered lives in the employer's population may be associated with prescription drug misuse of controlled substances. The paper shows key factors that could be used to identify patient characteristics associated with misuse. These key factors can then be used in an ex ante predictive model to take a regulatory approach. The paper concludes with a discussion of how point-of-service fraud detection and intervention systems used by banks and credit card vendors could be adapted to institute a more preventive ex ante regulatory mechanism to stop the actual provision of medication intended for misuse.

JEL Classification: I1, K2, K42

August 26, 2009

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This project was supported by The Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services
Contract Number: HHSP23320054100EC.

Introduction

The misuse of prescription drugs in the Unites States is a growing problem. Rates of prescription drug misuse in the United States have risen significantly during recent years, with one study reporting an increase of 2.5 million prescription drug misusers between 2002 and 2007[i]. The issue is not contained to the United States. A recent report from the UK's National Institute for Clinical Effectiveness (NICE) estimates that 280,000 Britons are abusing prescription opioids.[ii] This represents just under half of one percent of the UK's general population under the age of 65. The issue is complex because of the many agents engaged in the provision of prescription medications, as well as the regulations placed on the prescribing agents. Beyond the first party patient and the supplier of the prescription, there is the second party physician who prescribed the medication, followed by the third party public or private insurance company who financed the drug, and the fourth party prescription benefit management firm setting the price for the drug. Complicating matters further, insurance claims data provide an electronic trace of the entire set of transactions that could demonstrate misuse ex post. The complication stems from the fact that ex post measurement using electronic point-of-sale transaction data suggests that an ex ante regulatory approach might have limited the scope of the problem, had agents two, three and four used the available technology.

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[i] Substance Abuse & Mental Health Services Administration (SAMHSA). (2007). Results from the 2006 National Survey on Drug Use and Health. Rockville, MD: Office of Applied Studies.; McCabe, S. E., West, B. T., & Wechsler, H. (2007). Trends and college-level characteristics associated with the non-medical use of prescription drugs among US college students from 1993 to 2001. Addiction, 102(3), 455-465.

[ii] See: http://www.nice.org.uk/CG51

This paper presents an exploratory analysis of the extent to which prescription drug abuse for pain medication could be identified prospectively for intervention by health insurers, supported by law enforcement and the medical community. The paper proceeds first with a general distinction between misuse and abuse, and how its remedy would be considered in the insurance contract. The second part of the paper describes the current ex post process for detection after it has occurred by police and law enforcement. The third part presents an ex ante alternative to the ex post "litigation" approach. This alternative approach applies expert systems designed by doctors/pharmacists/statisticians/law enforcement/economists to insurance claims data in order to screen high probability misuse for intervention and education. The fourth section demonstrates how this "regulation" approach might work using the application of a published algorithm. The paper concludes with a discussion of how this might work as a regulatory approach, either in the hands of law enforcement or private health plans.

Misuse versus Abuse

When considering the prospect of drug misuse, the question of whether or not drug abuse has occurred is confusing and warrants attention. One of the clearest distinctions between abuse and misuse comes from the American Medical Association's Committee on Alcoholism and Addiction's 1966 definition where abuse of stimulants (amphetamines, primarily) was defined in terms of 'medical supervision'. Specifically, the Committee stated:[iii]

> "'Use' refers to the proper place of stimulants in medical practice; 'misuse' applies to the physician's role in initiating a potentially dangerous course of therapy; and

[iii] See: http://jama.ama-assn.org/cgi/content/abstract/268/8/1012

'abuse' refers to self-administration of these drugs without medical supervision and particularly in large doses that may lead to psychological dependency, tolerance and abnormal behavior."

