# U.S. OFFICE OF PERSONNEL MANAGEMENT
# OFFICE OF THE INSPECTOR GENERAL
# OFFICE OF AUDITS

# Final Audit Report

## Limited-Scope Audit of Blue Cross Blue Shield's Opioid Claims as Administered by CVS Caremark For the Service Benefit Plan in Contract Years 2017 through 2019

**Report Number 1H-01-00-20-015**
**May 26, 2021**

# EXECUTIVE SUMMARY

Limited-Scope Audit of Blue Cross Blue Shield's Opioid Claims as Administered by CVS Caremark for the Service Benefit Plan in Contract Years 2017 through 2019

**Report No. 1H-01-00-20-015** **May 26, 2021**

**Why Did We Conduct the Audit?**

The objective of the audit was to ensure that the Blue Cross Blue Shield Association (Carrier) and CVS Caremark (Pharmacy Benefit Manager or PBM) had proper controls in place to safely prescribe and dispense opioids to members of the Service Benefit Plan (Plan). Our audit covered contract years (CY) 2017 through 2019.

**What Did We Audit?**

The U.S. Office of Personnel Management, Office of the Inspector General has completed a limited-scope audit of the Plan's opioid claims that were processed by the PBM in CY 2017 through 2019. Our audit included a review of the Plan's opioid utilization and trends, fraud and abuse program, and opioid claims processing to determine if there were sufficient policies and procedures in place to reduce opioid misuse. We conducted fieldwork remotely from our offices in Cranberry Township, Pennsylvania and Jacksonville, Florida from May 26 to November 19, 2020.

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***Assistant Inspector General for Audits***

**What Did We Find?**

We determined that the Plan's opioid drug claims have decreased from 2017 through 2019 while membership remained steady. Although industry improvements were made over the years to help combat the opioid epidemic, our testing shows that the PBM needs to strengthen its controls to ensure that only allowable opioids are safely prescribed and dispensed to Plan members in order to help reduce the risk of opioid misuse.

Our audit results are summarized as follows:

- The PBM's claim system lacks edits that limit excessive quantities of opioids from being processed and paid for prescriptions that are for less than a 90-day supply in accordance with Centers for Disease Control and Prevention guidelines and the Carrier's policies.

- The PBM paid claims that exceeded a 7-day supply for opioid naïve members, and paid claims that exceeded 50 morphine milligram equivalent (MME) per day for immediate-release opioid and opioid combination drugs, without obtaining the prior approvals required by the Carrier's policies. This occurred because the PBM does not have the ability to calculate the daily MME on opioid prescriptions that are less than a 90-day supply (the majority of opioid prescriptions).

# ABBREVIATIONS

| | |
|---|---|
| **Carrier** | **Blue Cross Blue Shield Association** |
| **CDC** | **Centers for Disease Control and Prevention** |
| **CY** | **Contract Year** |
| **ER** | **Extended-Release** |
| **FEHBP** | **Federal Employees Health Benefits Program** |
| **HIO** | **OPM's Healthcare and Insurance Office** |
| **IR** | **Immediate-Release** |
| **MME** | **Morphine Milligram Equivalent** |
| **OIG** | **Office of the Inspector General** |
| **OPM** | **U.S. Office of Personnel Management** |
| **PA** | **Prior Approvals** |
| **PBM** | **Pharmacy Benefit Manager (CVS Caremark)** |
| **Plan** | **Service Benefit Plan** |
| **QVT** | **Quantity vs. Time** |
| **SIU** | **Special Investigations Unit** |

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# I. BACKGROUND

This report details the results of our limited-scope audit of Blue Cross Blue Shield Association's (Carrier) opioid claims as administered by CVS Caremark, the Carrier's Pharmacy Benefit Manager (PBM), for the Service Benefit Plan (Plan) in contract years (CY) 2017 through 2019. The audit included a review of the Plan's opioid utilization and trends, fraud and abuse program, and opioid claims processing. The audit was performed by the U.S. Office of Personnel Management's (OPM) Office of the Inspector General (OIG), as established by the Inspector General Act of 1978, as amended.

The Federal Employees Health Benefits Program (FEHBP) was established by the Federal Employees Health Benefits Act (Act), Public Law 86-382, enacted on September 28, 1959. The FEHBP was created to provide health insurance benefits for Federal employees, annuitants, and dependents. OPM's Healthcare and Insurance Office (HIO) has the overall responsibility for the administration of the FEHBP, including the publication of program regulations and agency guidance. As part of its administrative responsibilities, the HIO contracts with various health insurance carriers that provide service benefits, indemnity benefits, and/or comprehensive medical services. The provisions of the Act are implemented by OPM through regulations codified in 5 Code of Federal Regulations 890.

Pharmacy benefit managers are primarily responsible for processing and paying prescription drug claims. The services provided typically include retail pharmacy, mail order, and specialty drug benefits. For drugs acquired through retail, the PBM contracts directly with the approximately 50,000 retail pharmacies located throughout the United States. For maintenance prescriptions that typically do not need to be filled immediately, the PBM offers the option of a mail order pharmacy benefit. The PBM also provides specialty pharmacy services for members with rare and/or chronic medical conditions. The Carrier uses the PBM to develop, allocate, and control costs related to the pharmacy claims program.

The Carrier contracted with the PBM, located in Scottsdale, Arizona, to provide pharmacy benefits and services to Plan members in CYs 2017 through 2019. Section 1.11 of OPM Contract Number CS 1039 includes a provision that allows for audits of the program's operations. Our responsibility is to review the performance of the PBM to obtain reasonable assurance that only allowable opioid claims were safely prescribed and dispensed to Plan members and to determine if there were sufficient policies and procedures in place to reduce opioid misuse.

This is the OIG's first audit of the Plan's opioid drug claims as administered by the PBM. We discussed the results of our audit with Carrier and PBM officials at an exit conference on November 19, 2020. In addition, we provided a draft report, dated February 9, 2021, to the Carrier and PBM for review and comment. We considered the Carrier and the PBM's combined response to the draft report in preparing the final report and included the response as an Appendix to this report.

# II. OBJECTIVES, SCOPE, AND METHODOLOGY

## OBJECTIVES

The main objective of the audit was to ensure that the Carrier and the PBM had proper controls in place to safely prescribe and dispense opioids to Plan members in order to help reduce opioid misuse for CYs 2017 through 2019.

Our specific audit objectives were to determine:

**Opioid Utilization and Trends**

- The annual cost and total number of opioid claims each year along with the number of members, providers, and pharmacies associated with those claims.
- The trends in opioid utilization and to assess whether the Plan's opioid strategies reduced utilization among Plan members.
- The top 50 members with the most opioid claims for each year of the scope and identify trends among the highest utilizers.
- The top 50 providers who dispensed the most opioid claims each year of the scope and identify trends among the highest prescribers.

**Fraud and Abuse Program**

- Whether the Carrier's Special Investigations Unit's (SIU) initiatives and outreach efforts were sufficient to combat the opioid epidemic.
- Whether the Carrier and the PBM complied with the fraud, waste, and abuse requirements found in Carrier Letters 2017-13 and 2014-29, and if potential fraud cases were being reported to OPM.
- If the Carrier's and the PBM's opioid policies and procedures related to their fraud and abuse program were sufficient in identifying excessive amounts of opioids in prescriptions and providers who were potentially overprescribing when not medically necessary.

