

Follow the Money: Pharmaceutical Manufacturer Payments and Opioid Prescribing Patterns in New York State





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## **Key Findings**

- More than \$3.5 million in opioid-related payments were made to physicians in New York State by pharmaceutical companies; about one in ten physicians who prescribed opioids to Medicare patients received a payment.
- Physicians who received payments from opioid manufacturers prescribed more opioids to Medicare patients than physicians who did not receive any opioid-related payments.
- Moreover, a higher number of opioid prescriptions was associated with more opioid-related payments to physicians.
- Opioid-related payments from industry were concentrated within a small proportion of physicians, who tended to prescribe a large quantity of opioids. The top 1% of physicians in New York, in terms of the amount received in opioid-related payments, received more than 80% of total payments.
- Opioid-related payments may lead to an increase in opioid prescribing, based on comparisons with a matched group of similar physicians who did not receive any opioidrelated payments.
- While these results cannot determine the appropriateness of opioid prescribing, they add to a growing body of research raising concerns about potential conflicts of interest resulting from certain physician and industry financial relationships. Further monitoring of physician-industry relationships is needed and additional limitations on them should be considered.



## Background

#### THE OPIOID CRISIS IN NEW YORK STATE

Opioid misuse is a public health crisis for the nation and New York State. In 2016, there were 3,009 deaths resulting from opioid overdose in New York State, nearly a 40% increase from 2015.<sup>1</sup> Opioids were involved in about 80% of all drug overdose deaths in 2016.<sup>2</sup> According to a recent survey, nearly one in four New Yorkers knows a family member, friend, or acquaintance that has died from an opioid overdose.<sup>3</sup>

The epidemic is fueled by both lawful and illicitly obtained opioids. Nearly 9 million opioid prescriptions were dispensed in New York State in 2016.<sup>4</sup> While that figure has actually been declining in recent years, prescription opioids still accounted for more than one-third of deaths involving opioids in 2016 (1,100).<sup>5</sup>

#### POTENTIAL CONFLICTS OF INTEREST BETWEEN PHYSICIANS AND OPIOID MANUFACTURERS

This brief investigates how payments from opioid manufacturers to physicians may have influenced opioid prescribing in New York State. Financial relationships between physicians and drug manufacturers are common. They can include payments to physicians for services such as speaking or consulting fees, as well as various gifts such as meals. They can have positive outcomes, including improving physicians' education about new drugs. However, these financial relationships may also create conflicts of interest, blurring the lines between promotional activities and medical practice. Several studies have found that interactions with pharmaceutical representatives, even when involving small payments of less than \$20 in value, were associated with increased prescriptions for promoted medications.<sup>6,7</sup>

<sup>&</sup>lt;sup>1</sup> Seth P, Scholl L, Rudd RA, Bacon S. Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants — United States, 2015–2016. MMWR Morb Mortal Wkly Rep 2018;67:349–358. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm6712a1</u>

<sup>&</sup>lt;sup>2</sup> NCHS, National Vital Statistics System, Mortality. <u>https://www.cdc.gov/nchs/products/databriefs/db294.htm</u>.

<sup>&</sup>lt;sup>3</sup> Siena College. 2018. 54% of NY'ers Personally Touched by Opioid Abuse. <u>https://www2.siena.edu/news-events/</u> article/54-of-nyers-personally-touched-by-opioid-abuse.

<sup>&</sup>lt;sup>4</sup> New York State Department of Health. Opioid analgesic prescription rate per 1,000 population. <u>https://www.health.</u> <u>ny.gov/statistics/opioid/data/p22.htm</u>.

<sup>&</sup>lt;sup>5</sup> Seth P, Scholl L, Rudd RA, Bacon S. Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants — United States, 2015–2016. MMWR Morb Mortal Wkly Rep 2018;67:349–358. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm6712a1</u>.

<sup>&</sup>lt;sup>6</sup> Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA. 2000;283(3):373-80.

<sup>&</sup>lt;sup>7</sup> DeJong, C., Aguilar, T., Tseng, C. W., Lin, G. A., Boscardin, W. J., & Dudley, R. A. (2016). Pharmaceutical industrysponsored meals and physician prescribing patterns for Medicare beneficiaries. *JAMA internal medicine*, 176(8), 1114-1122. <u>https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2528290/</u>.



## Background (continued)

#### **ATTEMPTS TO MONITOR AND LIMIT PHYSICIAN-INDUSTRY RELATIONSHIPS**

Concerns over conflicts of interest have led to a number of efforts regulating physicianindustry financial relationships, some of which originated within the health care industry. According to a survey by SK&A, 40.3% of physicians in New York have essentially selfimposed regulations, designating themselves as "no access" to visits from pharmaceutical representatives as of August 2017.<sup>8</sup> Several health systems in New York, such as Mount Sinai and New York Medical College, have imposed limitations on industry gifts allowed to physicians, as well as on industry representatives' access to facilities.<sup>9</sup> In addition, medical associations including the American Medical Association, as well as the Pharmaceutical Research and Manufacturers of America (PhRMA), have adopted codes of conduct regarding physician-industry relationships.<sup>10,11</sup>

States have also taken the initiative to require disclosure of certain financial relationships.<sup>12</sup> In 2010, the Physician Payments Sunshine Act (PPSA) was passed along with the Patient Protection and Affordable Care Act to expand and standardize such efforts nationwide. PPSA mandates the reporting of payments or items of value received by physicians from drug, medical device, and biological agent manufacturers. Any payments or items of value greater than \$10, or \$100 in aggregate over a yearly basis, must be reported, with few exceptions (e.g., educational materials for patients). In addition to payments, ownership and investment interests in manufacturers held by physicians or their immediate family members must be reported, along with payments from industry supporting certain research. Penalties are imposed for failure to meet these reporting requirements. Reporting obligations began in 2013, with annual updates required.

