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United States Medicaid and Pharmacy Fraud: An Unintended Consequence of the Affordable Care Act

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UNITED STATES MEDICAID AND PHARMACY FRAUD: AN UNINTENDED CONSEQUENCE OF THE AFFORDABLE CARE ACT

ABSTRACT

Introduction: The Affordable Care Act (ACA) increased access to health insurance throughout the United States. To date, an estimated 20 million previously uninsured individuals have gained access to coverage since the expansion. As a result, the number of fraudulent schemes reported has been on the rise. Among the many fraudulent activities in the healthcare sector, abuse of pharmacy benefits has been the most prevalent. The misuse and abuse of opioids, and opioid related overdoses has created a widespread epidemic throughout the country, thus extending opportunities for potential fraud within the pharmaceutical industry.

Purpose of the Study: The purpose of the study was to determine if healthcare fraud has increased as an unintended consequence of ACA. Operating with the assumption that with greater access could have created an unintended incentive and greater opportunities for fraud. The focus was on provider and pharmacy fraud because they are the principal gatekeepers that control access to the supply that manufacturers must meet.

Methodology: The methodology for this qualitative study utilized a literature review. Eight databases were used to collect 1427 articles, studies, or abstracts. These sources were reviewed and reduced to 39 sources which were included in the written research. Of these, 20 were used in the results section.

Results: The results indicated that along with the expansion of Medicaid, outpatient prescriptions from Medicaid patients had risen. In order to deal with the influx of participants, a variety of changes in Medicaid programs have been considered or enacted to respond to the challenges arising.

Discussion/ Conclusion: The research illustrated that both Medicaid fraud and opioid misuse has become more prevalent since the enactment of the ACA by providers and patients. Fraud, as well as opioid misuse and abuse in Medicaid has cost states billions of dollars each year. Moreover, there has been a concerted effort to increase vigilance in preventing drug diversion and fraud. *Key Words:* Medicaid, Centers for Medicare and Medicaid Services (CMS), opioid, pharmacy, prescriptions, prescribers, Affordable Healthcare Act (ACA).

INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) has defined fraud as the intentional act of providing false information in order to get Medicaid to pay for those seeking medical care or other services (CMS, 2016). According to the National Healthcare Anti-Fraud Association (NHCAA) estimated that the financial losses due to health care fraud were in the tens of billions of dollars. Each year conservative estimates 3% of total healthcare expenditures while other law enforcement places the loss as high as 10% which could mean more than 300 billion (2018). While efforts have been provided to help prevent Medicaid and Medicare fraud from occurring, there was difficulty in confining the problem due to both patients, and healthcare organizations contributing to the issue of fraudulent crimes (Morris, 2009). The difficulty of addressing fraudulent activity became even more complicated as the implications of the Affordable Care Act were being implemented in 2010 (Rice, Thomas; Unruh, Lynn; Rosenau, Pauline; Barnes, Andrew et al. 2014). As Rosenbaum and Westmoreland (2012) assessed an important case the National Federation of Independent Business v. Sebelius, the US Supreme Court upheld the constitutionality of the requirement that all Americans have affordable health insurance coverage. But in an unprecedented move, seven justices first declared the mandatory Medicaid eligibility expansion unconstitutional. The decision enabled States to decide whether to

participate in Medicaid expansion in coordination with statutes within the Affordable Care Act (ACA) without losing federally matched dollars.

Medicaid expansion was a byproduct of the ACA; as a result 37 states and the district of Columbia opted to participate conversely 14 did not. (Kaiser Family Foundation, 2019). According to Medicaid and CHIP Payment and Access Commission (MACPAC) (2019) enrollment in Medicaid expansion states has increased by 13.1 million or 34.4 %; 21 of these states reported increases in enrollment of at least 25 percent. Also, according to Young (2019) in Kaiser Permanente from 2014 to 2017 increases in Medicaid outpatient prescriptions increased from 621.7 million to 752.9 million that corresponded to 45.9 billion to 63.6 billion in medical expenditures. Normal forms of pharmacy fraud have included: automatic refill fraud, pharmaceutical benefits manager fraud, illegal kickbacks, manufacturer price or, drug switching, and drug off-label marketing (Berger and Montague, 2019). Another scam according to a government organization funded by the DHHR and Administration for Community living (ACL) the Senior Medicare Patrol National Resource Center (2020): explained how fraudulent pharmacies may fill a partial month's drug supply and ask the beneficiary to come back for the rest. The pharmacist then billed Medicaid twice in one month for the full amount. An example of fraudulent pharmacy billing: NY Attorney General Letitia James alleged; a Long Island pharmacy owner ran a multi-million dollar Medicaid scam, in which they convinced poor patients with HIV and AIDS to sell back their medications (NY AG, 2019). The patients were paid usually between 50 to 100 dollars then Medicaid reimbursed the store for filling the expensive prescriptions and then the store would then put the drugs back on its shelves (Annese, 2019). Although there has been a concerted effort by many States, Counties and individuals to confront large pharmaceutical manufacturers such as Purdue Pharma. Purdue Pharma developed