**Opioid Claims Processing**

- If the Carrier paid claims for any Schedule I drugs in 2019.
- If the Carrier paid claims for any Schedule II drug refills in 2019.
- Whether the Carrier paid opioid claims without a prescriber's National Provider Identifier in 2019.
- Whether the Carrier had sufficient controls in place to ensure paid claims for prescriptions contained all requirements for a controlled substance.
- If the Carrier paid claims for greater than a 90-day supply of Schedule II drugs in 2019.
- If the Carrier paid claims for members who exceeded the maximum daily dose

(4,000 mg) of acetaminophen in 2019. Additionally, to determine whether the Carrier had sufficient controls in place to ensure the safe prescribing of acetaminophen in combination with opioids.

- Whether the Carrier paid claims in 2019 for dependents, under the age of 18, who received an opioid prescription with a supply exceeding seven days. Additionally, to determine whether the Carrier had sufficient controls in place to ensure the safe use of opioids by dependents under the age of 18.
- Whether the 2019 opioid claims with a morphine milligram equivalent (MME) over 300 received a prior approval (PA) indicating active cancer or a terminally ill patient, and to determine whether the PBM had sufficient controls in place to limit excessive quantities of opioids in accordance with the Carrier's PA policies.

## SCOPE AND METHODOLOGY

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient and appropriate evidence to provide a reasonable basis for our findings and conclusions based on the audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on the audit objectives.

This performance audit included a review of the Plan's opioid utilization and trends, fraud and abuse program, and opioid claims processing to determine if there were sufficient policies and procedures in place to reduce opioid misuse for CYs 2017 through 2019. We conducted fieldwork remotely from our offices in Cranberry Township, Pennsylvania and Jacksonville, Florida from May 26, 2020, to November 19, 2020.

The Carrier is responsible for providing FEHBP members with medical and prescription drug benefits. To meet this responsibility, the Carrier collected healthcare premium payments of approximately $[redacted] dollars in CYs 2017 through 2019, of which approximately two-thirds was paid by the government on behalf of Federal employees. In its annual accounting statements, the Carrier reported total pharmacy claims paid of approximately $[redacted] for CYs 2017 through 2019 (See below).

| Contract Year | Earned Healthcare Premiums | Amount of Pharmacy Claims Paid | Amount of Medical Claims Paid |
|---|---|---|---|
| **2017** | $[redacted] | $[redacted] | $[redacted] |
| **2018** | $[redacted] | $[redacted]* | $[redacted] |
| **2019** | $[redacted] | $[redacted]* | $[redacted] |
| **Totals** | **$**[redacted] | **$**[redacted] | **$**[redacted] |

* Denotes the amount of claims paid for retail and mail order pharmacies only since specialty was managed by a different PBM beginning in 2018.

In planning and conducting the audit, we obtained an understanding of the Carrier's and the PBM's internal control structures to help determine the nature, timing, and extent of our auditing procedures. This was determined to be the most effective approach to select areas of audit. For those areas selected, we primarily relied on substantive tests of transactions and not tests of controls. Additionally, since our audit would not necessarily disclose all significant matters in the internal control structure, we do not express an opinion on the Carrier's and the PBM's systems of internal controls taken as a whole.

We also conducted tests of accounting records and other auditing procedures as we considered necessary to obtain reasonable assurance that only allowable opioid claims were safely prescribed and dispensed to Plan members, and that the Carrier and PBM had sufficient controls in place to reduce opioid misuse. Exceptions noted in the areas reviewed are set forth in the "Audit Findings and Recommendations" section of this report. With respect to the items not tested, nothing came to our attention that caused us to believe that the Carrier and the PBM had not complied, in all material respects, with those provisions.

In conducting the audit, we relied to varying degrees on computer-generated data provided by the Carrier and PBM. Due to time constraints, we did not verify the reliability of the data generated by the various information systems involved. However, while utilizing the computer-generated data during our audit, nothing came to our attention to cause us to doubt its reliability. We believe that the data was sufficient to achieve our audit objectives.

To obtain reasonable assurance that only allowable opioids were safely prescribed and dispensed to Plan members, and that the Carrier and PBM had sufficient controls in place to reduce opioid misuse for CYs 2017 through 2019, we performed the following audit steps (all claims testing was completed using the most recent 2019 data):

**Opioid Utilization and Trends**

- We identified the annual trend for each year of the audit scope showing opioid utilization among members, providers, and pharmacies.

- We identified the top 50 members with the most opioid claims for each year of the audit scope (out of a cumulative total of 2,919,893 members) to determine if any patterns existed among them.

- We identified the top 50 providers who prescribed the highest quantity of opioids for each year of the scope (out of a cumulative total of 1,217,612 providers) to determine if any patterns existed among them.

**Fraud and Abuse Program**

- We reviewed the Carrier's response to OPM's call letters for 2018 and 2019, as well as its policies and procedures related to the PA process, to determine whether the Carrier's SIU initiatives and outreach efforts were sufficient to combat the opioid epidemic.

- We reviewed the Carrier's policies and procedures for fraud and abuse to ensure that they complied with Carrier Letters 2017-13 and 2014-29. Additionally, we reviewed all potential fraud and abuse cases that the PBM reported to the Carrier, to determine if those cases were subsequently reported to OPM.

- From a population of 4,365 opioid claims with an MME over 300 for 2019, we tested the Carrier and PBM's opioid policies and procedures related to their fraud and abuse programs and identified providers who were possibly overprescribing opioids when not medically necessary.

**Opioid Claims Processing**

- We reviewed all 2019 prescription drug claims (81,635,356 claims totaling $[redacted]) to determine if any benefits were paid for Schedule I narcotics.

- We reviewed all 2019 opioid claims (2,923,315 claims totaling [redacted]) to determine if any were paid for Schedule II drug refills, missing prescriber National Provider Identifiers, or were for day supplies over 90.

- From a population of 4,365 opioid claims with an MME over 300 for 2019, we randomly selected (using a random number generator in Excel) a sample of 50 claims and reviewed their prescriptions to ensure that they contained all of the Drug Enforcement Administration's requirements for a controlled substance.

- We reviewed all 2019 opioid combination drugs with acetaminophen to determine if the PBM had proper controls in place to regulate amounts exceeding the recommended maximum daily dose of 4,000 mg of acetaminophen.

- From the universe of 2,923,315 opioid claims for 2019, totaling [redacted], we reviewed all opioid claims that exceeded a 7-day supply for dependents age 17 and under to determine how many potentially unallowable claims were processed by the PBM. From that subset of 572 opioid claims for 363 dependents, we then randomly selected (using a random number generator in Excel) a sample of 50 dependents age 17 and under, totaling 114 opioid claims, to determine if the PBM had sufficient controls in place to limit opioids for dependents in accordance with the Carrier's policies.

- We reviewed the population of 2019 opioid claims with an MME greater than 300, totaling 4,365 claims for 1,066 members, to determine whether the PBM had sufficient controls in place to limit the quantity of opioids in accordance with the Carrier's policies.

The samples that were selected and reviewed in performing the audit were not statistically based. Consequently, the results were not projected to the universe since it is unlikely that the results are representative of the universe taken as a whole.

