

# Prespecification of Analyses for Schedule II Controlled Substances Letter Campaign

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*FINAL VERSION BEFORE UNBLINDING TO DATA*

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## **1 Introduction**

In this document we describe an analysis plan for a study on the effects of informative letters that were sent to high prescribers of Schedule II controlled substances in Medicare Part D. This analysis plan is prespecified in order to reduce the possibility of data mining for this set of results. At this time of writing, we have not yet extracted or viewed any data on the prescribers beyond the year 2013. We may perform additional analyses in the course of the study; when analyses were not pre-specified in this document we will make note of that fact.

The goal of this study is to understand the effects of the letters on both prescribers and patients. The primary outcome of the study is the effect of the letters on the prescribing of schedule II controlled substances over the 3 months following the initial sending of the letters. Prescribing is defined as the total “days supply” of schedule II controlled substances attributed to the prescriber, expressed in “30-day equivalents” i.e. divided by 30.

We consider additional outcomes as well. Through these additional analyses, we hope to understand the totality of the effects of the letters. Additional analysis for prescribers includes explorations of effect heterogeneity, quantile treatment effects, substitution toward other substances, and peer effects. We also conduct analyses looking at a cohort of patients who were treated by the prescribers prior to the sending of the letters. We will assign these patients to treatment and control groups based on whether their attributed prescriber was a treatment or control prescriber and study the receipt of controlled substances by patients, heterogeneity in treatment effects, substitution toward other substances, and health outcomes.

We observe the behavior of prescribers and outcomes of patients through our access to the CMS Integrated Data Repository (IDR), the live database used to administer Medicare and Medicaid. The IDR includes beneficiary enrollment information, Medicare Part A and B claims, Medicare Part C encounter data, and Medicare Part D prescription drug events.

## 2 Identification of Prescribers and Randomization

An analysis was conducted to identify outlier prescribers of Schedule II controlled substances in the Medicare Part D events file (analogous to a claims file) for each year 2011, 2012, and 2013. This analysis was conducted by Health Integrity, a contractor responsible for detecting fraud in the Medicare Part D program, with the supervision of the Centers for Medicare and Medicaid Services Center for Program Integrity (CMS/CPI).

First, a sample of prescribers with at least 100 schedule II prescription drug events (PDEs, or records in the Part D events file that are generated whenever patients fill prescriptions) or at least \$100,000 in total Part D payments for schedule II prescriptions was created. Any specialty that accounted for less than 1% of these prescribers was removed from the analysis. Prescribers with a specialty equal to “Specialist” were also removed as this description was considered too vague to permit analysis. The result was a sample of prescribers in 9 specialties: Anesthesiology, Emergency Medicine, General Care Prescriber (which includes General Practitioners, Family Practitioners, and Internal Medicine practitioners with no specialization), Nurse Practitioner, Orthopedic Surgery, Pain Medicine, Physical Medicine & Rehabilitation, Physician Assistant, and Psychiatry & Neurology.

Prescribers were then grouped by state and specialty (e.g. a prescriber’s peer group was other prescribers with his/her specialty in his/her state) and two outlier thresholds were calculated for each group. In order to be considered an outlier, the prescriber had to pass both thresholds. The first threshold was with respect to schedule II PDE, and it was set equal to the 75<sup>th</sup> percentile for prescribers within the state-specialty plus three times the interquartile range (called the Tukey method; see Tukey, 1977). The second threshold was with respect to schedule II 30-day equivalents – the total “days supply” of schedule II substances appearing in the prescribers’ PDE records, divided by 30. The threshold for 30-day equivalents was set by the same Tukey method.

When this analysis was conducted using 2011 PDE data, 1,529 outlier prescribers were identified. The 2012 data resulted in 1,656 outliers and the 2013 data resulted in 1,803 outliers. 1,525 prescribers were outliers in at least two of the three years, and these prescribers became the study sample.