The Centers for Medicare & Medicaid Services (CMS) makes the information required for reporting by PPSA available to the public as part of the Open Payments program.<sup>13</sup> On the Open Payments databases, all payments are tagged with the manufacturer and the

- <sup>10</sup> American Medical Association. AMA Code of Medical Ethics. <u>https://www.ama-assn.org/delivering-care/ama-code-medical-ethics</u>.
- <sup>11</sup> Pharmaceutical Research and Manufacturers of America. Code on Interactions With Health Care Professionals. <u>https://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals.</u>
- <sup>12</sup> Yeh, J. S., Franklin, J. M., Avorn, J., Landon, J., & Kesselheim, A. S. (2016). Association of industry payments to physicians with the prescribing of brand-name statins in Massachusetts. JAMA internal medicine, 176(6), 763-768.
- <sup>13</sup> Centers for Medicare & Medicaid Services. Open Payments. <u>https://www.cms.gov/openpayments/</u>.

<sup>&</sup>lt;sup>8</sup> SK&A. 2017. Commercial Access to Physicians Medical Industry Sales Reps Accessibility to U.S. Physicians. <u>http://www.skainfo.com/reports/access-to-physicians</u>. New York data provided by SK&A through special request.

<sup>&</sup>lt;sup>9</sup> Larkin I, Ang D, Steinhart J, et al. Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing. JAMA. 2017;317(17):1785–1795.



## Background (continued)

specific drug involved in the activity leading to the payment. Thus, it is possible to use the data to identify how much money individual physicians have received from specific drug manufacturers that were associated with specific drugs.

#### WHAT THIS STUDY DOES

Several studies have used data from Open Payments and information on drug utilization for the Medicare population to explore associations between physician-industry financial relationships and physician prescribing patterns of marketed drugs.<sup>14,15</sup> These studies have largely been national in scope, and have spanned various drugs and physician specialties. A consistent finding is that more payments are associated with higher prescribing.

A recent analysis by CNN and Harvard researchers focused on opioid prescribing and payments to physicians from opioid manufacturers. This analysis also found that higher payments from industry are associated with more prescribing.<sup>16</sup> Researchers at Boston Medical Center published similar national findings last month.<sup>17</sup> However, none of these studies have been able to distinguish whether industry payments lead to increased prescribing of promoted drugs, or if physicians who prescribe more promoted drugs are more likely to be targeted by industry for promotion and education activities.

The analyses presented in this brief also make use of the Open Payments and Medicare drug utilization data, but focus on the link between payments to physicians by manufacturers for an activity related to an opioid (termed opioid-related payments) and opioid prescribing in New York State. This report also aims to provide insight regarding the possible *effects* of opioid-related payments. In order to do this, the expenditures for opioid prescriptions filled (including refills) are compared between physicians who received opioid-related payments and a comparison group of similar physicians who did not receive such payments. Expenditures encompass the total amount paid for all associated claims, including by Medicare, the patient, and any other third party. Expenditures, as opposed to prescriptions dispensed, are used

<sup>&</sup>lt;sup>14</sup> Perlis, R. H., & Perlis, C. S. (2016). Physician payments from industry are associated with greater Medicare Part D prescribing costs. *PloS one*, 11(5), e0155474. Available at: <u>http://journals.plos.org/plosone/article?id=10.1371/journal.</u> <u>pone.0155474.</u>

<sup>&</sup>lt;sup>15</sup> Fleischman, W., Agrawal, S., King, M., Venkatesh, A. K., Krumholz, H. M., McKee, D., ... & Ross, J. S. (2016). Association between payments from manufacturers of pharmaceuticals to physicians and regional prescribing: cross sectional ecological study. *BMJ*, 354, i4189.

<sup>&</sup>lt;sup>16</sup> Kessler, A, Cohen, E, and Grise, G. 2018. CNN Exclusive: The more opioids doctors prescribe, the more money they make. <u>https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html</u>.

<sup>&</sup>lt;sup>17</sup> Hadland SE, Cerda M, Li Y, Krieger MS, Marshall BDL. Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing. *JAMA internal medicine*. Published online May 14, 2018. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2681059



## Background (continued)

as the focus of this analysis because they more directly reflect potential drug manufacturer revenues and should be correlated with both the amount of opioids prescribed and the different prices of opioids.

Moreover, longitudinal data from 2013 through 2015 are used to categorize physicians based on if and when they received a payment from industry. This framework enables the ability to see how opioid expenditures change for physicians after receiving an opioid-related payment, relative to the changes among similar physicians who did not receive opioid-related payments from industry during the same time period. Assuming that the two groups of physicians are similar with the exception that one received an opioid-related payment, the difference in opioid expenditures over time between the two groups can be interpreted as the effect of opioid-related payments on opioid prescribing. More details on the methods can be found in the **Appendix**.



## **Results**

#### MORE THAN \$3.5 MILLION IN OPIOID-RELATED PAYMENTS WERE MADE BY DRUG MANUFACTURERS TO PHYSICIANS IN NEW YORK STATE

Nearly \$200 million in payments were made from any drug manufacturer to physicians across New York State from August 2013 through December 2015 (**Exhibit A**). These payments were made to more than 50,000 physicians, more than half of the physicians in New York State who were associated with filled prescriptions to Medicare enrollees.<sup>18</sup>

EXHIBIT A. Payments Made to Physicians in New York State by Drug Manufacturers, August 2013-December 2015			
	ANY DRUG	OPIOID	
Total Amount of Payments	\$196,358,287	\$3,559,398	
Number of Payments	1,568,848	25,555	
Average Payment Amount	\$125	\$139	
Number of Physicians Receiving a Payment	50,971	3,389	
Average number of Payments per Physician	31	8	
Average Payment per Physician	\$3,852	\$1,050	

Source: NYSHealth analysis of CMS Open Payments database.