In this paper, we will measure both the misuse and abuse of prescribed controlled substances with an understanding that both terms can apply. Misuse will be used as the principal concern, since the medications considered are, at least in the United States, only obtainable through a physician prescription. This process automatically involves the physician, whether willfully giving a potential abuser a stimulant or being deceived by a patient who presents a false medical need (e.g., severe pain from a sprain with no easy way to verify physical evidence that indicates damage to the patient). NICE posits a more contemporary definition of misuse defined as:[iv]

"Intoxication by – or regular excessive consumption of and/or dependence on – psychoactive substances, leading to social, psychological, physical or legal problems. It includes problematic use of both legal and illegal drugs (including alcohol when used in combination with other substances)."

This definition of misuse suggests that the physician must be playing a role in the prescribing of controlled substances. Furthermore, it emphasizes the societal costs of misuse of controlled substances and why law enforcement agencies seek to mitigate and prevent the inappropriate use of these prescribed medications.

The Problem of Controlled Substance Misuse

The diversion, abuse, and inappropriate use of controlled substances are subjects of continuing concern to law enforcement, the medical community, insurers, and policy

[iv] See: http://www.nice.org.uk/CG51

makers alike. These parties seek a balance between preventing diversion/abuse and encouraging the use of controlled substances for legitimate medical need, particularly for pain management.[1-3] A number of clinical practice guidelines, consensus statements from professional associations, and state laws and policies emphasize that it is essential for opioid analgesics to be available for the treatment of moderate to severe pain, and that prescribing should be individualized to the patient. [2,4-14] Although some progress has been made in treating pain, under-treatment of pain is still prevalent.[15-17]

Media coverage of diversion and abuse of controlled substances, as well as uncertainty regarding potential disciplinary action, may cause physicians to hesitate when considering treatment for a patient who could require long-term or high doses of opioids. This is exacerbated when physicians have trouble discerning between a patient with a legitimate pain problem and one who is feigning pain to obtain drugs for abuse or diversion.[18] Because pain is subjective and cannot be measured or ruled out by laboratory tests or physical examination, physicians rely largely on their interpretation of patient interviews and histories to determine a patient's need for analgesics. However, they often find themselves in the predicament of wanting to treat seemingly legitimate patient needs without having information about their patients' prescription drug and medical histories, which would help identify and address any problems. A 1999 report from the Institute of Medicine stressed that most medical errors do not result from individual practitioners' recklessness. Instead, they can be attributed to faulty processes and systems that lead people to make mistakes or fail to prevent them through lack of information and support in a complex working environment.[19] Solving problems within the healthcare industry requires the design of systems and processes to help avoid errors,

to minimize the damage caused by errors that do occur, and to analyze the pattern of errors to discover ways to prevent them.

Despite technological advances and the wealth of strategic knowledge within administrative healthcare claims databases, currently only 17 states operate electronic prescription monitoring programs, which vary in their goals, structure, and oversight by the health profession.[20-25] Presently, few health plans analyze the data to identify potential misuse of controlled substances. Access to this aggregate information on patients is not readily provided to physicians, restricting their ability to provide quality care. In response to this need, we developed a software program that identifies patients with potential prescription mismanagement or abuse/diversion issues.

Comparing Ex Post Litigation versus Ex Ante Regulation of Drug Misuse

In the last two decades, many public policy initiatives have been started to mitigate the misuse of controlled substances through education programs in schools and communities. Despite this emphasis on prevention, the most likely public policy interaction occurs through ex post litigation, where law enforcement officials seek to detect and prosecute systematic misuse and diversion schemes. In these cases, evidence of misuse and diversion is used to prosecute the drug users as well as the physician prescribers. This ex post litigation approach is expensive, and it is difficult to show its impact beyond media coverage of exceptional cases.

In contrast, an ex ante regulatory approach to drug misuse would take prevention up a notch. It would combine the law enforcement activity with surveillance of electronic prescribing systems and interventions to stop or delay prescriptions in order to make sure diversion or patient-initiated abuse is not occurring. The intervention process

analysis uses the same data available to pharmacists (and some physicians) and could succeed in creating an ex ante regulatory system. Such a system would go beyond the current ex post use of electronic data to identify an adverse practice pattern for intervention as well as litigation. To be a truly ex ante system, the electronic data would be used in real time to prevent the prescription from being received by the abusing or diverting recipient. This ex ante approach would be more regulatory in nature and would have to carefully examine mechanisms to minimize false positives in misuse identification. Failure to do so would create an access-to-care problem for severe pain patients with legitimate need for prescribed medication.