# III. AUDIT FINDINGS AND RECOMMENDATIONS

## A. OPIOID UTILIZATION AND TRENDS

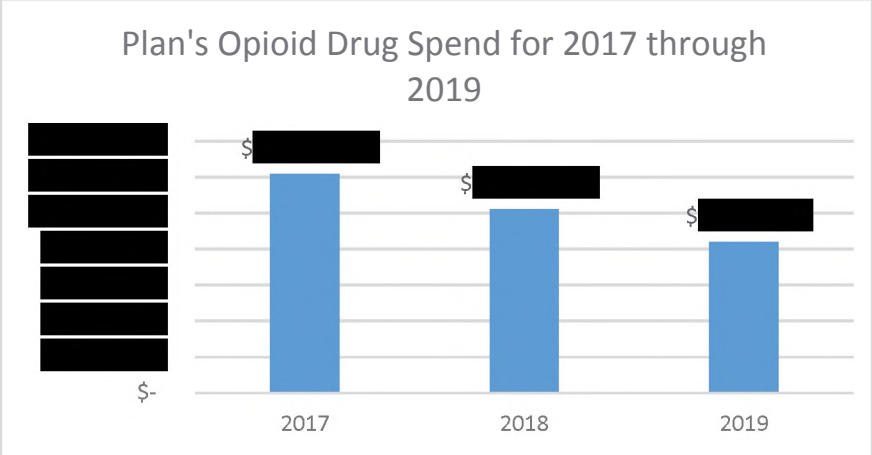
On October 26, 2017, then President Donald J. Trump issued a memorandum, *Combatting the National Drug Demand and Opioid Crisis*, which declared the opioid epidemic as a national public health emergency. The former President instructed Federal agencies to take action to combat the opioid epidemic and exercise appropriate emergency authorities to reduce the number of deaths and minimize the devastation that the drug demand has had on communities. As a result of the former President's memorandum, OPM issued a carrier letter requiring FEHBP carriers to strengthen their efforts to prevent opioid misuse and treat addiction.

In response to OPM's request for health insurance carriers to strengthen controls related to opioid usage within the FEHBP, the Carrier developed policies and procedures based on the Centers for Disease Control and Prevention's (CDC) *Guidelines for Prescribing Opioids for Chronic Pain* to limit the quantity and duration of opioid prescriptions for its Plan members. Additionally, the PBM implemented system edits to ensure that opioids are being prescribed and used appropriately to prospectively mitigate the risk of opioid misuse. Furthermore, the Carrier and the PBM developed and implemented numerous Member Quality Assurance Programs to retrospectively review opioid utilization and the prescribing patterns of providers, plus they established outreach programs to educate providers on safe prescribing practices and members about the risks of opioid use.

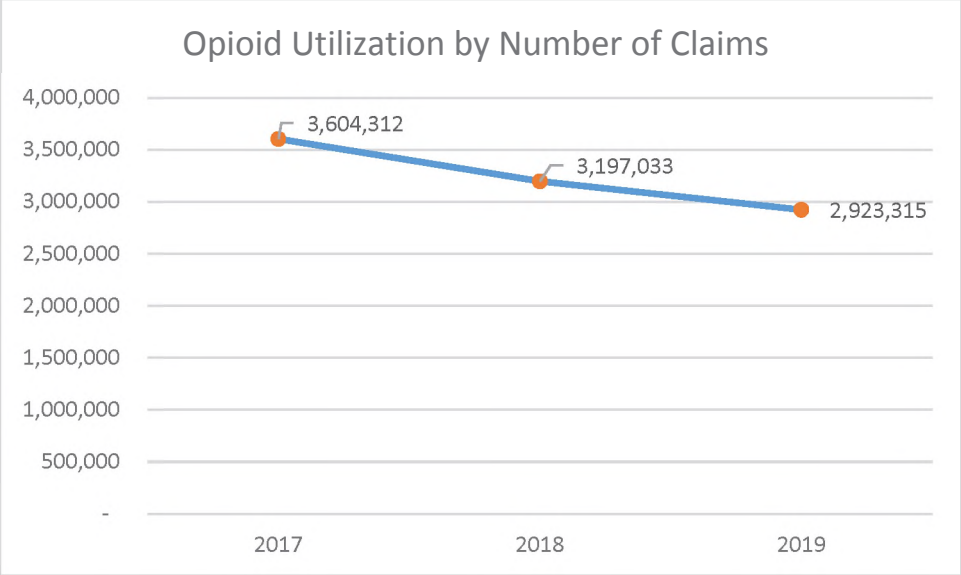
Overall Opioid Utilization within the Plan

Based on our review of the Plan's opioid prescription drug claims from 2017 through 2019, we identified an overall decrease in utilization of opioids during this 3-year period in both the number of claims and the quantity dispensed (membership remained steady at 5.4 million). Specifically, we found the following downward trends in opioid utilization for the scope of our audit:

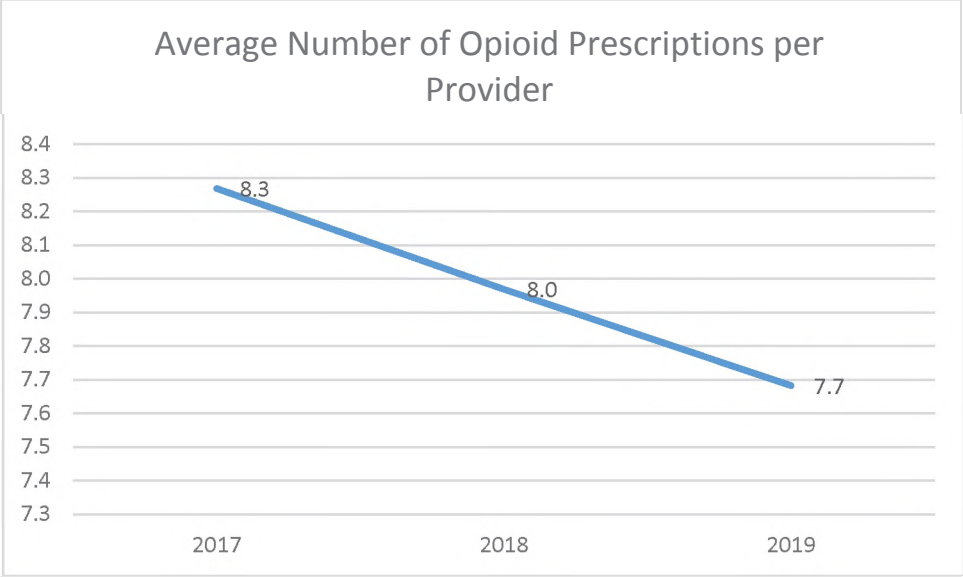
- The Plan's annual opioid drug spend decreased by approximately 31 percent ($[redacted] million to $[redacted] million);