Note: These amounts include a small number of payments made to non-physician clinicians.

Opioid-related payments totaled more than \$3.5 million, and were disbursed to 3,389 physicians across the State (more than 10% of all physicians who prescribed an opioid to Medicare enrollees in New York).<sup>19,20</sup> The **Appendix** describes the list of opioids used to identify opioid-related payments. Among physicians receiving any opioid-related payment, average total payments from August 2013 through December 2015 amounted to slightly more than \$1,000.

<sup>19</sup> It is possible that a single interaction between a provider and a drug manufacturer is reported on the Open Payments database as being associated with more than one drug.

<sup>&</sup>lt;sup>18</sup> According to the Medicare Prescriber Summary file, there were 89,057 different New York State-based health care providers associated with Part D claims in 2015. This likely represents an over-count of physicians, as some of the providers on the Medicare Prescriber Summary file may be organizations and non-physician clinicians.

<sup>&</sup>lt;sup>20</sup> According to the Medicare Prescriber Summary file, there were 29,247 different New York-based health care providers associated with opioid Part D claims in 2015. This likely represents an over-count of physicians, as some of the providers on the Medicare Prescriber Summary file may be organizations and non-physician clinicians.



## SPEAKING FEES AND HONORARIA COMPRISED THE LARGEST SHARE OF PAYMENTS

**Exhibit B** displays the distribution of opioid-related payments by payment type. The most dollars were spent in the category of speaking fees and honoraria, whereas the most frequent payments were for food and beverage. The form of payments included cash or cash equivalent, as well as the value of in-kind items or services. Cash or cash equivalents comprised the largest share of payments.



burce: NYSHealth analysis of CMS Open Payments database.

Note: These amounts include a small number of payments made to non-physician clinicians. \*Other includes gifts, grants, and education.

#### SEVERAL MANUFACTURERS MADE OPIOID-RELATED PAYMENTS TO HUNDREDS OF NEW YORK PHYSICIANS

INSYS Therapeutics (INSYS) accounted for more than half of all opioid-related payments from manufacturers to physicians in New York State (**Exhibit C**). INSYS manufactures Subsys, which is a spray form of fentanyl that gets delivered to the body through a fine mist underneath the tongue. The FDA has approved its use to help manage pain experienced by cancer patients. However, New York and other states are suing INSYS for marketing the drug for broader



use beyond cancer patients, as well as for downplaying its risks of addiction.<sup>21</sup> While drug manufacturers are not allowed to promote their drugs for uses that are not approved, it should be noted that it is legal for physicians to prescribe them for "off-label" use based on their own clinical judgment.

EXHIBIT C. Five Manufacturers with Largest Opioid-Related Payments to Physicians in New York					
MANUFACTURER	NUMBER OF PHYSICIANS WHO RECEIVED AN OPIOID- RELATED PAYMENT 2013-2015	NUMBER OF OPIOID- RELATED PAYMENTS 2013-2015	AMOUNT OF OPIOID- RELATED PAYMENTS 2013-2015	BRAND DRUGS ASSOCIATED WITH OPIOID-RELATED PAYMENTS	
INSYS Therapeutics, Inc.	823	5,864	\$1,891,168	Subsys	
Purdue Pharma L.P.	1,915	8,363	\$591,611	Butrans, Hysingla, Oxycontin	
Teva Pharmaceuticals USA, Inc.	438	2,671	\$336,863	Fentora	
Janssen Pharmaceuticals, Inc.*	489	1,545	\$205,174	Nucynta	
Depomed, Inc.*	558	1,891	\$189,634	Nucynta, Lazanda	

Source: NYSHealth analysis of CMS Open Payments database.

Note: These amounts include a small number of payments made to non-physician clinicians. \*Janssen Pharmaceuticals, Inc. divested its U.S. rights to the Nucynta franchise to Depomed, Inc. in 2015.

Purdue Pharma, which manufactures Oxycontin and other opioids, made the second-highest amount of opioid-related payments in New York State. Purdue Pharma is also facing dozens of lawsuits from municipalities across the country, including New York City.<sup>22</sup> As part of the lawsuits, Purdue Pharma and other drug manufacturers are charged with misrepresenting the safety and efficacy of long-term opioid use. Purdue Pharma has denied the allegations. However, it did announce earlier this year that it will stop promoting its opioid products to physicians.<sup>23</sup> The company will still handle requests from physicians who have questions about their opioid drugs, but through its medical affairs department. Its sales force will be reduced by half, with its remaining representatives in the U.S. focusing on the company's nonopioid products.

<sup>&</sup>lt;sup>21</sup> Office of the Attorney General, Eric T Schneiderman. A.G. Schneiderman Sues Fentanyl Maker Insys Therapeutics, Inc. For Dangerous And Deceptive Promotion Of Prescription Opioid Subsys. <u>https://ag.ny.gov/press-release/ag-schneiderman-sues-fentanyl-maker-insys-therapeutics-inc-dangerous-and-deceptive</u>

<sup>&</sup>lt;sup>22</sup> Office of the Mayor. 2018. Mayor de Blasio Announces Lawsuit Against Nation's Largest Opioid Manufacturers and Distributors. <u>http://www1.nyc.gov/office-of-the-mayor/news/054-18/mayor-de-blasio-lawsuit-against-nation-s-largest-opioid-manufacturers-distributors#/0</u>.