We randomly allocated each of the 1,525 prescribers to a treatment or control group. Randomization was performed in Stata with a pre-specified re-randomization procedure to ensure covariate balance between treatment and control groups (See Appendix 1). The first run of randomization passed the balance test so no re-randomization was conducted. 762 prescribers were allocated to the treatment group and 763 were allocated to the control group. Summary statistics about the prescribers follow:

| Summary Statistics about Prescribers            |  |                |                       |
|---|--|----------------|-----------------------|
| VARIABLES                                       | (1)<br>Treatment                       | (2)<br>Control | (3)<br>Equality P-val |
| Share Outlier in 2013                           | 0.835                                  | 0.845          | 0.57                  |
| Share Outlier in all 3 years 2011-2013          | 0.596                                  | 0.595          | 0.98                  |
| Average Sched II PDE Count for 2013             | 1,400                                  | 1,479          | 0.26                  |
| Average Sched II PDE Count for 2011-2013        | 4,153                                  | 4,245          | 0.59                  |
| Average Sched II Total Dollars Paid 2013        | 189,415                                | 205,393        | 0.30                  |
| Average Sched II Total Dollars Paid 2011-2013   | 585,179                                | 606,223        | 0.54                  |
| Share General Care Practitioner                 | 0.577                                  | 0.595          | 0.49                  |
| Share Nurse Practitioner or Physician Assistant | 0.188                                  | 0.212          | 0.23                  |
| Share Physician Specialist                      | 0.235                                  | 0.193          | 0.04                  |
|   | <i>Joint test of equality P-value:</i> |                | 0.44                  |
| Prescribers                                     | 762                                    | 763            |                       |

A PDE is a prescription drug event, a record that is triggered each time a Part D beneficiary fills a prescription. Total dollars paid refers to the total payments for the prescriptions, including payments from the Part D plan as well as out of pocket payments by the beneficiary. Column 3 lists p-values from t-tests that the mean of each variable is equal between treatment and control. The joint test is the Wilks lambda F test for equality of means of the variables (excluding share physician specialist, which is collinear with the other two shares).

Two treatment group and five control group providers were found to have died before the time the outlier analysis was conducted. We will remove deceased prescribers from the analysis. The table below repeats the summary statistics and balance tests on the sample with deceased prescribers removed and shows that there is effectively no change in balance:

| Summary Statistics about Prescribers (Deceased Prescribers Removed) |  |                |                       |
|---|--|----------------|-----------------------|
| VARIABLES   | (1)<br>Treatment                       | (2)<br>Control | (3)<br>Equality P-val |
| Share Outlier in 2013   | 0.837                                  | 0.848          | 0.54                  |
| Share Outlier in all 3 years 2011-2013                              | 0.597                                  | 0.596          | 0.97                  |
| Average Sched II PDE Count for 2013                                 | 1,403                                  | 1,486          | 0.24                  |
| Average Sched II PDE Count for 2011-2013                            | 4,160                                  | 4,251          | 0.60                  |
| Average Sched II Total Dollars Paid 2013                            | 189,914                                | 206,259        | 0.29                  |
| Average Sched II Total Dollars Paid 2011-2013                       | 586,063                                | 607,070        | 0.55                  |
| Share General Care Practitioner                                     | 0.578                                  | 0.594          | 0.53                  |
| Share Nurse Practitioner or Physician Assistant                     | 0.188                                  | 0.214          | 0.21                  |
| Share Physician Specialist  | 0.234                                  | 0.193          | 0.05                  |
|   | <i>Joint test of equality P-value:</i> |                | 0.42                  |
| Prescribers   | 760                                    | 758            |                       |

A PDE is a prescription drug event, a record that is triggered each time a Part D beneficiary fills a prescription. Total dollars paid refers to the total payments for the prescriptions, including payments from the Part D plan as well as out of pocket payments by the beneficiary. Column 3 lists p-values from t-tests that the mean of each variable is equal between treatment and control. The joint test is the Wilks lambda F test for equality of means of the variables (excluding share physician specialist, which is collinear with the other two shares).

Treatment group prescribers were sent a letter detailing their schedule II prescribing behavior (see attachment at end of document). Deceased prescribers in this group were not sent a letter. The resulting 760 letters were sent on 9/11/2014. Of these letters, 131 were returned to sender. CMS resolved the addresses of letters that were returned to sender and re-sent the letters to the new addresses in batches. If a re-sent letter was returned to sender (which happened for 11 re-sent letters), CMS would continue to attempt to resolve the address of the prescriber and send the letter again. As of January 20, 2015, the schedule of mailing was as follows:

| Letter Mailing Schedule |              |                  |
|-------------------------|--------------|------------------|
| Date                    | Letters Sent | Letters Returned |
| 9/11/14                 | 760          | 131              |
| 9/25/14                 | 29           | 11               |
| 10/17/14                | 66           |                  |
| 10/23/14                | 11           |                  |
| 11/14/14                | 36           |                  |

Control group prescribers received no letter.