A regulatory approach could also be viewed as a fraud mitigation device. For example, the ex ante risk scoring of credit card transactions at the point of sale to reduce fraudulent purchases is quite analogous to the issue of preventing prescribed medication misuse. Healthcare fraud is a serious and expensive issue in the United States. The National Health Care Anti-Fraud Association (NHCAA) estimates that in calendar year 2003, at least $51 billion, or 3% of the nation's annual healthcare outlay, was lost to outright fraud. Other estimates by government and law enforcement agencies place the loss as high as 10% of our annual expenditure or, in 2009 dollars, $250 billion.[v] In a conceptual model of fraud, a fraudulent consumer/potential patient derives no benefit from medical care through an improvement in health status. Fraud activities diminish the consumer welfare by providing an additional cost (directly or indirectly) to patient care to cover the expense to the consumer or the consumer's insurer of an unneeded and possibly

[v] *Healthcare Fraud: A Serious and Costly Reality for All Americans*, National Health Care Anti-fraud Association, http://www.nhcaa.org/pdf/all_about_hcf.pdf site visited on 8/14/2005.

fictitious good or service. Thus, a regulatory mechanism that detects prescribed medication misuse can be defined as an activity that uncovers fraud and thereby restores societal resources lost to that crime.

Methods

The methods for this analysis have three components. First, metrics for identifying drug misuse are introduced based on a set of existing algorithms. Second, the study population for this analysis is introduced. Finally, the empirical specification for a multivariate analysis to identify the patient level attributes associated with most common metrics of abuse is presented.

Identifying Metrics for Drug Misuse

For this analysis, we will use a drug misuse algorithm developed in consultation with key experts in the field including a multidisciplinary expert panel consisting of addictionists pain physicians, psychologists, psychiatrists, law enforcement officials and pain management nurses. This algorithm, called CS-PURE, published in 2004[vi], represents the most comprehensive non-proprietary tool available at present to measure drug misuse. CS-PURE can be applied to claims databases in order to identify possible abuse or diversion of controlled substances by patients, or mismanagement by prescribers. The CS-PUREs are not conclusive of inappropriate use; rather they aim at improving patient safety and outcomes by alerting prescribers and insurers of potential problems so that further evaluation can be conducted. The expert panel reached consensus on a 38 prototype CS-PURE for evaluation. Some of the CS-PUREs were

[vi] Parente, S.T., Kim, S., Finch, M., Schloff, L., Rector, T., Seifeldin, R., Haddox, J.D. "Using Claims Data to Identify Controlled Substance Patterns of Utilization Requiring Evaluation." *American Journal of Managed Care,* November 2004; 10(11 Pt 1):783-90.

based on similar patterns, but reflected variations in specific medications used and changes in the duration of consecutive or overlapping days of medication use; for example, continuous overlap of two or more benzodiazepines for at least 30, 60, or 90 days.

Computer programs based on the expert panel's originally suggested 38 CS-PURE patterns were developed using SAS, to apply the CS-PURE to the healthcare claims data. Detailed utilization profiles were produced for the patients identified by each of the prototype CS-PUREs. A project team, comprised of pharmacists, computer programmers, and health services researchers, reviewed and assessed these profiles for the accuracy of the computer coding. At the conclusion of this process, the original 38 CS-PUREs were reduced to 34 CS-PUREs. This change reflected the deletion of four of the original CS-PUREs because they identified an extremely low number of patients and, thus, were determined to be of comparably limited use.