the opioid OxyContin and was a creator of aggressive models of drug marketing (Zee, 2009). Purdue Pharma has long been blamed for setting off what became the opioid epidemic. (Walsh, 2019) As a consequence it has offered to settle 2000 claims for 10-12 billion dollars and has subsequently filed for chapter 11 bankruptcy, because it was bleeding revenue through expensive litigation and a tarnished reputation (Walsh, 2019). Drug diversion occurred when a prescription drug was taken out of the normal chain of commerce and diverted for sale or use in some illegal activity. (Senior Medicare Patrol National Resource Center, 2020) The misuse and abuse of opioids, and opioid related overdoses has created a widespread epidemic throughout the country, thus extending opportunities for potential fraud within the pharmaceutical industry (Ghate, Haroutiunian, Winslow, and Mcadam-Marx, 2010). In fact, the opioid drug problem has reached crisis levels in the United States. Over 50,000 Americans died of a drug overdose in 2015, of which 63 percent (33,091) reportedly involved opioids.(Council of Economic Advisors, 2017). Drug seeking patients' use of multiple prescribers has presented difficult issues for their physicians, who must navigate changing dosages and potentially risky drug interactions, while also providing compassionate care and working to manage chronic pain (Katz, 2016). Strategies have been placed in order to help decrease the probability of "doctor shopping," which involved a number of Medicaid patients visiting multiple physicians to procure prescriptions (Lineberry and Bostwick, 2004).

Programs such as Medicaid Lock-In Programs (MLIPs) have responded to this type of fraud and are designed to prevent the overutilization of controlled substances committed by Medicaid patients (Skinner, Ringwalt, Naumann, Roberts, Moss, Sachdeva, Farley, 2016). MLIPs have used payment records to identify any suspicious activity regarding a patients' prescription patterns. Therefore, this has allowed Medicaid (or another payer) from paying for

opioid prescriptions for those individuals, unless the prescription comes from a designated physician and pharmacist (Gertner, 2018). Other methods of prevention will be evaluated and verified as technology progresses.

The purpose of the study was to determine if healthcare fraud has increased as an unintended consequence of ACA. Operating with the assumption that with greater access could have created an unintended incentive and greater opportunities for fraud. The focus was on provider and pharmacy fraud because they are the principal gatekeepers that control access to the supply that manufacturers must meet.

METHODOLOGY

The primary hypothesis of this research study was there has been an increase in fraud among the pharmaceutical industry both locally, and nationally specifically pharmacies within the US due to the enactment of the ACA. The secondary hypothesis of this research study was there has been a widespread misuse of prescription opioids by pharmacies due to greater access and participation in Medicaid expansion programs which has enabled criminal fraud activity.

The conceptual framework for this study was based on finding the common ways to commit pharmacy fraud and the impact of the ACA unintentionally had on expanding pharmacy fraud. Following the common types of pharmacy fraud and how the change in regulations in the ACA this study used steps from Joshua Pirestani the president of the American Pharmacy Purchasing Alliance (APPA,2019). Also used by this study to help create the framework was the outline of the Department of Justice Office of Public Affairs false claims cases (Department of Justice Office of Public Affairs, 2018). A focus of this study was to understand and create preventive measures against pharmaceutical Medicaid fraud. As seen with Figure 1 from the expansion ACA leading to unintentional increase opportunities in Medicaid fraud, leading to

both provider fraud and our focus pharmacy fraud, ending with increased revenue for the pharmaceutical companies.