### 3 Overview

In this section we provide background on how we will specify the regressions in the paper. We also discuss the sets of controls that will be used in each analysis as well as the time horizons at which the outcomes will be defined.

#### 3.1 Form of regressions

The physician level regressions will be of the form:

$$y_i = \alpha + \beta * treat_i + X_i\Gamma + e_i$$

Where  $i$  indexes physicians,  $y_i$  is the outcome (e.g. number of prescriptions),  $treat_i$  is an indicator for physician  $i$  receiving the letter, and  $X_i$  is the set of physician controls.  $\beta$ , the effect of the treatment on the outcome, is the coefficient of interest.

The patient level regressions will be of the form:

$$y_j = \alpha + \beta * treat_{i(j)} + X_{i(j)}\Gamma + Z_j\Theta + e_j$$

Where  $j$  indexes patients,  $i(j)$  is patient  $j$ 's physician,  $y_j$  is the outcome (e.g. prescriptions filled by the patient),  $treat_{i(j)}$  is an indicator for the patient's physician receiving the letter,  $X_{i(j)}$  is the set of controls for characteristics of the patient's physician, and  $Z_j$  is the set of controls for characteristics about the patient.  $\beta$ , the effect of the treatment on the outcome, is the coefficient of interest.

Standard errors will be clustered at the level of the physician in all regressions.

#### 3.2 Controls

Since the letters were randomized without stratification, the regressions will produce valid estimates of the coefficients of interest even without controls. However, controls can raise power by reducing the variance of the error term.

We will use three sets of controls. The baseline specification (reported in main tables) will be the one with the richest set of controls.

##### 3.2.1 No controls

One specification will include no controls at all.

##### 3.2.2 Lagged outcome controls

This specification will control for the lagged measure of the outcome (before the letters were sent.) In the patient level specifications we will include the lagged value of the physician outcome as well, when possible.

##### 3.2.3 Lagged outcome controls + additional controls

We will include additional controls about the prescriber, potentially including the values that were used to classify the prescriber as an outlier in the report, the prescriber's specialty, information from the Fraud Investigation Database (FID), information on whether

Health Integrity had previously investigated the prescriber, and lags of other outcome variables.

In patient-level specifications we will, in addition, include more controls about the patient. These controls may include e.g. interactions with 5-year age categories (with the last age category being 90+), race, and sex; prior utilization of prescription drugs and other health services; and claims-based indicators that suggest prescription drug abuse (e.g. Parente et al 2004).

We will choose the set of controls by analyzing the explanatory power of the variables listed above and potentially other medically and economically relevant variables. To assess explanatory power we will run regressions looking only at the control group prescribers and compare the adjusted  $R^2$  of different combinations of candidate control variables.

### 3.3 Time Horizon

We are interested in the evolution of the effects of the letters. To that end, all regressions in this document will be performed with the outcome defined at the following time horizons (starting from the day after the letters were first sent, 9/12/2014):

- 1 month
- 3 months
- 6 months
- 9 months
- 1 year

When appropriate we will visualize outcomes using graphs showing the evolution of the outcomes over this horizon.

## 4 Balance Tests

In section 2 we showed that based on the information already available to us, prescriber characteristics are balanced between treatment and control group. Once we are unblinded to the full set of data on the prescribers we will perform further balance tests. For each of the covariate sets that we will use as controls (see section 3.2), we will perform a joint test of equality of means between treatment and control groups.

We will also test whether there is balance in the number of audits conducted by Health Integrity in late August/early September, after the randomization list was created but before the letters were sent. According to the contractor, the randomization list was never observed by any individuals who were responsible for conducting audits or investigations. This test would confirm that the contractor's investigators never saw the randomization list or based their audits on the list.