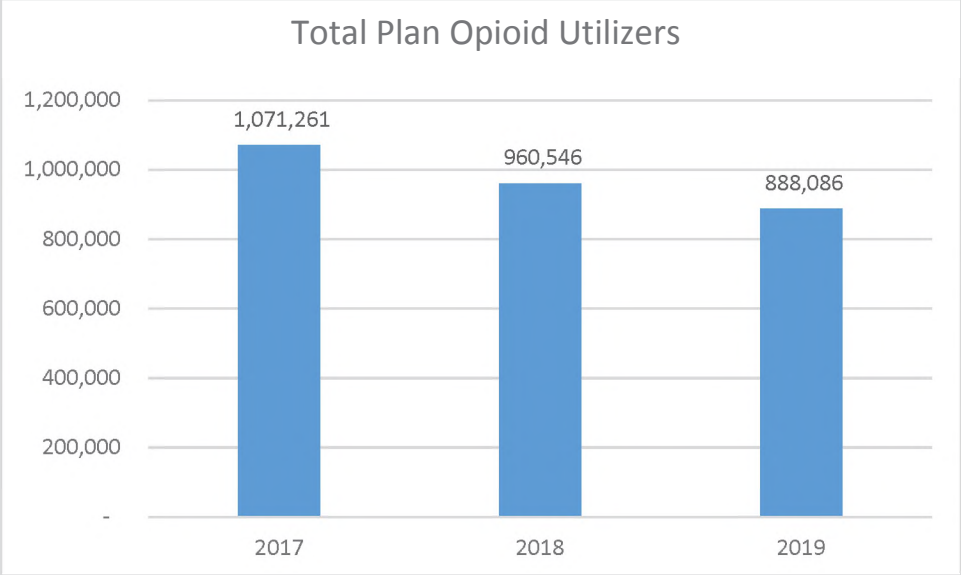
- The number of annual opioid claims decreased by approximately 19 percent (3.6 million to 2.9 million);



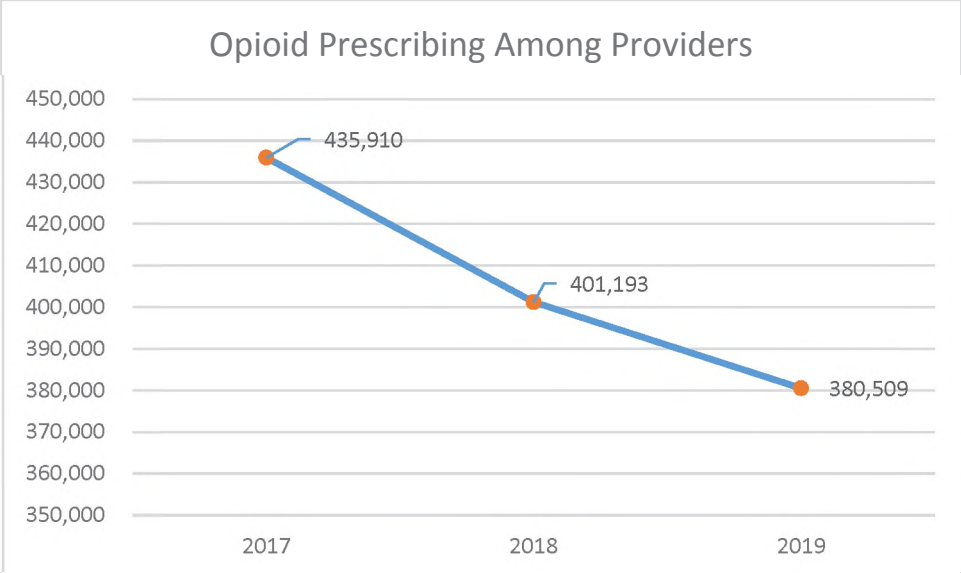

- The average number of annual opioid claims per each prescriber in the opioid population (all claims in which opioids were dispensed) decreased 7 percent (8.3 to 7.7 opioid claims per each provider who prescribed opioids);



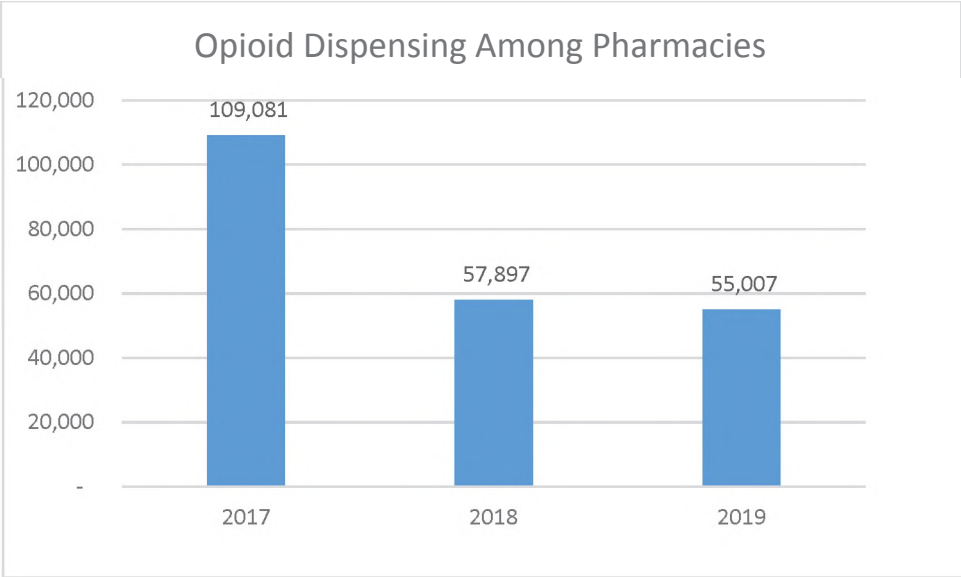
- The annual number of Plan members using opioids decreased by approximately 17 percent (1,071,261 to 888,086);




- The annual number of opioid prescribers decreased by approximately 13 percent (435,910 to 380,509); and



- The annual number of pharmacies dispensing opioids decreased by approximately 50 percent (109,081 to 55,007).




Trends among the Highest Member Utilizers

Among the top 50 opioid utilizers each year from 2017 through 2019, we found that:

- 22 percent of the utilizers were the same in each year; and
- Half of the utilizers were the same in two out of the three years.

Trends among the Highest Prescribing Providers

Among the top 50 opioid prescribers each year from 2017 through 2019, we found that:

- Half of the prescribers were the same in each year;
- The majority of the prescribers were Pain Management Specialists; and
- Oklahoma and Alabama had the most prescribers in each year.

## B. FRAUD AND ABUSE PROGRAM

To test the Carrier's and the PBM's opioid policies and procedures related to their fraud and abuse programs, we reviewed all 2019 opioid claims that exceeded 300 MME in order to identify providers who were potentially overprescribing opioids when not medically necessary. After excluding active cancer treatment, palliative care, end-of-life care, and substance abuse treatment, our review identified 59 new (never reported) potential fraud and abuse cases that were referred to the Carrier and the PBM's SIU for further review related to the overprescribing of opioids. Additionally, we referred 3 out of the 50 highest prescribers from 2019 to the SIUs

based on concerns arising from both the type of medical practice prescribing opioids as well as the volume of opioids prescribed.

The PBM reviewed our 62 fraud and abuse referrals, and determined that 7 cases required further investigation. There were no other exceptions noted in this area, and there will be no findings related to identifying fraud and abuse since these were only referrals.

## C. OPIOID CLAIMS PROCESSING

### 1. Insufficient System Edits for Excessive Opioids — Procedural

During our review of the Plan's 2019 opioid claims, we found that the PBM processed and paid 30,014 claims for opioids exceeding the Carrier's policy limit of 200 MME per day. In addition, a more detailed review of the 2019 opioid claims exceeding 300 MME showed that 53 percent of the claims were processed and paid without the PAs that were required by the Carrier to document a medically necessary exception (i.e., terminally ill and cancer patients).