<sup>&</sup>lt;sup>23</sup> Hopkins, J. (2018, February 9). Pain Pill Giant Purdue to Stop Promotion of Opioids to Doctors. Bloomberg Markets. https://www.bloomberg.com/news/articles/2018-02-10/pain-pill-giant-purdue-to-stop-promotion-of-opioids-to-doctors.



#### PHYSICIANS WHO RECEIVED AN OPIOID-RELATED PAYMENT PRESCRIBE MORE OPIOIDS

**Exhibit D** compares the expenditures for opioid prescriptions filled by the patients of physicians who received an opioid-related payment, and the respective expenditures for patients of physicians who did not receive such payments. Opioid expenditures are substantially higher for physicians who received an opioid-related payment. This disparity is expected, as it makes sense for opioid manufacturers to focus promotion activities on physicians who are more likely to prescribe opioids based on their clinical specialty and patient needs.

EXHIBIT D. Opioid Expenditures for Physicians Who Received an Opioid-Related Payment from Industry vs. Physicians Who Did Not, 2013–2015



Source: NYSHealth analysis of CMS Open Payments database and Medicare Provider Utilization and Payment Data: Part D Prescriber Provider Summary Files. Note: These amounts include a small number of payments made to non-physician clinicians. \*Only health care providers who prescribed more than 10 opioid claims under Medicare Part D in each year are included. Also, because of differences in how providers were identified on the Medicare Part D and Open Payments files, it was not possible to identify opioid utilization data for some providers on the Open Payments database. See Appendix for more information on the methods.

Physicians receiving opioid-related payments also had a higher average number of opioid claims, opioid days supply, and Medicare enrollees treated with opioids (**Exhibit E**).



EXHIBIT E. Average 2013-2015 Medicare Opioid Claims Filled, Expenditures, Days Supply and Enrollees Treated for Physicians Who Received an Opioid-Related Payment vs. Physicians Who Did Not						
	OPIOID-RELATED PAYMENT STATUS	NUMBER OF PHYSICIANS*	MEAN NUMBER OF OPIOID CLAIMS	MEAN OPIOID CLAIM EXPENDITURES	MEAN OPIOID DAYS SUPPLY FILLED	MEAN MEDICARE ENROLLEES TREATED WITH OPIOID CLAIMS*
	Received Opioid-Related PaymentAny Year	1,932	904	\$100,639	24,196	206
	No Opioid-Related Payments	19,383	301	\$17,509	6,595	118

Source: NYSHealth analysis of CMS Open Payments database and Medicare Provider Utilization and Payment Data: Part D Prescriber Provider Summary Files.

Note: These amounts include a small number of payments made to non-physician clinicians. \*Only health care providers who prescribed more than 10 opioid claims under Medicare Part D in each year are included. Also, because of differences in how providers were identified on the Medicare Part D and Open Payments files, it was not possible to identify opioid utilization data for some providers on the Open Payments database.

# Given small sample sizes and reporting restrictions, 1,065 providers were excluded from mean enrollee calculations. See Appendix for more information on the methods.

#### OPIOID-RELATED PAYMENTS ARE HIGHER FOR PHYSICIANS WHO PRESCRIBE MORE OPIOIDS

**Exhibit F** shows the relationship between the amount of opioid-related payments to physicians and the expenditures associated with their dispensed opioids prescriptions. While these cross-sectional data cannot establish a causal relationship between payments from opioid manufacturers and physician opioid prescribing, they do clearly show that physicians who prescribe more opioids get more opioid-related payments. Physicians who received less than \$20 from opioid manufacturers from August 2013 through December 2015 prescribed the least amount on average—\$34,266. As the amount of opioid-related payments increases, the associated prescription opioid expenditures also increase. Physicians who received at least \$20, but less than \$50, prescribed an average of \$49,885 worth of opioids. The group of physicians that received more than \$10,000 worth of opioid-related payments had substantially larger opioid prescribing expenditures—\$1,247,896 on average—than physicians receiving lower payment amounts.



EXHIBIT F. Average Expenditures for Opioid Claims for Subgroups of Physicians Based on How Much They Received in Opioid-Related Payments, 2013-2015



Source: NYSHealth analysis of CMS Open Payments database and Medicare Provider Utilization and Payment Data: Part D Prescriber Provider Summary Files. Note: These amounts include a small number of payments made to non-physician clinicians. \*Only providers who prescribed more than 10 opioid claims under Medicare Part D in each year are included. Also, because of differences in how providers were identified on the Medicare Part D and Open Payments files, it was not possible to identify opioid utilization data for some providers on the Open Payments database. See Appendix for more information on the methods.

#### Opioid-Related Payments are Concentrated among High-Volume Opioid Prescribers

The majority of physicians received a small amount in opioid-related payments (**Exhibit G**). However, the top 1% of physicians in New York State, in terms of the amount received in opioid-related payments during the August 2013 through December 2015 time frame, accounted for more than 80% of total payments (\$2.8 million).





EXHIBIT G. Distribution of Opioid-Related Payments to Physicians, August 2013-December 2015

Source: NYSHealth analysis of CMS Open Payments database.

Note: These amounts include a small number of payments made to non-physician clinicians.

**Exhibit H** displays the total opioid-related payments for each physician in the top percentile. Each dot represents a physician. The five dots in red represent physicians charged in federal court with taking kickbacks for opioid prescriptions.<sup>24</sup> The indictment implicates INSYS in paying the physicians, in some cases more than \$100,000, in return for prescribing millions of dollars' worth of the company's painkiller product (Subsys).

<sup>24</sup> Weiser, B &Thomas, K. (2018, March 16). 5 Doctors Are Charged With Taking Kickbacks for Fentanyl Prescriptions. *The New York Times*. https://www.nytimes.com/2018/03/16/nyregion/fentanyl-subsys-drug-kickbacks.html.