## 5 Effect of letters on prescribers

### 5.1 Total schedule II prescribing

Our first analysis will look at the effect of the letter on overall schedule II prescribing behavior. The **primary outcome** of the study will be total 30-day equivalent prescriptions at the 3 month horizon. We will study this outcome at the other horizons as secondary outcomes.

In addition we will look at the following measures for schedule II controlled substances as secondary outcomes:

- Total prescriptions filled (known as prescription drug events or PDE)
- Total Part D payments for prescriptions
- Part D payments for prescriptions made by beneficiaries (i.e. out of pocket)
- Part D payments for prescriptions made by plans
- 30 day equivalent prescriptions / number of beneficiaries receiving any prescription from the provider
- 30 day equivalent prescriptions / number of beneficiaries being seen by the physician (e.g. unique beneficiaries receiving an E&M code)

### 5.2 Heterogeneous effects

We will test for heterogeneous effects across several physician categories, which we now describe:

#### 5.2.1 By previous fraud investigation

The letters may have a different effect depending on whether the doctor was already investigated for fraud. To test whether this is the case, we split the sample of physicians into those who were previously investigated for fraud before the letters were sent out vs. those who were not investigated.

We will define fraud investigation on the basis of information in the FID as well as the Health Integrity Tracking System (HITS) database, the Compromised Numbers Database, and the National Fraud Prevention System (NFPS).

#### 5.2.2 By volume of prescribing

The letters may affect physicians at different points in the prescribing distribution differently. To test this, we split the physicians into two groups (above median and below median) based on their total 30-day equivalent prescriptions of schedule II controlled substances before the letters were sent out.

Although the letters were only supposed to be sent to the biggest outlier prescribers, the method of identifying outliers used old data – the prescriber had to be an outlier in 2 years between 2011 and 2013. Thus some prescribers may have reformed their prescription rates by the time the letters were sent. This gives us variation in the prescribing rates which we exploit here.

### 5.2.3 By risk-adjusted volume of prescribing

The CMS method does no risk adjustment, so physicians may be outliers because they are fraudulent prescribers *or* because they have high patient volume or very sick patients. We will risk-adjust the prescriber's 30-day equivalent prescriptions of schedule II controlled substances using his/her patients' characteristics. Then we will divide the prescribers into groups (above median and below median) based on their risk-adjusted volume.

## 5.3 Effects on treatment volume and revenue

We will look at the following outcomes to test for whether the letters affect the prescriber's overall volume and revenue:

- Total 30-day equivalent prescriptions
- Total PDE
- Total Part D payments
- Total number of patient visits (e.g. E&M codes)
- Total number of unique patients
- Total revenue for treating patients
- Revenue per patient visit
- Revenue per unique patient

## 5.4 Effects on distribution of schedule II prescribing

The effects of the letters on the distribution of prescribing behavior are also of interest. To analyze quantile treatment effects, we will run quantile regressions looking at the outcomes in section 5.1. We will look at the following quantiles:

- p10
- p25
- p50
- p75
- p90

## 5.5 Analysis by type of schedule II substance

We will explore whether the letters induce a change in prescribing that is concentrated among particular types of drugs in Schedule II. We will look at 30-day equivalent prescriptions of the following schedule II controlled substance classes:

- Opiates
  - Total opiate 30-day equivalents
  - Morphine equivalent dose (MED) 30-day equivalents
- Stimulants
- Depressants
- Other (precursor drugs, hallucinogens, intermediates)



## 5.6 Substitution toward other schedules

Physicians are told that their Schedule II prescribing is being monitored, which may induce them to substitute their prescriptions toward non-Schedule II drugs. To test for substitution, we will look at the 30-day equivalent prescription and total part D dollars paid for the following substitutes:

- Schedule III drugs
- Schedule IV drugs
- Schedule V drugs
- Sum of Schedule III+IV+V drugs
- Unscheduled drugs
- All drugs excluding Schedule II

And we will next zoom in on the following potential substitutes for schedule II opiates and put 30-day equivalent prescriptions of them (and total part D dollars paid when possible) on the left-hand side:

- Opiates not on schedule II
  - Total opiate 30-day equivalents
  - Morphine equivalent dose (MED) 30-day equivalents
- Non-opioid analgesics
  - Total opiate 30-day equivalents
  - Morphine equivalent dose (MED) 30-day equivalents (if possible)