Table 1 presents the top 10 metrics of prescribed opioid misuse based on the final 34 published CS-PUREs. The top 10 metrics' distinction was based on an optimal mix of period prevalence of the pattern found in the population. In addition, the percent of expert agreement in patient profile review of whether the algorithm truly found a misuse case was also considered. The largest two metrics, measured at the patient level, defined as >=6 pharmacies dispensing scripts to a patient for opioids and >=4 physicians prescribing controlled substances in a year, constitute .21% and .13% of the health plan's population, respectively. Law enforcement officials agreed with roughly half of the cases. For two of the other eight remaining metrics, law enforcement agreed with 100% of the cases, presented through claims data alone, that intervention was required.

Table 1 – Top 10 Metrics for Prescribed Opioid Misuse

CS-PURE	Pattern of controlled substance misuse	Period Prevalence	Experts agree misuse			Experts agree evaluation	Experts agree intervention
			Overall	Clinical	Legal		
1	**Multiple prescribers (≥6 prescribers for same drug)**	0.21%	55%	59%	48%	60%	59%
2	**Multiple pharmacies (≥4 different pharmacies for same drug)**	0.13%	59%	64%	51%	64%	64%
3	Chronic use of (≥4 prescriptions in 6 months) carisoprodol	0.13%	64%	68%	58%	68%	71%
4	Continuous overlap of ≥2 different benzodiazepines for ≥30 days, when 1 is for alprazolam	0.06%	56%	58%	50%	56%	55%
5	**Estimated ≥4 g of acetaminophen/day**	0.03%	100%	100%	100%	100%	100%
6	**≥2 prescriptions for meperidine with >2 days supply**	0.02%	100%	100%	100%	100%	100%
7	Chronic use of (≥4 prescriptions in 6 months) butorphanol	0.02%	56%	50%	67%	100%	100%
8	Continuous overlap of ≥2 different benzodiazepines for ≥90 days, when 1 is for clonazepam	0.01%	63%	67%	54%	65%	63%
9	Continuous overlap of ≥2 different benzodiazepines for ≥90 days, when 1 is for diazepam	0.00%	63%	65%	60%	60%	60%
10	Overlap of ≥2 different sustained-release or long-acting opioids for ≥90 consecutive days	0.00%	63%	67%	50%	69%	69%

Used for Study

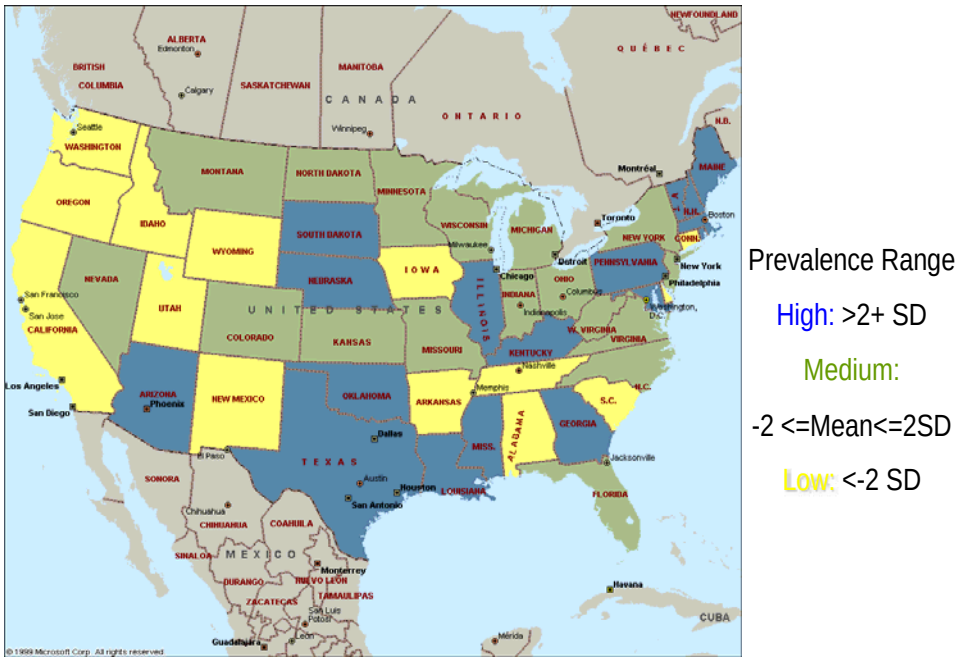
In Figure 1 a national representation of drug-misuse from the >=4 prescriber algorithm shows significant regional heterogeneity with no clear pattern by large regional census areas of the Northeast, South or Midwest and West, or urban and rural state comparisons. At the very least, a national representation can help to prioritize resources for possible ex ante intervention. The data presented in Figure 1 are from 2002. As a verification of the algorithm's potential, the state of Kentucky stands out as a high potential drug misuse and diversion state. This is supported by the July 2002 National Drug Intelligence Center report, which stated that from 1998 through 2000, treatment for the abuse of prescription drugs accounted for 20 percent of all treatment admissions in the state, and the number of patients seeking treatment for Oxycodone addiction increased 163 percent.[vii] Since that time, Kentucky has installed an electronic prescriber early warning system, the Kentucky All Schedule Prescription Electronic Reporting