**The PBM lacked sufficient system edits to limit the quantity of opioids in accordance with the CDC's guidelines and the Carrier's policies.**

The CDC's *Guidelines for Prescribing Opioids for Chronic Pain*, issued in 2016, recommended limiting the quantity of opioids prescribed to 90 MME per day and having providers carefully justify decisions to exceed 90 MME per day based on diagnosis and an individualized assessment of benefits and risks.

Additionally, the Carrier developed PA criteria based on the CDC's *Guidelines for Prescribing Opioids for Chronic Pain* that allowed the following:

- A pre-PA allowance (quantity available without PA) of up to 90 MME per day for both extended-release (ER) opioid drugs and immediate-release (IR) opioid drugs.
- A maximum quantity limit (quantity available when the PA criteria requirements are met and the Carrier has authorized the request) of 200 MME per day, with a PA, for both ER and IR opioid drugs.
- A pre-PA allowance limit at 50 MME per day and PA limit of 90 MME per day when opioid combination drugs are prescribed for chronic pain.

As part of our review, we originally selected all opioid claims that exceeded 200 MME from the most recent year of our audit scope to determine if the proper controls were in place to reduce opioid misuse. Due to the population over 200 MME being too large (30,014 claims), we reduced our review to all opioid claims exceeding 300 MME per day. Based on our review of this population over 300 MME, we found that the PBM processed and paid 2,333 out of 4,365 opioid claims exceeding 300 MME without ever having PAs. When we

provided the claims to the PBM, it stated that the system edits to prevent members from receiving a cumulative quantity of opioids over 300 MME were not in effect until January 1, 2020. The PBM also stated that the PA limits did not pertain to all opioids (i.e., no edit for fentanyl patches) since it could not implement point-of-sale edits or a way to calculate MME from the day supply. Instead, the MME limit is calculated based on a quantity of opioids (i.e., number of pills) per each National Drug Code that exceeds 200 MME, or the later 300 MME, over a 90-day period. While we acknowledge that the PBM's edits to limit a cumulative quantity exceeding 300 MME were not in effect in 2019, the Carrier still had a policy that required PAs for opioids exceeding 90 MME per day, and an overall limit not to exceed 200 MME per day since 2018.

Additionally, the PBM's edit that calculates MME based on the quantity of opioids spread out over a 90-day period is flawed. Since the majority of opioids dispensed are limited to a 30-day supply, the 90-day quantity limit is three times greater than the maximum daily MME limit for a 30-day supply (e.g., the same quantity of opioids for 200 MME over 90 days equates to 600 MME over 30 days). This means that the daily MME can easily exceed the limits set by the Carrier and CDC for most, if not all opioid prescriptions, thereby making the PBM's 90-day edit ineffective at combatting opioid addiction.

Without point-of-sale edits in place that require PAs for opioids exceeding 90 MME per day and limit opioid claims to 200 MME per day (regardless of the day supply), the Carrier is unable to fully implement its policy to help reduce fraud and abuse related to opioids that are less than a 90-day supply. As a result, the Carrier and the PBM lack adequate controls to help reduce the overprescribing of opioids when not medically necessary, thereby causing a patient safety risk to FEHBP members.

**Recommendation 1**

We recommend that the PBM implement point-of-sale edits that calculate MME based on the actual day supply instead of a maximum quantity limit for the opioid taken over a 90-day period. If the PBM is unable to calculate the true daily MME, it should then base the maximum quantity limits on the more common 30-day supply instead of 90 days.

**PBM's Response:**

**"The Plan has managed opioids even before the CDC Guideline … were released in 2016, and has continued to implement edits through 2020. … Controls were implemented pursuant to a phased-in strategy that took into account a gradual tapering we refer to as a 'stepwise' reduction in opioid use among Plan members to ensure that these members were not abruptly discontinuing their opioid therapy. This strategy also ensured that there were programs in place to ensure that behavioral support programs and non-opioid therapy options for pain were also available to members. This more evolved approach has been strongly advocated by the CDC since the Guideline was released.**

**Caremark maintains that it has edits in place that sufficiently limit excessive opioid prescriptions and use. Caremark utilizes a quantity-versus time (QVT) edit equivalent to 90 milligram morphine equivalents (MME) per 90 days, and a cumulative 300 MME/day edit that will require a prior authorization (PA).**

**The report asserts that the edits are flawed because they calculate MME over a 90-day period rather than a 30-day period, which allows for the possibility of the member exceeding 200 MME/day for a shorter period. However, the OIG-recommended 30-day edit would not remedy the short-term excessive use concern identified. A member with a 30-day prescription that is under the 90 MME limit could exceed 200 MME/day for up to two weeks, and any prescription totaling more than 200 MME over any period is subject to potential excessive use over a shorter period of time than the intended prescription duration.**

**A QVT-based strategy was determined to be the best way to manage patients in a phase-in approach based on consideration of the CDC Guideline and consultation with OPM. QVT is a commonly-used quantity-limit mechanism utilized by payers across the industry. It provides flexibility for the payer to control the number of units a member can access over a defined period of time while ensuring that members have adequate access to treatment for chronic pain. The combination of the QVT edit and the maximum MME/day edit sufficiently address excessive use concerns."**

**<u>Carrier's Response</u>:**

**"As the report notes, the CDC issued Guideline limiting prescriptions for opioids that exceed 90 MME/day without justification, and in 2019, BCBSA developed QVT guidelines consistent with the CDC's Guideline limiting prescriptions to 90 MME/day without PA. Caremark implemented edits consistent with these guidelines in 2020.**

**BCBSA is confident that the existing controls strike a successful balance between monitoring and preventing excessive opioid use, on the one hand, and ensuring adequate access to appropriate medication for members and respect for decisions of licensed physicians and pharmacists, on the other hand. These controls include not just the edits, but claims review by Caremark's MQA Department for potential safety concerns. As the report notes, these controls resulted in a 31% decrease in opioid spend and a 19% decrease in opioid claims over the period examined. BCBSA's data further demonstrates that long-acting opioid MME average usage decreased by 26% between 2016 and 2020. … BCBSA contends that these results demonstrate successful efforts to limit opioid quantities. While BCBSA acknowledges the continuing risk of short-term overuse of a prescribed supply, a shorter edit period would not address this concern, and BCBSA firmly believes that additional restrictive measures would likely unreasonably restrict members from accessing medically-necessary medication.**

**For these reasons, BCBSA disagrees with Recommendation 1. The OIG-recommended edits would not eliminate the possibility of short-term misuse. As the current edits have successfully reduced opioid use, BCBSA's position is that modifications to the edits are unwarranted absent evidence that the OIG-recommended edit would lead to superior outcomes without excessive burden on members in need of pain medication."**

**OIG Comments:**

The PBM and the Carrier both acknowledge that members can exceed the daily MME limits listed in their policies when receiving less than a 90-day supply. Instead of calculating MME based on the actual day supply, the PBM and the Carrier are more focused on long term use of opioids over a 90-day period, known as the QVT edit. This is the critical issue being questioned since the QVT edit does not curb opioid addiction or abuse that can affect a member using a large quantity of opioids in a short period of time. If the QVT edit is the industry standard from which we continue seeing an opioid epidemic, then the PBMs need to do more to reduce opioid abuse, starting with limiting the large quantities of opioids being dispensed in a short period of time. The best edit to address this issue is to calculate the actual daily MME based on the prescription's day supply at the point-of-sale.