We will also look at prescriptions of drugs that aid in the treatment of dependency to see if physicians are trying to switch their patients onto them:

- Buprenorphine (schedule III)
- Methadone (schedule II)

## 5.7 Audits and behavior related to evading punishment

The prescriber may react to the letter by changing her behavior in order to avoid an audit or other punishment. We will test whether the letter has the effect of reducing the probability of an audit or punishment happening by exploring outcomes relating to fraud detection and investigation in our data. Some examples include:

- Receipt of an audit by Health Integrity (e.g. the HITS database)
- Receipt of an investigation in the Fraud Investigation Database (FID)
- Being flagged in the Compromised Numbers Database (CNC)
- Being identified as potentially fraudulent by the National Fraud Prevention System (NFPS)
- Revocation of provider from PECOS (e.g. provider is disenrolled from Medicare)

The prescriber may also change his/her address (in the Medicare database or in reality) to reduce the chance of being punished. This action could be evasive or an attempt to correct

the record following earlier evasion. We will explore address change outcomes to uncover evidence of this kind of behavior. Examples include:

- Change of address
- Change of address to better match location of prescribers' patients (e.g. a more accurate address)
- Change of address to a location farther from prescribers' patients (e.g. an apparent move to a new area)
- Change of location of patients (e.g. the prescriber appears to have moved based on the location of residence of his/her patients)

Finally, prescribers may attempt to evade detection by removing themselves from the Medicare system entirely. We will explore outcomes related to leaving the system including, for example:

- Indicators for having no patient visits and/or prescription drug events (defined based on claims or events in the last month of the outcome horizon, not the whole horizon)
- Indicator for having deregistered from PECOS, the Medicare enrollment database

## 5.8 Analysis of prescribing generic vs. brand name

We will look at the 30-day equivalent prescription and total Part D payments for the following:

- Generic schedule II controlled substances
- Brand name schedule II controlled substances

## 6 Effect of letters on patients

We will explore whether the letters induce patients to change their drug use and other behaviors. To do so we will construct a baseline cohort of patients and track the evolution of their behavior after their physicians receive the letters.

### 6.1 Definition of patient cohort

In a patient-level regression, it is important that we analyze a set of beneficiaries defined based on pre-letter criteria. This is because the letter may change the composition of a prescriber's patients — a contemporaneously defined set of patients could differ in unobservables between treatment and control.

Potential patient cohort definitions include:

- Patients who received an evaluation and management (E&M) service from the provider
- Patients who had a schedule II controlled substance prescription from the provider
- Patients who received any prescription from the provider

- Patients who received more than some cutoff of schedule II controlled substances. i.e. high utilizers of controlled substances.

Some patients may be traced to multiple physicians in the sample. In this case the patient will enter the regression multiple times, each instance being attributed to a different physician. In case of this overlap, physicians that are connected by common patients will be part of the same cluster when calculating clustered standard errors.

## 6.2 Patient receipt of schedule II substances

A key question is whether targeting outlier prescribers reduces the receipt of controlled substances by patients – or whether patients find new physicians to supply them with the drugs. To this end, we will analyze the overall receipt of these substances by patients, then break receipt down into the component from the targeted physician and the component from other physicians.

We will put the following patient-level outcomes on the left-hand side:

- Total 30-day equivalent schedule II prescriptions
- Total Part D payments for schedule II prescriptions
- Out of pocket payments for schedule II prescriptions

We will also look at these outcomes defined separately based on prescriptions from (1) the prescriber to which the patient was attributed and (2) all prescribers excluding the one to which the patient was attributed.

## 6.3 Effects on distribution of patient receipt of schedule II substances

The effects of the letters the distribution of patient receipt of the substances are also of interest. To analyze quantile treatment effects, we will run quantile regressions looking at the outcomes in section 6.2. We will look at the following quantiles:

- p10
- p25
- p50
- p75
- p90

## 6.4 Heterogeneous effects

If the letters are causing reductions in the receipt of controlled substances, it would be interesting to see if the reductions were concentrated in certain types of patients. We will examine heterogeneity in effects across a number of different patient groups:

### 6.4.1 By risk for controlled substance abuse

We call on a measure of risk for controlled substance abuse from Parente et al (2004). The paper constructs claims-based markers called CS-PURE that are predictive of such abuse. They propose 10 such markers. We will calculate them using beneficiary claims prior to the

letters being sent. Then we will divide the patients into groups based on the number of CS-PURE markers that were triggered.