[vii] See: http://www.medicalnewstoday.com/articles/135591.php

(KASPER), to allow law enforcement officials to monitor controlled substance prescriptions dispensed in Kentucky.

Figure 1

National Variation in Pain Medication Misuse, Multiple Prescribers, >=4, 2002



For this analysis, we focused on the four substance abuse misuse algorithms. The criteria used for selection were the most prevalent patterns and those where law enforcement officials have the greatest agreement for intervention and, thus, support an ex ante regulatory mechanism. These algorithms are used in the empirical analysis described below:

- Multiple Prescribers (6 or more prescribing physicians) for controlled substance in one year.
- Multiple Pharmacies (4 or more) where controlled substances were received in one year.
- Chronic Use (180+ days four or more grams), Stadol.
- 2+ concurrent scripts for Demerol w/day supply greater than two.

Data Sources

The data source for the analysis is a large national employer with over 300,000 covered lives in multiple states. Both medical and pharmacy claims data for two years were available for analysis. Enrollment data were available as well to ensure that the employee or their dependents were enrolled in a health plan for two years to avoid omitted variable bias. The employer's human resource data also included salary information of the contract holder. The data used in the analysis have a common structure, similar to that used by any employer, insurer, or government health insurance program such as Medicaid.

Empirical Approach

The empirical approach for this analysis was completed in three steps. First, the CS-PURE algorithms were run for the employer data described above; this provided analytic files to generate descriptive statistics and run a bivariate analysis where the personal attributes of the population are compared between a group with any CS-PURE identification and those without any CS-PURE association. In the second step, a logistic regression analysis was completed to identify the factors most associated with the two most prevalent CS-PURE algorithms. The independent variables used in the regression model include:

- Age (& age-squared) and gender

- Primary contract holder (i.e., subscriber)
- Medicare/retiree contract
- Out of pocket premium for insurance contract
- Wage salary
- Prior year incidence of exceeding consumer cost of insurance (premium and pharmacy copayments).

Beyond the age, gender, and income variables, additional information was included to provide a proxy for health risk, as well as prior consumption based the previous year's claims data. Specifically, the dollar amount of a person's excess expenditure beyond their own cost sharing contribution to the health plan was computed for the prior year (2004). The cost sharing contribution included premium price, copayments, deductibles, and coinsurance paid by the employee. In terms of insurance, a positive excess amount would be regarded as a medical loss greater than the insured contribution to the health plan. The expectation was that a patient with a history of health problems and a higher level of medical loss in the previous year would be likely to have high consumption in a second year. Also included in the model was whether or not the contract was for a Medicare recipient who would have prescription drug coverage provided by their employer as well as retiree designation, which could occur before the age of 65. The concurrent out-of-pocket premium was also included to provide a control for the generosity of the health plan benefit, which could influence the likelihood someone would get a less costly (in terms of reduced cost sharing) prescription, intended for misuse or diversion, from their physician.