Additionally, greater than 98 percent of the opioid prescriptions are 30 days or less, meaning the PBM's edits fail to accurately calculate the daily MME on most of the opioid prescriptions that it processes. The PBM and the Carrier should not ignore large quantities of opioids prescribed over what they consider a short period of time (less than 90 days). Addiction can start in as soon as five days with the chance of opioid overdose doubling at 50 MME per day. The OIG recommends an edit that simply calculates MME based on the prescription's day supply. A member taking 200-300 MME of opioids every day for a 90-day period is too much and too long. Even worse is taking that maximum quantity of opioids allowed for a 90-day period and having a member obtain that same quantity with a prescription lasting only a few days or weeks.

Finally, the PBM and the Carrier should not rely heavily on the prescribers and pharmacies to properly prescribe and dispense opioids. This reliance alone is not working effectively as evidenced by opioid misuse reaching epidemic proportions in the United States. The PBM and the Carrier have an opportunity to add another layer of safety edits to address inappropriate utilization at the time of dispensing by limiting MME based on the day supply.

**Recommendation 2**

We recommend that the PBM require PAs for opioids exceeding 90 MME per day, and reject claims over 200 MME per day, unless the PA shows that the patient is excluded from the limitation due to active cancer, palliative, or other end-of-life care.

**Carrier's Response:**

**"BCBSA will need to discuss this recommendation with the OPM contracting officer in order to determine the best way to manage the potential member impact. We estimate that a 90 MME/day PA requirement would affect 12,865 Plan members. If this recommendation is implemented, these members would all require a PA to continue treatment. If this recommendation were implemented, many FDA-approved products such as morphine 100 mg, Opana ER 40 mg, Oxycontin 80 mg, and Nucynta 250 mg would all require PA because the morphine equivalence in these standard doses exceeds 90 MME. BCBSA will also need to discuss the 200 MME/day maximum dose edit under consideration with OPM. Setting a point-of-sale (POS) maximum MME/day limit would impact the ability of members to receive certain FDA-approved drugs such as Duragesic, whose standard doses exceed the 200 MME/day maximum."**

**OIG Comments:**

The 90 MME per day PA requirement is the Carrier's established policy. Our audit uncovered the fact that the PBM's system edits differ from the Carrier's policy since it preloads the maximum quantity of drugs over a 90-day period and only prompts the PA process once the total quantity of drugs allowed for 90 days is exceeded, regardless of the actual day supply. Over half of the prescriptions we reviewed with an MME greater than 300 did not have PAs. Our recommendation is that the PBM calculate the true MME based on the prescriptions day supply and then apply the PA process to all claims over 90 MME. Justification for excessive amounts of opioids should be documented within the PA process to show why such extreme quantities of opioid drugs need to be prescribed for pain.

**Recommendation 3**

We recommend that the PBM implement point-of-sale edits to limit excessive distributions of fentanyl patches in line with the Carrier's PA and MME policies. This drug should not be excluded from point-of-sale edits since it is one of the most dangerous opioids, being 50 to 100 times stronger than morphine and accounting for 60 percent of opioid-related deaths in 2017.

**PBM's Response:**

**"The statement in the report that the Plan has no limits on fentanyl patches and that fentanyl patches were excluded from the edits is inaccurate. There has always been a PA on fentanyl products for the Plan, and a QVT edit that would reject if more than 30 patches were used in 90 days. The max allowance was based on the prescribing information of 300 mcg/3 days. As of January 2020, per BCBSA direction, Caremark changed that edit to include all opioids, including fentanyl patches, in the max 300 MME/day edit. Caremark had the ability to calculate MME at the POS but this is not the approach the Plan adopted prior to 2020, again, to balance member disruption and**

**to ensure that members received appropriate care as their opioids were tapered off. This gradual stepwise approach was very effective since it allowed members to work with their doctors to reduce their opioid intake to prevent withdrawal."**

**Carrier's Response:**

**"BCBSA recognizes the concerns articulated in the report regarding fentanyl patches. BCBSA is planning on implementing a maximum dose of 200 MME/day for opioid products beginning in January 2022 that will include fentanyl patches, subject to consideration of the effect this restriction will have on FDA-approved opioid medications like Duragesic 100 mcg/hr, which would no longer be covered by the Plan if the Recommendation is implemented as stated in the report."**

**OIG Comments:**

The PBM and Carrier's responses do not align with each other. Evidence was provided during our audit showing that Fentanyl patches were excluded from system edits. We acknowledge the Carrier's willingness to include Fentanyl patches in its 200 MME per day limit and expect this recommendation to be resolved once both parties agree to implement point-of-sale edits for Fentanyl. Contrary to what the Carrier states, the OIG is not recommending that a drug be excluded from benefits. Instead, we are recommending that the actual MME be calculated from the day supply and any exceptions to the MME limits be documented with the PA process. Exceptions should continue to be allowed for active cancer, palliative care, and end-of-life care.

**Recommendation 4**

We recommend that the Carrier verify that the PBM implemented system edits at the point-of-sale, effective January 1, 2020, to prevent a member's cumulative quantity of opioids from exceeding 300 MME per day, especially for the most common 30-day supplies (not 90-day supply).

**Carrier's Response:**

**"As of January 2020, BCBSA has adopted guidelines that include a 300 MME/day edit. A customized MME calculator was added in 2020 to check for excessive opioid utilization via cumulative morphine equivalent doses across multiple drugs and prescriptions in the Plan population. This edit will identify all active opioid prescriptions in a member's drug profile and converts the opioid dose to the equivalent dose of morphine. The MME calculation is not based on QVT, so the new edit is not affected by the days' supply. The edit calculates the MME at the POS based on all opioid prescriptions in the member's claim history that are still active on the day of the new opioid claim."**

**OIG Comments:**

We acknowledge the Carrier's willingness to implement a 300 MME per day POS edit that calculates the actual daily MME instead of setting a maximum quantity of opioids allowed over a 90-day period (the QVT edit). We expect this recommendation to be resolved once proof of the edit is provided.

## 2. Prior Approval Limits for Opioid Naïve and Combination Drugs — Procedural

During our review of opioid use by dependents age 17 and under, we found that the PBM paid claims that exceeded a 7-day supply for opioid naïve members (those with no opioid claims in the previouse 180 days), and paid claims that exceeded 50 MME per day for opioid combination drugs, without obtaining the PAs that were required by the Carrier's policies.

The Carrier's PA criteria states that members will be limited to a 7-day pre-PA allowance for IR opioid and combination drugs if they are opioid naïve.

Additionally, the Carrier developed PA criteria for opioid combination drugs that set a pre-PA allowance limit at 50 MME per day.

As part of our review of opioid use by dependents age 17 and under, we identified all opioid claims that exceeded a 7-day supply for children in 2019. From the population of 572 opioid claims for 363 dependents, we then selected a random sample of 50 dependents, with a total of 114 opioid claims, for further review. The results showed that the PBM processed and paid 9 out of the 114 sampled opioid claims without the PAs required by the Carrier, as detailed below:

**The PBM is unable to calculate the daily MME for prescriptions less than a 90-day supply resulting in patient safety concerns.**

- The PBM paid two claims without the PAs required for opioid naïve members exceeding the 7-day pre-PA allowance limit for IR opioid and combination drugs.
- The PBM paid seven opioid claims without the PA required for opioid combination drugs exceeding the pre-PA allowance limit of 50 MME per day.