(INSERT CONCEPTUAL FRAMEWORK FIGURE 1)

This study's methodology was a secondarily sourced literature review and case study research with semi-structured interview of an expert in the field of healthcare. The study was created to find with the intention to answer the question of could the expansion of the ACA create more Medicaid fraud. Also, there was a structured interview portion of the study that used 10 open ended questions for experts (1-5) in the healthcare field. Due to the COVID-19 pandemic the interview was unable to be conducted due to the prospective interviewees being overwhelmed with increased workload due to the pandemic. The inclusion criteria was based on geographic location and access to healthcare professionals within the Marshall Health system or Public Health connected with DHHR or equivalent State agency would be considered an expert. This study of both literature and cases used multiple search engines. EBSCOHOST, PubMed, Academic Search Premier, Business Source Premier which were connected to Marshall University's search catalog. Bing, Google and Google scholar and Science Direct were also used to review scholarly literature. The key words used for the search were "Medicaid", "Fraud" OR "CMS", AND "Opioid", "Pharmacy" OR "Prescriptions" OR "Prescribers", AND "Affordable Healthcare Act." All sources were from the years 2005-2020 using English in sources searched. The literature search was conducted by SM and DB; and validated by AC who confirmed the criteria of the references of the research study. Having applied the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) method, the search identified 1459 relevant citations. Articles were excluded (N=1427) if they did not meet inclusion principles. Articles were included (N=21) if they described fraud in the pharmaceutical industry within the United

States: articles from other sources (N=39) were also included in this search. These 39 references were subject to full-text review, and these citations were included in the data abstraction and analysis. Only 20 references were used in the results section (see Prisma figure) (Moher, Liberati, Tetzlaff, & Altman, 2009).

RESULTS

In order to deal with the influx of participants on State managed programs they have considered or have enacted a variety of changes in their Medicaid programs to respond to the challenges arising from increased demand for higher costs of prescription drugs. According to the National Conference of State Legislatures (2018) state legislation related to Medicaid prescription drugs generally was designed around new or expanded applications of management tools already available to States through federal law. Among the strategies receiving legislative attention have been use of prior authorization lists, pharmacy benefit managers, utilization reviews, in coordination with third party providers to review policy and procedures .According to Maclean, Cook, Carson, Pesko (2018) At the National Bureau of Economic Research reported that postexpansion the number of Medicaid-financed psychotropic prescriptions increased by 22.3% in expanding states relative to non-expanding states. (Insert Expansion versus Non expansion graph) As a result of the increased participation in Medicaid there has been a concerted effort to increase vigilance in preventing drug diversion and fraud. One study suggested decision support to help prevent doctor shopping. The overall correct classification rate of the decision tree was 95.3%, with a 2.4% false positive rate and 4.0% false negative rate for lock-in versus prescriberalert letter recommendations. When a Medicaid recipient received prescriptions for controlled substances at 8 or more pharmacies, the likelihood of a lock-in recommendation is 90% (Mailloux, Cummings, and Mrinal, 2010). Also related to pharmacy fraud in which investigators

found settlements with pharmacy chains accounted for \$221 million and 6 cases. Three cases resolved allegations of switching prescriptions for Medicaid beneficiaries to more expensive capsule (vs tablet) formulations or billing for pharmaceuticals not received by patients. (Oureshi, Liu, Sartor, Oliver et al, 2011). Also, according to an OIG analysis from FY 2018 Civil settlements and Judgements pharmaceutical manufacturers had the most with 217 cases and with the second most retail and institutional wholesale pharmacies had the second most cases with 101 cases. (insert table and chart from Appendix). Because drug diversions typically involved both provider and pharmacies as source suppliers investigators thought it wise to show an increased trend as well. According to the Office of Inspector General of HHS annual report (2017) showed drug diversion and convictions had increased in 2015, 117 convictions with 4.4 million in recovery to 191 convictions with 28.4 million in recovery in 2017. Subsequent findings from a recent OIG analysis of Annual Statistical Reports (2018) convictions from drug diversion cases has continued to increase from 117 in the year 2015 to 199 in the year 2018. (Insert Graph Drug Diversion). Along the same lines of evidence according to the latest data from DOJ (2018) there has been a steady increase of arrests in relation to national healthcare fraud and opioid take down trends in May 2014, 90 defendants were charged with a loss amount of 260 million in June of 2018 there was 601 defendants with a loss amount of 2 billion. Clearly from this data there has been a substantial increase of arrests during that 4-year period in which there was nearly a 7-fold increase in arrests connected with healthcare fraud and opiate abuse. (Insert DOJ Chart 2018). Also, the impact on children and adolescents due to the opiate epidemic was devastating according to a study by Suzanne Brundage, Adam Fifield and Lee Partridge with the United Hospital Fund and Boston Consulting Group (2019) group estimated 2.2 million

children and adolescents in crisis as of 2017 28 out of 1,000. If current trends hold an estimated 4.3 by 2030 with a cumulative cost of 400 billion in additional spending and healthcare costs.