The regressions will show whether the effect of the letter is stronger (or weaker) for patients who seem more at risk of controlled substance abuse (as proxied by having more CS-PURE markers).

#### **6.4.2 By prior use of controlled substances**

For all patients in the sample, we calculate their prior utilization of schedule II controlled substances. Then we divide patients into groups based on that utilization. This will show us whether the letters have different effects depending on whether the patient was a high or low user of controlled substances.

One concern with this specification is that if the sample includes low and high prescribing doctors (because some doctors reformed prior to letter receipt), being a low using patient may just proxy for being a patient of a low prescribing doctor. To address this, we can include physician fixed effects in the specification.

#### **6.4.3 By share of substances the patient got from prescriber**

We will explore whether the effects are different for patients who were getting controlled substance prescriptions from other doctors. These patients may be more able to evade any effect of the letter on the targeted doctor.

For each patient, we calculate the percent of her schedule II controlled substances in the prior year that she received from the physician in question. Then we calculate groups based on this share (we may, for example, use two groups: 100% from the physician in question and <100%).

We will consider including physician fixed effects in this specification so that the results are “within” patients attributed to the same prescriber.

### **6.5 Substitution toward other schedules**

If patients are induced to consume fewer schedule II controlled substances, they may substitute toward other (less restrictively controlled) substances. The substitution outcomes we will study are those listed in section 5.6.

### **6.6 Health outcomes**

We will also consider whether the letters have an effect on patients’ health outcomes. By reducing patients’ access to controlled substances, the letters may lead to fewer adverse health outcomes. With less access, patients may be induced to seek mental health treatment. Alternatively, the inability to procure these substances from a legal source may cause patients to substitute toward other (perhaps more dangerous) substances, raising the chance that they experience an adverse outcome.

We will analyze the following health outcomes:

- Any ED encounter
- ED encounter for a drug overdose
- ED encounter for mental health reasons
- Any inpatient stay (including at an inpatient rehabilitation facility)
- Inpatient stay for a drug overdose
- Inpatient stay for mental health reasons
- Receipt of outpatient mental health services (e.g. therapy and counseling)
- Receipt of physical therapy
- Count of physician office visits
- Any change of address
- Change of address to a long term care facility (subject to data availability)
- Change of address to a jail/prison (subject to data availability)
- Death

We will also explore using the letter as an instrument for controlled substance use to establish a causal effect of reduced prescription of controlled substances on health outcomes.

## 7 References

Lock Morgan, Kari and Donald B. Rubin. 2012. "Randomization to Improve Covariate Balance in Experiments." *The Annals of Statistics*, 40(2): 1263-1282.

Parente, Stephen T., Susan S. Kim, Michael D. Finch, Lisa A. Schloff, Thomas S. Rector, Raafat Seifeldin, and J. David Haddox. 2004. "Identifying Controlled Substance Patterns of Utilization Requiring Evaluation Using Administrative Claims Data." *The American Journal of Managed Care*, 10(11): 783-790.

Tukey, John W. 1977. *Exploratory Data Analysis*. Reading, MA: Addison-Wesley.

# APPENDIX

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## 1 Re-Randomization Procedure

The re-randomization procedure, specified prior to randomization, was as follows:

1. Random values are generated. Prescribers with values less than the median are assigned to the control group. All other prescribers are assigned to the treatment group.
2. We test balance for a set of covariates using the Mahalanobis distance. This balance criterion is recommended in Lock Morgan and Rubin (2012), who note that in the two group case it is equivalent to a MANOVA F test. Since we have two groups, treatment and control, we implement the test using MANOVA. It is similar to running individual regressions of each covariate on a treatment indicator, then

jointly testing whether all the coefficients on the treatment indicators equal zero.