EXHIBIT H. Opioid-Related Payments to Each Physician in the Top Percentile of Opioid-Related Payments Received, August 2013-December 2015



Source: NYSHealth analysis of CMS Open Payments database.

Together, these five physicians accounted for more than \$18 million in prescription opioid spending under Medicare Part D, ranging from \$1.5 million to more than \$6 million per physician (**Exhibit I**). The average 2013 through 2015 opioid spending for physicians who had more than 10 opioid claims filled in each year during the study period was around \$25,000.



EXHIBIT I. Expenditures of Opioids Prescribed Under Medicare Part D for Each Physician in the Top Percentile of Opioid-Related Payments Received, 2013–2015



Source: NYSHealth analysis of CMS Open Payments database.

Note: Medicare Part D data for 8 physicians are not available because of inability to match providers across Open Payments and Medicare Part D data.

More than two-thirds of physicians in New York State receiving an opioid-related payment received less than \$100 from opioid manufacturers from August 2013 through December 2015. However, dozens of physicians received more than \$10,000 from a single opioid manufacturer (**Exhibit J**). INSYS and Purdue Pharma had the most financial relationships of this kind during that time frame.





#### EXHIBIT J. Number of Physicians Receiving More Than \$10,000 From One Manufacturer, August 2013-December 2015

#### **Opioid Prescribing Increases Following Opioid-Related Payments**

The previous sections explored how the level of opioid-related payments received is associated with the level of opioid prescribing, as measured by expenditures for dispensed opioid prescriptions. In this section, we explore the relationship between payments received by physicians and how the amount of opioids they prescribe changes over time. More specifically, the trends for physicians who received an opioid-related payment are compared to those of a matched comparison group of similar physicians who did not receive such payments. The two groups are matched to ensure similar clinical specialties and levels of opioid prescribing in years prior to receiving opioid-related payments. More details on how the comparison group is created are described in the **Appendix**.

**Exhibit K** displays average opioid expenditures for physicians who received opioid-related payments in 2014 and 2015, but not in 2013, compared to a matched group of similar physicians who did not receive payments in any year. This comparison is important because neither group of physicians received an opioid-related payment from industry in 2013 and the two groups have a similar specialty mix and levels of opioid prescribing in 2013. In 2014, average opioid expenditures for the group of physicians that started receiving opioid-related



payments increased 37.2% from 2013 levels (amounting to an \$8,009 increase per physician from 2013 levels). By comparison, opioid expenditures increased 15.6% (\$3,582) for the group of physicians that did not receive any opioid-related payments. The difference in the growth in opioid expenditures is especially notable between 2014 and 2015, as expenditures increased 24.7% for the group of physicians that received opioid-related payments (\$7,301), compared to 1.9% (\$505) for the group of similar physicians that did not.

EXHIBIT K. Average Expenditures on Medicare Part D Opioids for Physicians Before and After Receiving an Opioid-Related Payment in 2014 and 2015, Relative to a Comparison Group of Similar Physicians Who Did Not Receive a Payment



Source: NYSHealth analysis of CMS Open Payments database and Medicare Provider Utilization and Payment Data: Part D Prescriber Provider Summary Files. Note: Only matched physicians are included in these calculations. More details on matching are provided in the Appendix.

**Exhibit L** displays average opioid expenditures for physicians who received opioid-related payments from industry in 2015, but not in 2013 or 2014, compared to a matched group of similar physicians that did not receive payments in any year. Both groups of physicians had a relatively similar increase in opioid expenditures from 2013 to 2014 (15.0% for those receiving opioid-related payments and 17.8% for those that did not, or \$1,983 and \$2,434, respectively). Neither group received industry payments during this time. However, the increase in expenditures was notably higher from 2014 to 2015 for the group of physicians that began receiving payments in 2015 (8.6% compared to 2.1%, or \$1,303 compared to \$337).



EXHIBIT L. Average Expenditures on Medicare Part D Opioids for Physicians Before and After Receiving an Opioid-Related Payment in 2015, Relative to a Comparison Group of Similar Physicians Who Did Not Receive a Payment



Source: NYSHealth analysis of CMS Open Payments database and Medicare Provider Utilization and Payment Data: Part D Prescriber Provider Summary Files. Note: Only matched physicians are included in these calculations. More details on matching are provided in the Appendix.



## **Discussion**

#### **SUMMARY OF FINDINGS**

These analyses show clear links between the amount of opioid prescriptions prescribed by physicians and filled by patients, and payments that physicians receive from pharmaceutical companies that manufacture opioid pain medications. That is, physicians who received payments from opioid manufacturers had higher opioid prescribing to Medicare patients than physicians who did not receive any opioid-related payments. Moreover, higher payment amounts to physicians are associated with higher opioid prescribing. In addition, opioid-related industry payments are concentrated within a small proportion of physicians who tend to prescribe a large quantity of opioids. These findings are consistent with a prior report on the link between opioid prescribing and opioid-related payments from industry.<sup>25</sup>

When comparing physicians who received opioid-related payments from industry with a matched group of similar physicians who did not receive any opioid-related payments, there is evidence that such payments do lead to an increase in opioid prescribing. Both the group of physicians that began receiving industry payments in 2014 and the group that began receiving payments in 2015 had larger increases in opioid prescribing in years receiving the payments relative to the comparison group of physicians that did not receive any opioid-related payments.

For the group of physicians that began receiving payments in 2014, expenditures on opioid prescriptions for their patients increased \$4,427 more, on average, from 2013 to 2014 than the increase among patients of similar physicians who did not receive opioid-related payments.<sup>26</sup> This increase in opioid prescription expenditures is nearly 13.8 times the amount that these physicians received in opioid-related payments in 2014 (\$322).