The last part of the empirical modeling was a GLM regression model on the overall CS-PURE count. This approach accounts for the fact that a patient may use

multiple methods for drug misuse. Thus, a positive and significant coefficient would be associated with attributes of an individual likely to escalate drug misuse and diversion.

Results

Table 3 presents the period prevalence of the misuse metrics selected for analysis. One thing to note is the significant increase in the prevalence of multiple prescriber and multiple pharmacy algorithms compared to the 2004 article where they were first reported with a national sample of claims data. For example, in Table 1, the period prevalence for multiple prescribers was 0.21%. In Table 3, the prevalence has increased dramatically to 0.90%. Just over two percent (2.19%) of the population would be flagged for any CS-PURE. This is also a substantial increase since 2004 when the prevalence of any CS-PURE was 0.5%. With respect to the misuse metrics most identified by law enforcement as needing intervention, the prevalence ranged from 0.04% to 0.0089%. 0.04% of this employer's population would be 81 individuals a year that could face criminal charges for misuse or diversion.

Table 3 – Misuse Pattern Period Prevalence in Sample (N=202,791)

Variable Description	*Sample Mean*
CS-PURE	
Multiple Prescribers (6 or more prescribing physicians) for controlled substance in one year.	0.9024%
Multiple Pharmacies (4 or more) where controlled substances were received in one year.	1.6115%
Chronic Use (180+ days 4 or more grams), Stadol	0.0464%
Chronic Use (180 days), Demerol, Brand+generic	0.0207%
2+ concurrent scripts for Demerol w/day supply greater 2.	0.0089%
Any CS-PURE	2.19%
CS_PURE Count	0.03

Table 4 shows the results of the bivariate analysis. Of 202,791 continuously enrolled members, over 2%, or 4,431, have any indication of misuse indicated by CS-PURE metrics chosen for this analysis. Those who have a misuse flag are younger, are associated with a higher earning employee, and are less likely to be the contract holder. If not the contract holder, the insured would be the spouse or dependent of the contract holder. Those with less out-of-pocket payments are more likely to have a misuse flag. However, if the insured members have expenses greater than the amount paid for the insurance contract (including premium and copayments), they were more likely to have been flagged. This may be a cause for concern, as it suggests a serial pattern of fraud and misuse. It also could indicate someone in great pain from a chronic condition who relies on multiple pharmacies and prescribers. Even in the most generous cases, law enforcement officials found half of these flagged cases required intervention.

Table 4 – Attributes of Individuals with any CS-PURE

	Any CS-PURE Flag		No CS-PURE Flag		
Variable Description	*Sample Mean*	*Standard Deviation*	*Sample Mean*	*Standard Deviation*	*T-test*
Insured Chararacteristics	N=4,431		N=198,360		
Insured age in 2005	52.08	19.28	56.30	21.01	***
Age squared in 2005	3084.30	1897.92	3611.34	2132.14	***
Insured is female=1, male=0	62.5%	48.4%	62.0%	48.5%	
Wage Salary ('000s)	$42.57	$32.78	$40.54	$34.56	***
Insured is a primary contract holder=1, else 0	58.6%	49.3%	68.8%	46.3%	***
Medicare/retiree contract=1, else 0	26.0%	43.8%	37.5%	48.4%	***
Out of pocket insurance premium '05 ('000s)	$0.69	$1.54	$0.74	$1.47	*
Amount over loss ratio in '04 ('000s)	$5.62	$7.27	$2.24	$4.01	***

Statistical Significance

*** p<=.001, ** p<=.01, *P<=.05

Tables 5 and 6 display the logistic regression results of the attributes of a person associated with the two most prevalent misuse metrics. In both tables, the attributes' statistical significance and direction of effect on the probability of misuse are nearly identical. While age is positively associated with misuse, older members have a more negative relationship as indicated by age squared term. Gender and retiree status are not significant factors. Income is negatively associated with misuse for both metrics. Out-of-pocket premiums have a negative but statistically insignificant association with misuse. However, the dollar amount paid in the previous year for insured care beyond the consumer's purchase of the insurance contract that year is positively and significantly associated with misuse. If the insured person is genuinely misusing a controlled substance, this suggests a serial behavior and significant opportunity for intervention, given that they would have been caught by law enforcement if ex post methods were successful. If ex post methods are used successfully, this person would have been caught.