The covariates are:

- a. Outlier in 2013 (indicator)
  - b. Outlier in 2012 (indicator)
  - c. Outlier in 2011 (indicator)
  - d. Schedule II PDE Count, 2013
  - e. Schedule II PDE Count, 2012
  - f. Schedule II PDE Count, 2011
  - g. Schedule II Total \$ Paid from Part D, 2013
  - h. Schedule II Total \$ Paid from Part D, 2012
  - i. Schedule II Total \$ Paid from Part D, 2011
  - j. Address in Census Northeast (CT, ME, MA, NH, RI, VT, NJ, NY, PA) (indicator)
  - k. Address in Census Midwest (IL, IN, MI, OH, WI, IA, KS, MN, MO, NE, ND, SD) (indicator)
  - l. Address in Census West (AZ, CO, ID, MT, NV, NM, UT, WY, AK, CA, HI, OR, WA) (indicator)
  - m. Specialty is General Care Practitioner (indicator)
  - n. Specialty is Nurse Practitioner or Physician Assistant (indicator)
  - o. Specialty is Anesthesiology or Pain Medicine or Physical Medicine & Rehabilitation (indicator)
3. If the p-value of the F test is  $< 0.4$ , return to step 1 and restart the procedure. Otherwise accept the randomization.

## 2 Poisson Regression Specification

We may consider Poisson regressions because we are often interested in percent changes in outcomes due to the letter. The Poisson regression will let us produce these statistics even if the outcome is sometimes zero.

The regressions will assume that the physician-level outcome takes the form:

$$y_i = \exp(\alpha + \beta * treat_i + X_i\Gamma) + e_i$$

And they will assume that the patient-level outcome takes the form:

$$y_j = \exp(\alpha + \beta * treat_{i(j)} + X_{i(j)}\Gamma + Z_j\Theta) + e_j$$

The coefficient of interest in the Poisson regressions is  $\beta$ . This coefficient can be interpreted as the percent change in  $y$  due to the letter, analogous to an OLS regression with  $\ln(y)$  on the left-hand side.

# Attachments

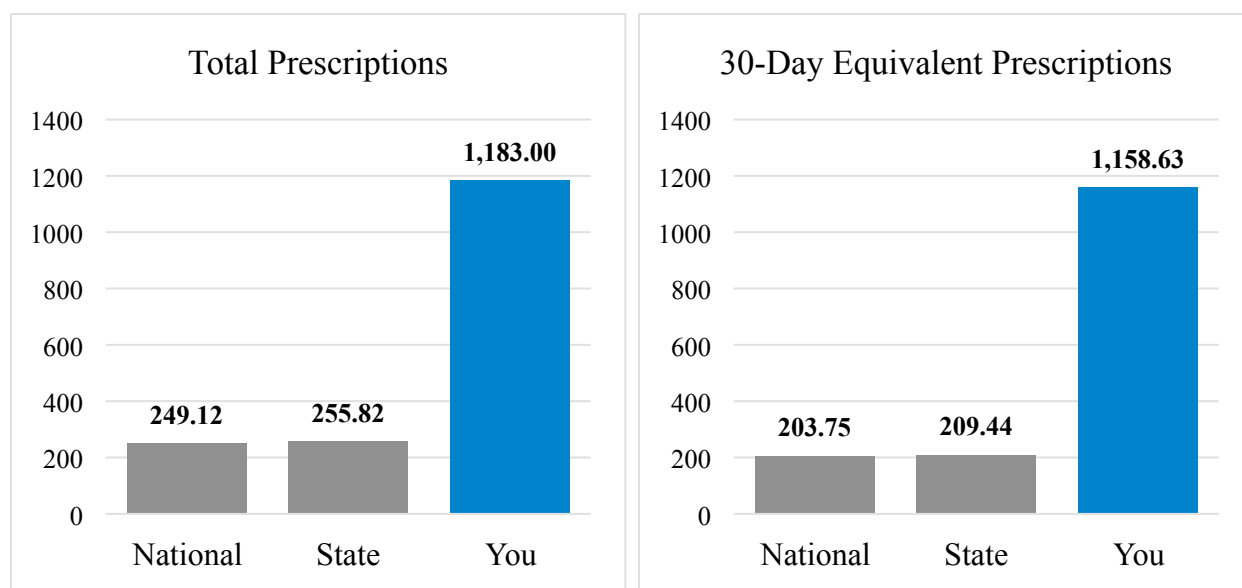
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**Sample of letter sent to treatment group prescribers follows on next page.**

September 5, 2014

Pat Q. Provider MD  
1234 Main St  
Columbia, MD 21045  
NPI: 1234567890  
Specialty: General Care Practitioner

**Re: You prescribed 362% MORE Schedule II controlled substances than your peers.**



Dear Dr. Provider,

The figures above display the total count (left) and 30-day equivalent (right) of your Schedule II prescribing, compared to the national and state averages of those within your specialty. As can be seen, you prescribed far more – 362% more – than similar specialists within your state.