The average total payment to physicians receiving their initial opioid-related payment in 2015 was approximately \$100. For these physicians, expenditures on opioid prescriptions increased \$966 more, on average, from 2014 to 2015 than the increase among similar physicians who did not receive payments. That amounts to nearly 10 times the average opioid-related payment.

These figures do not take into account the cumulative effects of opioid-related payments over time. Evidence from the group of physicians that received payments in 2014 and 2015

<sup>&</sup>lt;sup>25</sup> Kessler, A, Cohen, E, and Grise, G. 2018. CNN Exclusive: The more opioids doctors prescribe, the more money they make. <u>https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html</u>.

<sup>&</sup>lt;sup>26</sup> These calculations are based on nominal estimates and do not take into account drug price inflation.



### **Discussion** (continued)

suggests that the disparity in opioid prescribing between physicians who receive opioidrelated payments and those who do not may increase over time. Potential spillover effects across physician networks are also not accounted for in these analyses. That is, physicians who received opioid-related payments from industry may influence colleagues and other clinicians in their networks who also prescribe opioids and did not have any financial relationships with industry.

#### **POLICY IMPLICATIONS**

While these data cannot determine whether the changes in opioid prescribing patterns that are associated with industry payments led to inappropriate opioid use, these analyses do add to the growing public policy concern that pharmaceutical companies that manufacture opioids have worked to influence physician prescribing. Multiple pathways may warrant exploration in seeking ways to mitigate the risks for adverse consequences from certain promotional activities directed toward physicians.

One potential solution is further regulating physician-industry interactions. Consideration should be given to banning most, if not all, physician-industry promotional interactions, particularly for controlled substances such as opioids. While it is possible that prescribing may sometimes be improved by such interactions, the evidence appears to suggest that positive effects are likely to be outweighed by adverse consequences. A literature review on how information from pharmaceutical companies influences physician prescribing concludes that, "with rare exceptions, studies of exposure to information provided directly by pharmaceutical companies have found associations with higher prescribing frequency, higher costs, or lower prescribing quality or have not found any significant associations."<sup>27</sup>

Alternatively, an opt-in approach could be taken, whereby promotional and educational activities take place only at a physician's request. This is essentially the approach that Purdue Pharma is taking, as it still handles requests from physicians who have questions about their opioid drugs, but no longer actively sends representatives to initiate promotional meetings with physicians.

According to a recent survey conducted by Siena College, most New Yorkers identify

<sup>&</sup>lt;sup>27</sup> Spurling, G. K., Mansfield, P. R., Montgomery, B. D., Lexchin, J., Doust, J., Othman, N., & Vitry, A. I. (2010). Information from pharmaceutical companies and the quality, quantity, and cost of physicians' prescribing: a systematic review. *PLoS medicine*, 7(10), e1000352. <u>http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000352</u>



## **Discussion** (continued)

physicians and pharmaceutical companies as being responsible for the current level of opioid misuse.<sup>28</sup> A growing number of lawsuits are being filed across the country against opioid manufacturers alleging that their promotional activities contributed to the opioid crisis. In New York, various authorities at the state, city, and county levels have filed more than a dozen lawsuits against INSYS Therapeutics, Purdue Pharma, Teva, Johnson & Johnson, Janssen, and other opioid manufacturers.<sup>29</sup> The lawsuits attempt to hold the manufacturers responsible for hundreds of millions of dollars in costs related to the deadly opioid epidemic. These costs include millions of dollars spent on opioid use disorder treatment programs, hospital services, emergency medical services, and law enforcement.

Lawsuits have also been filed against individual doctors in New York State who are accused of essentially taking kickbacks for opioid prescriptions.<sup>30</sup> Some of the physicians in New York who have received the most payments from opioid manufacturers are among those facing lawsuits. Additional investigations may be warranted. Dozens of New York State physicians have received \$10,000 or more from opioid manufacturers during the study time frame.

These analyses and related research also draw attention to the importance of making information on potential conflicts of interest, such as payments to physicians from the pharmaceutical industry, publically available. Moreover, it is critical to be able to link this information to health care utilization and quality data. Under current policy, physicians' National Provider Identifier (NPI) numbers are not available on the Open Payments databases; federal policymakers should reconsider this practice and make that information public. This will help improve the ability of third-party users to link the industry payment data to information on the cost and quality of care delivered by those physicians.

#### LIMITATIONS

Although there is a clear association between industry payments and increases in opioid prescribing after receiving those opioid-related payments, this study cannot conclusively determine a causal link between the two. It is possible that changes in drug prescribing reflect

<sup>&</sup>lt;sup>28</sup> Siena College. 2018. Most Responsible for Opioid Abuse: MD's Over-prescribing. <u>https://www2.siena.edu/news-events/article/most-responsible-for-opioid-abuse-mds-over-prescribing.</u>

<sup>&</sup>lt;sup>29</sup> Goodman, JD & Neuman, W. (2018, January 23). New York City Sues Drug Companies Over Opioid Crisis. The New York Times. <u>https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html.</u>

<sup>&</sup>lt;sup>30</sup> Weiser, B & Thomas, K. (2018, March 16). 5 Doctors Are Charged With Taking Kickbacks for Fentanyl Prescriptions. The New York Times. <u>https://www.nytimes.com/2018/03/16/nyregion/fentanyl-subsys-drug-kickbacks.html</u>.



## **Discussion** (continued)

changes in physicians' patient panels (e.g., they are treating more patients who require pain management) or in specific patients' needs, rather than other influences such as opioidrelated payments. More information would be needed to identify a definitive causal link.