Table 5 – Logistic Regression Results- >=6 Prescribers

Variable	*Description*	*Coefficient*	*Standard Deviation*	*P-value*	*Odds Ratio*
Intercept		-4.858	0.1219	<.0001	
Insured age in 2005		0.064	0.0059	<.0001	1.066
Age squared in 2005		-0.001	0.0001	<.0001	0.999
Insured is female=1, male=0		-0.026	0.0493	0.60	0.975
Wage Salary ('000s)		-0.00203	0.000877	0.02	0.998
Insured is a primary contract=1, else 0		-0.5577	0.0516	<.0001	0.572
Medicare/retiree contract=1, else 0		0.1395	0.101	0.17	1.15
Out of pocket insurance premium '05 ('000s)		-0.0307	0.0175	0.08	0.97
Amount over loss ratio in '04 ('000s)		0.057	0.003	<.0001	1.059
Observations		202,791			

Table 6 – Logistic Regression Results- >=4 Pharmacies

Variable	*Description*	*Coefficient*	*Standard Deviation*	*P-value*	*Odds Ratio*
Intercept		-4.430	0.0997	<.0001	
Insured age in 2005		0.033	0.0042	<.0001	1.034
Age squared in 2005		0.000	0.0001	<.0001	1.000
Insured is female=1, male=0		0.111	0.0376	0.00	1.117
Wage Salary ('000s)		-0.0035	0.000678	<.0001	0.997
Insured is a primary contract=1, else 0		-0.3133	0.0397	<.0001	0.731
Medicare/retiree contract=1, else 0		-0.0829	0.071	0.24	0.92
Out of pocket insurance premium '05 ('000s)		0.00159	0.0124	0.90	1.002
Amount over loss ratio in '04 ('000s)		0.087	0.003	<.0001	1.091
Observations		202,791			

Table 7 reports the results of a GLM regression to show the attributes most associated with multiple instances of misuse. This model shows more significant relationships with potential fraud/misuse than the metric focused logistic regressions. Age remains a significant factor where older, but not too much older, insured individuals are more likely to misuse. There is now a significant and positive relationship associated with a female contract holder. One of the strongest negative relationships is associated with non-primary contract holders. This makes sense because the consequence of being discovered misusing drugs would mean more to an employee; they could face job termination if caught. The consequences for a spouse or dependent are less direct and explain the negative relationship with primary contract holders. Income remains a negative factor. The loss ratio metric, however, is quite significant and positive.

Table 7 – GLM Regression – CS-PURE Count

Variable	*Description*	*Coefficient*	*Standard Deviation*	*T-Stat*
Intercept		0.021448	0.002114	10.15
Insured age in 2005		0.000533	0.000085	6.30
Age squared in 2005		-0.000009	0.000001	-9.04
Insured is female=1, male=0		0.003191	0.000837	3.81

Discussion

There are several original findings from this analysis. With respect to identifying patterns that could be used for ex ante regulation of controlled substance misuse, the analysis suggests that those likely to misuse are older (but not very much older), low wage earners, women, not the primary insurance contract holder, and are expending more than the actuarial fair value of an insurance contract. The analysis also indicates that the overall period prevalence for abuse may have increased from 2002 to 2005. Although it is only a first step in developing a predictive model for an ex ante screening algorithm, the results show there are some person level attributes that could be strong factors for consideration in designing and implementing a regulatory mechanism.