According to HHS OIG (2018), the Medicaid Fraud Control Units (MFCUs) has investigated and prosecuted Medicaid provider fraud as well as patient abuse or neglect in health care facilities. An objective measure was needed that used consistent data across time and relative to State statistics and that objective measure was found to be in the number of investigations. The annual report was broken down into fraud and abuse and neglect only fraud was used. The authors of the study created a chart in which the data was compiled from the Medicaid Fraud Control units (MFCU) annual reports from the years 2010 to 2018. A regional comparison was chosen as an indicator of healthcare fraud 3 States were selected as Medicaid expansion: West Virginia, Ohio, Kentucky and 3 were selected as non-expansion States Virginia, North Carolina, South Carolina due to the geographic location and because of media reports (Campbell, Robertson The New York Times, 2018; Knisely Amelia Ferrell, Charleston Gazette, 2019) labeling increased activity "the opiate epidemic". The fraud investigations tab on the MCFU chart were compiled and compared for trends (Insert data and chart). In Ohio from 2010 there were 457 investigations by 2018 there were 867 by comparison in Virginia in 2010 246 investigations in 2018 there were 385. In Ohio the investigations doubled. Although each State was unique in demographics there was a dramatic difference in investigations. The trends showed an increase of investigations in expansion States compared to non-expansion States. After looking at the various trends of greater pharmaceutical expenditures increases, and subsequent law enforcement tracked with fraudulent activity in Medicaid expansion States.

DISCUSSION

The purpose of this study was to analyze the Medicaid fraud schemes committed in association with the pharmacies affected local versus national patients, as a consequence of the Affordable Care Act. It was also wanted to understand if there were ways to prevent future fraud from occurring by understanding the policies and the opportunities given in the Affordable Care Act. *Findings*

From the research we have conducted that Medicaid fraud has increased since the enactment of the Affordable Care Act, not only has it increased, but the specifically how much pharmaceutical industries had benefited and affected patients in a negative way. Focusing on Ohio, a brief from the Office of Inspector General stated that Ohioans received high amounts of opioids and were not a cancer or hospice patient (HHS 2018). Though this may not be fraud or abuse, it has however the foundation upon providers and patients have used to create fraud and abuse. Guidelines were put in place to curb the opioid abuse and over prescribing, but since the Affordable Care Act opioid abuse and over prescription has increased (Cher, Morden, and Meara 2019). Medicaid Part D claims increased from 2010 to 2016, mostly being prescribed opioids and prescribers who wrote those orders were significantly more likely to continue to prescribe those opioids than their peers (HHS 2018).

The Medicaid expansion promoted a growth in over prescription which then leads to opioid abuse, that created a cycle of continued over prescription and more opioid abuse. Though at the same time drugs used to treat opioid abuse also rose and actually overtook the growth rate of opioid prescription (Cher et al, 2019). The only real beneficiaries that could be found in all of this expansion was actually the pharmaceutical industry. They created the drugs used in both the opioid crisis and the treatment of the crisis. The Medicaid expansion helped break financial barriers for opioid treatment medication (Wen, Hockenberry, Borders, and Druss, 2017).

Limitations

A limitation of this study was the need to conduct further research in order to obtain more information on Medicaid fraud, specifically over a longer period of time after the enactment of the ACA (i.e. longer than ten years). The vast majority of information obtained in this study has come from the 2010-2019 time period, not allowing further information on the long-term impacts of the ACA Medicaid fraud and the adjustments made. Due to the COVID-19 pandemic the planned interview was unable to happen due to increased strain on the healthcare system and inability to receive any further correspondence with prospective interviewees. Additionally, the cases that have been used have mostly been limited to local and smaller states that normally have poorer quality of care, which could easily skew the data when compared to larger states and economies. Furthermore, this study was limited to a search of only 8 databases. As such, findings are subjected to potential publication bias. Lastly, due to the substantial presence of opioid misuse and abuse in the area where members of this group are located, research bias could be introduced.

Practical Implications

The practical implications of this literature review could have been used when the legislature was first formed the rules and laws surrounding Medicaid expansion and the pharmaceutical corporations. Having applied our review to future laws and regulations the legislature can commit more resources to the Medicaid Fraud Units and have stricter laws on opioid pharmaceutical corporations. With the data found, it can be used to help reduce the cost of Medicaid fraud and the abuse of opioids.