In addition, access to specific dates identifying when opioid prescriptions were written were not available for this analysis. Having the specific dates for both when the prescriptions were written and when the industry payments were made could better clarify the impacts of payments on opioid prescribing. However, to the degree that industry payments were made later in a calendar year, there may be an underestimate of the effect that industry payments would have on opioid prescribing. Similarly, industry payment data are only available for half of 2013. Thus, it may be possible that some physicians who received a payment in the first half of 2013 and not in the second half are counted in the comparison group, further biasing the results against finding an effect. Also, it is possible that interactions between industry representatives and physicians that do not involve a financial transaction can also influence prescriber behaviors. These are not identified in the analysis.

It should also be noted that this analysis explores the link of any opioid related payment by industry to the changes in aggregate opioid prescribing. The links would likely be stronger if payments from industry were matched to utilization for the specific opioid that was being promoted.

In addition, the drug utilization data used for the analysis only reflect data for opioid prescriptions filled under Medicare. They do not include prescriptions written but not filled, or prescriptions for patients with other types of insurance.



# **Appendix: Description of Methods**

#### DATA

#### **Open Payments**

The 2013 through 2015 Open Payments general payments data were used to identify all physician-industry financial relationships.<sup>31</sup> Data for 2013 only include payments from August through December.

The general payments include direct and indirect payments as well as payments in kind, such as the value of food and gifts. Payments related to research costs and the information on equity stakes were excluded from the analysis, as these payments tend to be higher than the general payments and may include compensation for intellectual property. Research payments are also less likely to target specific prescribing behaviors and may be provided to physicians not actively practicing medicine. Payments to hospitals were also excluded.

The Open Payments data provide detailed information on each payment, including which manufacturer made the payment, when the payment was made and what it covered, how much, and in what form, as well as what specific drug was associated with the payment. The data also include the name, specialty, and location of physicians and other health care providers receiving the payments.

#### Medicare Provider Utilization and Payment Data: Part D Prescriber

In order to explore how prescribing patterns are associated with payments received from manufacturers, Medicare Provider Utilization and Payment Data: Part D Prescriber Public Use Files were used.<sup>32</sup> These data provide information on the prescription drugs prescribed by individual physicians and other health care providers and paid for under the Medicare Part D Prescription Drug Program.

The data identify providers by their name, location, and National Provider Identifier (NPI) number. For each prescriber and drug, the dataset includes the total number of prescriptions that were dispensed, which include original prescriptions and any refills, and the total expenditures for the drug. The total expenditures cover the ingredient cost of the medication, dispensing fees, sales tax, and any applicable administration fees and is based on the amount paid by the Medicare Part D plan, Medicare enrollee, government subsidies, and any other

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<sup>&</sup>lt;sup>31</sup> Centers for Medicare & Medicaid Services. Open Payments. <u>https://www.cms.gov/openpayments/</u>.

<sup>&</sup>lt;sup>32</sup> Centers for Medicare & Medicaid Services. Medicare Provider Utilization and Payment Data: Part D Prescriber. <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html</u>



#### third-party payers.

There are two versions of the Part D Prescriber Public Use Files: (1) Detailed Data and (2) Provider Summary Data. The Detailed Data provides prescriber information for specific drugs. The Provider Summary Data includes aggregated drug utilization and payment information at the physician level, including information for certain classes of drugs, such as opioids, as well as for all drugs prescribed. For this analysis, only the Provider Summary Data was used.

#### **LIST OF OPIOID DRUGS**

CMS reports aggregate opioid utilization and expenditures as part of its Medicare Part D Opioid Prescribing Mapping Tool. The list of brand and generic name opioid drugs that CMS uses to identify opioids prescribed under Part D is available on the CMS website.<sup>33</sup> This study uses the same list to identify opioid-related payments, with a few exclusions. Namely, all buprenorphine drugs, including buprenorphine/naloxone formulations are excluded, as they are used for opioid addiction treatment. In addition, nonsteroidal anti-inflammatory drugs (NSAIDs) are excluded.

Not all drugs that appear on the CMS list were found in the Open Payments database. Thus, the list of drugs that are aggregated into the opioid estimates on the Part D Prescriber Provider Summary Data is likely to be more expansive than the list of opioids identified on the Open Payments database.

Because of differences in drug name spelling, descriptions, and text-formatting between the CMS opioid list and the way drugs are described in the Open Payments data, it is likely that opioid-related payments in the Open Payments database are also under-identified.

#### **MERGING THE PART D AND OPEN PAYMENTS DATA**

NPI numbers were explicitly forbidden by statute from release as part of the Open Payments program. Hence, matching the information from the Open Payments data to the Part D data required using a "string-matching" algorithm based on the provider names and locations

<sup>33</sup> Centers for Medicare & Medicaid Services. 2017. Medicare Part D Opioid Prescribing Mapping Tool Methodology. Available as of April 9, 2018 at: <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Opioid</u> Methodology.pdf



on each data set. Similar approaches have been conducted in previous studies.<sup>34</sup> Matching was done first by requiring a match of first name, last name, middle initial, and ZIP code. A second, less stringent, attempt at matching was conducted with the providers who were left unmatched from the first attempt, based on first name, last name, and ZIP code only. A prior study also used a third attempt of matching that removed location as a criterion. The researchers of that study also conducted a sensitivity analysis of more and less stringent approaches to matching and did not find meaningful differences in results.<sup>35</sup>

#### **DEVELOPMENT OF INTERVENTION AND COMPARISON GROUPS**

After the Part D and Open Payments data were merged, a pool of providers was identified comprising providers who each received an opioid-related industry payment and prescribed more than 10 dispensed Medicare Part D opioid claims each year from 2013 through 2015. These providers were eligible to be in the intervention group for the analysis; i.e., the analytic sample of providers that received an opioid-related payment from industry.