From a litigation and regulatory perspective, this analysis demonstrates the potential of an ex ante approach that could go beyond programs like Kentucky's KASPER. This analysis demonstrates that the ex ante approach needs to do more than simply monitor prescriptions out the door. It would need to actually assemble person level profiles of drug utilization and update them in real time. While this would appear to be an aggressive step, it does have precedent in retail sector fraud detection and prevention systems used by the banking and credit card industries. In those systems, multiple data sources at the consumer level are combined and analyzed at the point of sale to suggest an apparent pattern, and to restrict a retail transaction such as the purchase of a flat panel TV at a discount electronics store. Many consumers experience this system when they travel out-of-state, use their credit cards to buy gas more than 500 miles away, and receive challenge questions for their zip code. Likewise, a consumer may be denied until completing a phone call with the credit card company when buying

an extraordinary retail purchase. The technology exists, and this sort of ex ante regulatory mechanism could be used for controlled substances misuse prevention. A likely obstacle will be privacy advocates. However, a small pilot using credit and debit card purchases of controlled substances could be undertaken using the existing fraud and abuse infrastructure as a regulatory precedent.

The analysis has three limitations. First, the sample used – while large and located in several U.S. states – is not sufficiently large enough for a comprehensive analysis. This could be addressed with a larger sample from an insurer. However, the insurer will not necessarily have the wage information or the contract information that was helpful in identifying a patient level attribute of potential misuse. A second limitation is that the false positive misuse-flagging rate for the two most common metrics is 50%. While better than nothing, it suggests that a completely automated ex ante system would require refinement. Our more specific metrics with 100% law enforcement agreement had relatively low prevalence, but would need to be re-tested to make sure the accuracy of the metric has not degraded since 2004. A final limitation is that the algorithms could potentially be out of date, since they are based on older national drug codes. However, the therapeutic class based algorithms should be accurate for the more specific metrics. Also, not expanding the algorithms to include new prescribed medications/controlled substances on sale since 2004 could constitute a more conservative metric of misuse.

New electronic health records systems could offer even more opportunities for ex ante regulatory mechanisms. Electronic health record interoperability has tremendous potential to coordinate data systems, create more robust misuse surveillance systems, and

could substantially lower detection costs.[viii] The current CS-PUREs have substantially lower costs to identify cases with otherwise labor intensive police detective work through the ex post and litigation mechanisms. Interoperability allows for corroborating the validity of online and automated transactions from multiple data sources for any given patient in real or near real time. Interoperability and a demand for cross-entity standardization of codes, data structures, and terminologies may be the key to creating the necessary incentive for better care practices, including controlled substance mitigation.

A critical issue to consider is the cost for identification and lack of intervention. Following the publication of the CS-PUREs in 2004, the manufacturer of an oxy-codeine product encouraged the use of the algorithms to mitigate misuse. The response from health plans was initially positive in 2005 and 2006. Subsequently, the health plans' implementation of the metrics have been challenged by some of the health plans' legal counsel about the consequences of identifying, but not intervening, and possibly being found negligent if an adverse event tied to misuse occurred. If this is indeed a threat to the use of these algorithms, there needs to be some regulatory protection for public and private insurers to detect, monitor, and develop (but not yet deploy) cost-effective strategies, possibly in consultation and open communication with law enforcement. If such a compact was developed, the best of the litigation and regulatory approaches could be combined to address this societal problem.

[viii] Brushwood, DB. Maximizing the Value of Electronic Prescription Monitoring Programs. *The Journal of Law, Medicine & Ethics* Volume 31 Issue 1, Pages 41 – 54, Published Online: 24 Jan 2007.

Conclusion

This paper demonstrates the potential of a regulatory mechanism that could be used on an ex ante basis to detect drug misuse for future intervention by law enforcement officials. An analysis from a large employer shows the scope of the problem as well as the opportunity. The cost of insurance claims and e-prescribing surveillance is modest compared to the human capital expense of detection. Effective intervention continues to carry a substantial cost for controlled substance misuse. The opportunity to direct resources toward addressing problems from using electronic data can help better utilize limited resources for a greater societal benefit.

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