CONCLUSION

The primary hypothesis of this research study was there has been an increase in fraud among the pharmaceutical industry both locally, and nationally specifically pharmacies within the US due to the enactment of the ACA. The secondary hypothesis of this research study was there has been a widespread misuse of prescription opioids by pharmacies due to greater access and participation in Medicaid expansion programs which has enabled criminal fraud activity. The research illustrated that both Medicaid fraud and opioid misuse has become more prevalent since the enactment of the ACA by providers and patients. Moreover, there has been a concerted effort to increase vigilance in preventing drug diversion and fraud.

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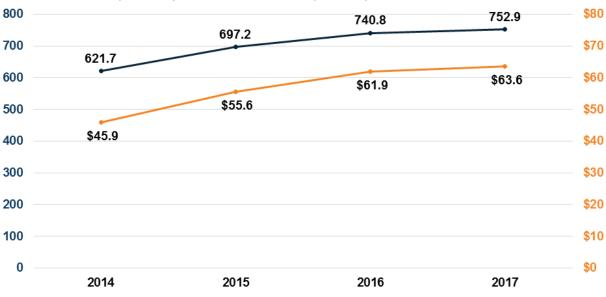
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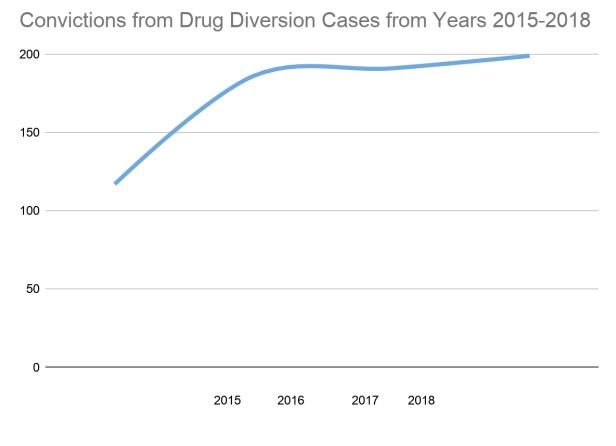
APPENDIX Figure 1 Trend in Number and Spending for Medicaid Outpatient Prescriptions, 2014-2017 Total Number of Prescriptions Medicaid Paid Amount for Prescriptions (in millions) 800 700 607.2 740.8 752.9 601.9 \$63.6



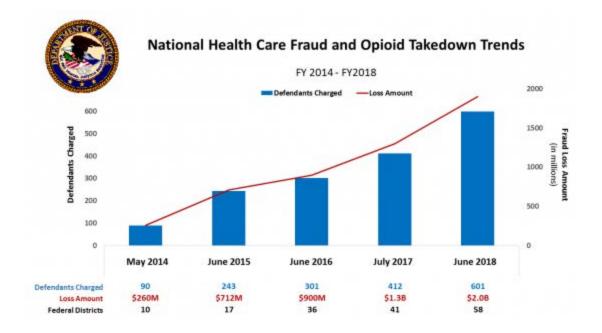
Note: Spending amounts do not include rebates.

Sources: Kaiser Family Foundation analysis of 2014-2017 State Drug Utilization Data; Wolters Kluwer Clinical Drug Information, Inc., 2018.

KFF



Source: OIG analysis of Annual Statical Reports form 2015-2018 https://oig.hhs.gov/oei/reports/oei-09-19-00230.pdf

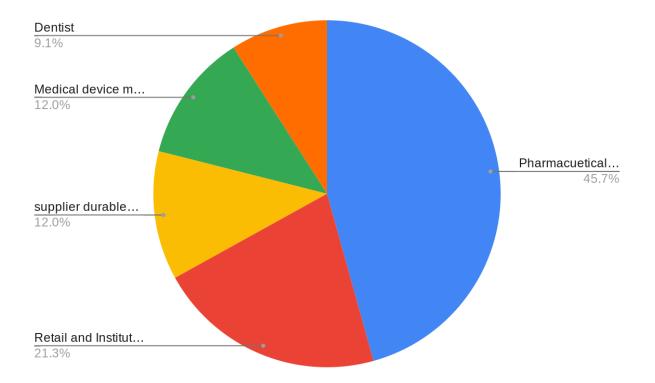


Source: OIG (2018)

Civil Settlements and Judgements FY 2018

Pharmaceutical Manufacturers	217
Retail and Whole Sale Pharmacies	101
Supplier Durable Equipment	57
Medical Device Manufacturer	57
Dentists	43