Any provider who did not receive a payment from industry and who was associated with more than 10 opioid claims for each year 2013 through 2015 was eligible for the comparison pool. A matching technique based on "stratification" called Coarsened Exact Matching was implemented to ensure that a comparison group of providers would have a similar specialty mix and similar levels of associated opioid expenditures in a baseline period relative to the intervention group.<sup>36</sup>

Given that providers associated with higher opioid utilization and expenditures are more likely to have financial relationships with drug manufacturers, it is critical to control for this factor in any comparisons between groups receiving and not receiving industry payments. Matching was done using opioid expenditures in the "pre-intervention" period. That is, 2013 expenditures were used for matching when conducting the analysis for providers who did not receive payments in 2013, but did in 2014 and 2015. Both 2013 and 2014 expenditures were used for

<sup>36</sup> Iacus, S. M., King, G., & Porro, G. (2012). Causal inference without balance checking: Coarsened exact matching. *Political analysis, 20*(1), 1-24.

<sup>&</sup>lt;sup>34</sup> Perlis, R. H., & Perlis, C. S. (2016). Physician payments from industry are associated with greater Medicare Part D prescribing costs. *PloS ONE*, 11(5), e0155474. Available at: <u>http://journals.plos.org/plosone/article?id=10.1371/journal.one.0155474</u>.; Kessler, A, Cohen, E, and Grise, G. 2018. CNN Exclusive: The more opioids doctors prescribe, the more money they make. <u>https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html</u>.

<sup>&</sup>lt;sup>35</sup> Perlis, R. H., & Perlis, C. S. (2016). Physician payments from industry are associated with greater Medicare Part D prescribing costs. *PloS ONE*, 11(5), e0155474. Available at: <u>http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0155474</u>.



matching when conducting the analysis for providers who did not receive payments in 2013 and 2014, but did in 2015. Opioid expenditure strata were created based on the distribution of expenditures of the intervention providers. Ten strata were made based on the deciles of the 2013 expenditure distribution. In order to ensure that the expenditures were on a similar preintervention trajectory for the group of providers that only received industry payments in 2015 (and not in 2013 and 2014), 20 strata were used for matching based on every 5th percentile of the 2014 opioid cost distribution (as well as the 10 strata based on 2013 expenditures).

Similar to expenditures, the specialty of a provider can also be a confounding factor, as specialties that are more likely to treat patients in need of pain management can also be expected to be more likely to have interactions with opioid manufacturers. Also, because of the different patient needs, each specialty may be more or less likely to prescribe specific kinds of opioids. The list of specialties used to categorize and "match" each provider in the intervention and comparison groups is shown in **Exhibit A-1**. The groupings are based on those used to stratify providers for the National Ambulatory Medical Care Survey.<sup>37</sup> Only physicians were included for the analyses involving matched samples. Non-physician clinicians were excluded. Specialties that did not exist in both the intervention and comparison groups are based or matched.

<sup>37</sup> Center for Disease Control and Prevention, National Center for Health Statistics. 2015 NAMCS Micro-data File Documentation. <u>ftp://ftp.cdc.gov/pub/Health\_Statistics/NCHS/Dataset\_Documentation/NAMCS/doc2015.pdf</u>



EXHIBIT A-1. List of Specialties Used to Categorize Physicians for Matching

Addiction Medicine & Psychiatry	Non-Oncology Surgical Subspecialty
Addiction Medicine	Cardiac Surgery
Neuropsychiatry	Colorectal Surgery (formerly proctology)
Psychiatry	General Surgery
Anesthesiology and Pain Management	Hand Surgery
Anesthesiology	Neurological Surgery
Interventional Pain Management	Neurosurgery
Pain Management	Obstetrics/Gynecology
Dentist	Ophthalmology
Dentist	Orthopaedic Surgery
Oral Surgery (dentists only)	Orthopedic Surgery
Diagnostic Radiology and Interventional Radiology	Otolaryngology
Diagnostic Radiology	Peripheral Vascular Disease
Interventional Radiology	Plastic Surgery
Nuclear Medicine	Plastic and Reconstructive Surgery
Hospice and Palliative Care	Thoracic Surgery
Hospice and Palliative Care	Urology
Hospital-Based Non-Surgical	Vascular Surgery
Critical Care (Intensivists)	Oncology Medical Specialty
Emergency Medicine	Hematology
Hospitalist	Hematology/Oncology
Neurology	Medical Oncology
Neurology	Radiation Oncology
Psychiatry & Neurology	Oncology Surgical Subspecialty
Non-Ocology Medical Specialty	Gynecological/Oncology
Allergy/Immunology	Surgical Oncology
Cardiac Electrophysiology	Physical Medicine & Rehabilitation and Sports Medicine
Cardiology	Neuromusculoskeletal Medicine, Sports Medicine
Dermatology	Physical Medicine & Rehabilitation
Endocrinology	Physical Medicine and Rehabilitation
Gastroenterology	Sports Medicine
Infectious Disease	Primary Care
Interventional Cardiology	Family Medicine
Nephrology	Family Practice
Pathology	General Practice
Pulmonary Disease	Geriatric Medicine
Rheumatology	Internal Medicine
Sleep Medicine	Osteopathic Manipulative Medicine
Specialist	Pediatric Medicine
Podiatry	Preventive Medicine
Podiatry	



The intersection of the cost and specialty strata comprised all of the strata used for matching. Any strata that did not include both intervention and comparison physicians were excluded from the analysis.

Weighting was used to take into account that certain strata may have more or fewer comparison physicians relative to intervention physicians.<sup>38</sup>

<sup>38</sup> King, G. 2012. An Explanation for CEM Weights. Available at: <u>https://docs.google.com/document/d/1xQwyLt\_6EXdNp\_A685LjmhjO20y5pZDZYwe2qeNoI5dE/edit</u>.

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