We hope that you will use the information provided to see if your high prescribing level is appropriate for your patient population. Read on for more information about the methodology used to analyze your prescribing behavior, and to learn what actions to take next.

Sincerely,

Mark Majestic, Director  
Medicare Program Integrity Group




## Introduction

Prescribers and pharmacies have a frontline role in assisting the Centers for Medicare & Medicaid Services (CMS) to effectively manage Medicare resources and monitor prescribing practices. CMS and its partners acknowledge the daily challenges prescribers and pharmacies face in serving Medicare beneficiaries and the complexity of billing for prescription drugs.

The Office of Inspector General (OIG) released a study in June 2013 showing over 1 million individual prescribers ordered drugs paid by Medicare Part D in 2009. Prescribing patterns varied widely by specialty. Over 700 general-care physicians had questionable prescribing patterns.<sup>1</sup> Although some of this prescribing may be appropriate, the OIG's study expressed the need to further scrutinize such questionable patterns.

Using a similar methodology to that used in the OIG study, CMS analyzed prescription drug event (PDE)<sup>2</sup> data for 2012 and 2013. Based on this analysis, CMS has determined that the number and quantity of your Schedule II prescriptions exceeded the established threshold (see box on right). The intent of this letter is to inform you of the extent of your potential outlier status relative to the Schedule II controlled drugs attributed to your prescribing practice compared to your peers within your specialty and state.



**Methodology**  
  
To learn more, visit:  
<http://go.cms.gov/CPImethodologyhr1>

We hope you find this information helpful and that it will provide insights into your current and future prescribing practices. We also hope that you will use the information provided to see if your high prescribing level for Schedule II drugs is appropriate for your patient population.

## Your Results

Table Key:

**PDE:** The number of Schedule II prescriptions attributed to you

**30-Day:** The aggregate “days’ supply” of your Schedule II prescriptions divided by 30

**Table 1: Summary of Values Used to Determine Your Status**

| Categories                     | PDE     | 30-Day  |
|--------------------------------|---------|---------|
| <b>Your Values</b>             | 1183.00 | 1158.63 |
| <b>State Specialty Mean</b>    | 255.82  | 209.44  |
| <b>National Specialty Mean</b> | 249.12  | 203.75  |

<sup>1</sup> OIG, Prescribers with Questionable Patterns in Medicare Part D, OEI-02-09-00603, June 2013

<sup>2</sup> A Prescription Drug Event (PDE) is a summary record submitted by a drug plan sponsor every time a beneficiary fills a prescription under Medicare Part D. The PDE data are not the same as individual drug claim transactions, but are summary extracts using CMS-defined standard fields. The PDE record contains prescription drug cost and payment data that enables CMS to make payments to plans and otherwise administer the Part D benefit. Further information can be found by accessing the following link: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PartDDData.html>

## Action

After reviewing this communication, you may be able to identify areas where your prescribing patterns could be modified, and we encourage you to share the trends that were identified with other clinicians. We hope you find this information helpful and that it will provide insight into your current and future prescribing practices.

If you would like to provide feedback on this analysis, please contact the NBI MEDIC at 1-877-7SafeRx (1-877-772-3379) or CMS at [CPIMedicarePartD\\_Data@cms.hhs.gov](mailto:CPIMedicarePartD_Data@cms.hhs.gov). If you believe your prescriptions are being forged, please contact the NBI MEDIC at 1-877-7SafeRx (1-877-772-3379).

If you would like more resources for detecting possible drug-seeking behavior on the part of your patients, please review the MLN Matters article on Prescription Drug Monitoring Programs (PDMPs) at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1250.pdf> on the CMS website.

Thank you for your diligence and partnership with CMS in detecting, deterring and preventing fraud, waste and abuse in the Medicare Part C and Part D programs.