Source: OIG analysis of 2018 Annual Statistics Report

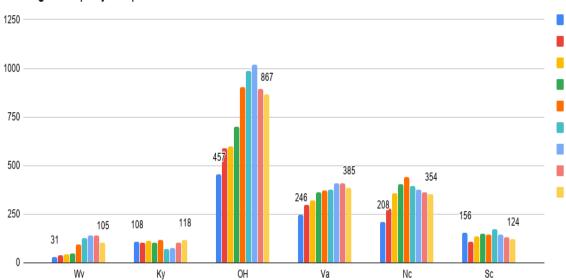


Fraud Investigations per State per Year

	2010	2011	2012	2013	2014	2015	2016	2017	2018
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WV	31	37	45	49	96	128	143	142	105
KY	108	104	114	104	118	72	77	105	118
ОН	457	587	600	701	903	986	1017	894	867
VA	246	296	319	363	373	378	409	408	385
NC	208	280	357	402	439	397	378	362	354
SC	156	107	138	151	146	172	146	130	124

Data was compiled from the MFCU's (Medicaid Fraud Control Unit) annual report from years 2010-2018.



Investigations per year per State 2010-2018

Research Framework

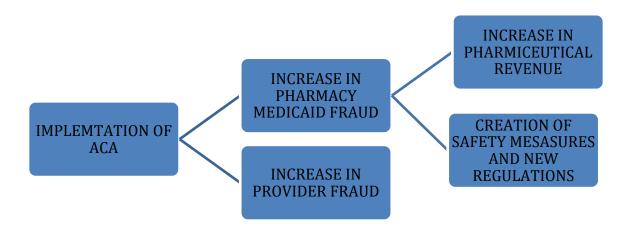
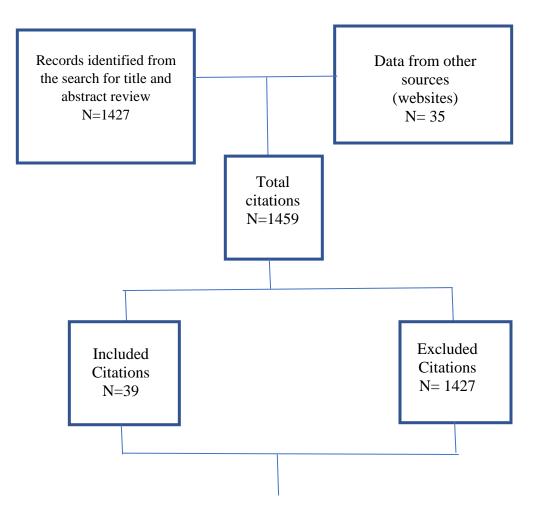
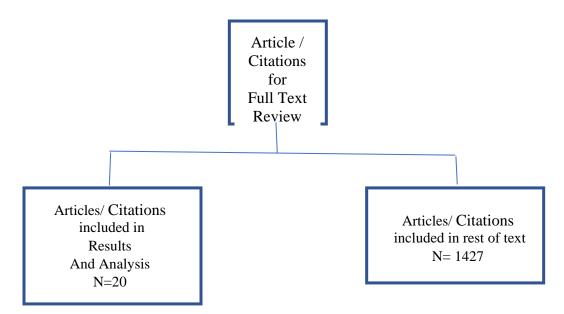


Figure 1 Research Framework adapted from Pirestani, 2017 and Department of Justice Office of Public Affairs, 2018

Overview of Literature Evaluation





Overview of Literature Evaluation adapted from Moher, Liberati, Tetzlaff, Altman, The

PRISMA Group (2009) For more information, visit www.prisma-statement.org

Semi-structured Interview Questions

1. How has the ACA directly affected the amount of fraud seen in WV?

2. What are some recent Medicaid fraud preventive measures that have worked?

3. What are some Medicaid fraud preventive measures that have not worked and impacted access to care?

4. In your opinion could more third person audits of prescription drugs help or hurt Medicaid fraud and access to care?

5. What do you believe should be done to help create safer access to care and less Medicaid fraud through pharmacies?

6. What can Pharmacies workers do to help prevent pharmacy Medicaid Fraud?

7. Can direct intervention by the state or federal government help prevent pharmacy Medicaid Fraud?

8. Could more regulations on the Pharmaceutical companies help reduce Medicaid Fraud?

9. Is there any easy common-sense regulations that should be enacted?

10. Are chain pharmacies less likely to commit Medicaid fraud?