Although the PBM could not provide a valid explanation for why the opioid naïve member claims were paid without PAs, the opioid combination drugs exceeding 50 MME were paid without a PA because the PBM stated that it does not have the capability to calculate both the quantity and MME from the day supply. Instead, the PBM has a Quantity vs. Time (QVT) edit that looks at a preset quantity that has been calculated to below the pre-PA allowance limit of 50 MME for a 90-day timeframe. The PBM's QVT edit reportedly does not have the

ability to calculate the daily MME on opioid prescriptions less than 90 days in order to comply with the Carrier's policies.

Furthermore, the PBM reported that as of January 1, 2020, it implemented system edits at the point-of-sale that reduced the pre-PA allowance from a 7-day to a 3-day limit for opioid naïve members age 17 and under who are receiving IR opioid and combination drugs.

As a result of the PBM lacking an effective way to limit the day supply based on MME in accordance with the Carrier's policies, there is an increased risk of FEHBP members being overprescribed opioids that may lead to addiction and abuse.

**Recommendation 5**

We recommend that the Carrier ensure that the PBM has implemented system edits at the point-of-sale that require PAs when opioids exceed the 3-day limit for opioid naïve members age 17 and under for IR opioid and combination drugs, and when opioids exceed 50 MME per day for all members receiving opioid combination drugs. The MME should be calculated based on the actual day supply, not the total quantity of opioids allowed over 90 days.

**PBM's Response:**

**"Caremark disagrees with the OIG recommendation. Although the MME-based POS edit was available, the Plan first chose to follow a QVT approach as part of a phased approach to the management of members impacted by members using opioids. As reported during the audit, there were edits in place and none of the nine identified claims were for opioid naïve members, as each member had prior opioid claims. The audit only looked back 90 days for previous claims and our automated edit looks back 180 days for opioid claims. As a result, these individuals were not naïve … .**

**Caremark's approach to calibrate opioid restrictions by age , including a 7-day supply for patients 18 and older naïve to opioids, aligns to the CDC Guideline and the standards implemented by CMS for Medicare Part D. As of January 2020:**

- **For immediate release (IR) opioids: patients 17 and under naïve to opioids are limited to a 3-day supply limit as well as a 90 MME QVT edit. Patients 18 and older naïve to opioids are limited to a 7-day supply and a 90 MME QVT edit.**

- **For opioid combination products: Patients 17 and under naïve to opioids are limited to a 3-day supply limit and a 50 MME QVT edit. Patients 18 and older naïve to opioids are limited to a 7-day supply and a 50 MME QVT edit."**

**Carrier's Response**

**"The OIG recommendation to limit naïve patients to a 3-day limit for all ages for both IR and opioid combination drugs would have a significant and possibly detrimental impact on Plan members suffering serious pain.**

**The Plan currently limits adults to a 7-day supply and children to a 3-day supply of IR opioid and combination drugs. BCBSA estimates that more than 134,000 members would be impacted by the imposition of a 3-day limit for all naïve patients irrespective of age. Such a limit could result in needless suffering and inadequate acute pain relief for adult patients with legitimate need for access to pain relief for more than three days due to surgery or other painful acute situations. BCBSA would need to discuss this recommendation and the potential impact on members with the OPM contracting officer before implementing it.**

**BCBSA will consider implementing the recommendation of a POS 50 MME/day non-QVT edit for IR opioid combination drugs for all ages, subject to discussions with the OPM contracting officer."**

**OIG Comments:**

The PBM was mistaken when it assumed that the audit only looked back 90 days for the two opioid naïve dependents age 17 and under. The audit looked back 180 days and found that the two dependents were opioid naïve, yet they each had an opioid claim paid exceeding a 7-day supply without a PA. Based on the evidence provided by the PBM, one claim was paid because the PBM accidentally "gold carded" an Otolaryngologist as an Oncologist for one of the dependents, and the PBM accidently counted a 2/14/18 opioid claim as 2/14/19 for the other dependent. These human errors should not have occurred if the PBM properly implemented system edits at the "point-of-sale."

The Carrier was mistaken when it thought that the PBM's 3-day limit was for members of all ages. The 3-day limit is only for opioid naïve dependents age 17 and under. The edit for members of all ages is only related to combination drugs at 50 MME. We added additional language in our report to clarify the PBM's edits. Our recommendation is simply asking that the Carrier ensure that the PBM's edits are working at the "point-of-sale" since we found multiple errors. Our greatest concern still remains that the PBM needs to calculate the daily MME based on the actual day supply of the prescription being filled, not on a maximum quantity limit of opioids to reach 50 MME over 90 days.

# APPENDIX

BlueCross BlueShield

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March 18, 2021

Mr. James L. Tuel Jr.
Chief, Special Audits Group
Office of the Inspector General
U.S. Office of Personnel Management
1900 E Street, Room 6400
Washington, DC 20415-11000

**Reference: Limited-Scope Audit of Blue Cross Blue Shield's Opioid Claims as Administered by Caremark for the Service Benefit Plan for the Years 2017 - 2019**
**Audit Report No. 1H-01-00-20-015 (Dated February 9, 2021)**

Dear Mr. Tuel:

This letter is the response of Blue Cross and Blue Shield Association (BCBSA) and CaremarkPCS Health, L.L.C. (Caremark) to the above-referenced U.S. Office of Personnel Management (OPM) Office of Inspector General (OIG) Draft Audit Report.

In sum, BCBSA and Caremark believe that proper controls are in place, and have been in place, to reduce opioid misuse and to ensure that opoid claims are safely prescribed and dispensed to members of the Service Benefit Plan (the "Plan"). As elaborated upon below, BCBSA and Caremark dispute multiple findings in Section C.1 of the report. Specifically, they dispute that:

- The Pharmacy Benefit Manager (PBM), Caremark, "lacked sufficient system edits to limit the quantity of opioids in accordance with the CDC's guidelines and the Carrier's policies";
- BCBSA and Caremark are "unable to fully implement its policy to help reduce fraud, waste, and abuse related to opioids that are less than a 90-day supply"; and
- BCBSA and Caremark "lack adequate controls to help reduce the overprescribing of opioids when not medically necessary, thereby causing a patient safety risk to FEHBP members."

***Section deleted by OIG – Irrelevant to findings***

**Section C.1 – Procedural**

*Caremark Response*

The OIG's reliance on Caremark's payment of 53% of high-MME claims in support of its finding that Caremark lacked adequate controls and edits is misplaced. Out of the 2,333 high-MME

claims paid, 715 were for cancer patients who were properly prescribed high MME opioids and 759 were for members in treatment for opioid addiction who were not subject to MME reduction because of the likely medical harm that such reductions would risk. The remaining 859 Claims comprise less than twenty percent (20%) of the total high-MME claims and would all be addressed by the edits Caremark implemented in 2020A summary of these claims is included as **Attachment 1**. At BCBSA's direction, Caremark is utilizing a gradual stepwise approach to reduce MME for these members. To summarize, 80% of the high-MME claims were for appropriate opioid prescriptions, while the remaining 20% would not be paid without PA under Caremark's current controls and edits, mitigating the need for the recommended changes.

**Section C.1 – Recommendation 1**

*Caremark Response*

The Plan has managed opioids even before the CDC Guideline (**Attachment 2**) were released in 2016, and has continued to implement edits through 2020. See **Attachment 3.** Controls were implemented pursuant to a phased-in strategy that took into account a gradual tapering we refer to as a "stepwise" reduction in opioid use among Plan members to ensure that these members were not abruptly discontinuing their opioid therapy. This strategy also ensured that there were programs in place to ensure that behavioral support programs and non-opioid therapy options for pain were also available to members. This more evolved approach has been strongly advocated by the CDC since the Guideline was released.

Caremark maintains that it has edits in place that sufficiently limit excessive opioid prescriptions and use. Caremark utilizes a quantity-versus time (QVT) edit equivalent to 90 milligram morphine equivalents (MME) per 90 days, and a cumulative 300 MME/day edit that will require a prior authorization (PA).[1]

The report asserts that the edits are flawed because they calculate MME over a 90-day period rather than a 30-day period, which allows for the possibility of the member exceeding 200 MME/day for a shorter period. However, the OIG-recommended 30-day edit would not remedy the short-term excessive use concern identified. A member with a 30-day prescription that is under the 90 MME limit could exceed 200 MME/day for up to *two weeks*, and any prescription *totaling* more than 200 MME over *any* period is subject to potential excessive use over a shorter period of time than the intended prescription duration.

A QVT-based strategy was determined to be the best way to manage patients in a phase-in approach based on consideration of the CDC Guideline and consultation with OPM. QVT is a commonly-used quantity-limit mechanism utilized by payers across the industry. It provides flexibility for the payer to control the number of units a member can access over a defined period of time while ensuring that members have adequate access to treatment for chronic pain. The combination of the QVT edit and the maximum MME/day edit sufficiently address excessive use concerns.

*BCBSA Response*

As the report notes, the CDC issued Guideline limiting prescriptions for opioids that exceed 90 MME/day without justification, and in 2019, BCBSA developed QVT guidelines consistent with

[1] The edit criteria also prevent dual therapy using multiple opioids.

the CDC's Guideline limiting prescriptions to 90 MME/day without PA. Caremark implemented edits consistent with these guidelines in 2020.

BCBSA is confident that the existing controls strike a successful balance between monitoring and preventing excessive opioid use, on the one hand, and ensuring adequate access to appropriate medication for members and respect for decisions of licensed physicians and pharmacists, on the other hand. These controls include not just the edits, but claims review by Caremark's MQA Department for potential safety concerns. As the report notes, these controls resulted in a 31% decrease in opioid spend and a 19% decrease in opioid claims over the period examined. BCBSA's data further demonstrates that long-acting opioid MME average usage decreased by 26% between 2016 and 2020.[2] See **Attachment 4**. BCBSA contends that these results demonstrate successful efforts to limit opioid quantities. While BCBSA acknowledges the continuing risk of short-term overuse of a prescribed supply, a shorter edit period would not address this concern, and BCBSA firmly believes that additional restrictive measures would likely unreasonably restrict members from accessing medically-necessary medication.

For these reasons, BCBSA disagrees with Recommendation 1. The OIG-recommended edits would not eliminate the possibility of short-term misuse. As the current edits have successfully reduced opioid use, BCBSA's position is that modifications to the edits are unwarranted absent evidence that the OIG-recommended edit would lead to superior outcomes without excessive burden on members in need of pain medication.

**Section C.1 Recommendation 2**

*BCBSA Response*

BCBSA will need to discuss this recommendation with the OPM contracting officer in order to determine the best way to manage the potential member impact. We estimate that a 90 MME/day PA requirement would affect 12,865 Plan members. If this recommendation is implemented, these members would all require a PA to continue treatment. If this recommendation were implemented, many FDA-approved products such as morphine 100 mg, Opana ER 40 mg, Oxycontin 80 mg, and Nucynta 250 mg would all require PA because the morphine equivalence in these standard doses exceeds 90 MME. BCBSA will also need to discuss the 200 MME/day maximum dose edit under consideration with OPM. Setting a point-of-sale (POS) maximum MME/day limit would impact the ability of members to receive certain FDA-approved drugs such as Duragesic, whose standard doses exceed the 200 MME/day maximum.

**Section C.1 Recommendation 3**

*Caremark Response*

The statement in the report that the Plan has no limits on fentanyl patches and that fentanyl patches were excluded from the edits is inaccurate. There has always been a PA on fentanyl products for the Plan, and a QVT edit that would reject if more than 30 patches were used in 90 days. The max allowance was based on the prescribing information of 300 mcg/3 days. As of January 2020, per BCBSA direction, Caremark changed that edit to include all opioids, including

[2] Meanwhile, there was no increase in short-acting opioid MME usage over this time, establishing that the reduction marked a true decrease in use rather than merely switches to different opioid types.

fentanyl patches, in the max 300 MME/day edit. Caremark had the ability to calculate MME at the POS but this is not the approach the Plan adopted prior to 2020, again, to balance member disruption and to ensure that members received appropriate care as their opioids were tapered off. This gradual stepwise approach was very effective since it allowed members to work with their doctors to reduce their opioid intake to prevent withdrawal.

*BCBSA Response*

BCBSA recognizes the concerns articulated in the report regarding fentanyl patches. BCBSA is planning on implementing a maximum dose of 200 MME/day for opioid products beginning in January 2022 that will include fentanyl patches, subject to consideration of the effect this restriction will have on FDA-approved opioid medications like Duragesic 100 mcg/hr, which would no longer be covered by the Plan if the Recommendation is implemented as stated in the report.

**Section C.1 Recommendation 4**

*BCBSA Response*

As of January 2020, BCBSA has adopted guidelines that include a 300 MME/day edit. A customized MME calculator was added in 2020 to check for excessive opioid utilization via cumulative morphine equivalent doses across multiple drugs and prescriptions in the Plan population. This edit will identify all active opioid prescriptions in a member's drug profile and converts the opioid dose to the equivalent dose of morphine. The MME calculation is not based on QVT, so the new edit is not affected by the days' supply. The edit calculates the MME at the POS based on all opioid prescriptions in the member's claim history that are still active on the day of the new opioid claim.

See **Attachment 5** for an example of how the edit looks on the Caremark claims system and **Attachment 6**, which provides information on how often the edit was issued in 2020.

**Section C.1 Recommendation 5**

*Caremark Response*

Caremark disagrees with the OIG recommendation. Although the MME-based POS edit was available, the Plan first chose to follow a QVT approach as part of a phased approach to the management of members impacted by members using opioids. As reported during the audit, there were edits in place and none of the nine identified claims were for opioid naïve members, as each member had prior opioid claims. The audit only looked back 90 days for previous claims and our automated edit looks back 180 days for opioid claims. As a result, these individuals were not naïve, as explained in **Attachment 7.**

Caremark's approach to calibrate opioid restrictions by age , including a 7-day supply for patients 18 and older naïve to opioids, aligns to the CDC Guideline and the standards implemented by CMS for Medicare Part D. As of January 2020:

- For immediate release (IR) opioids: patients 17 and under naïve to opioids are limited to a 3-day supply limit as well as a 90 MME QVT edit. Patients 18 and older naïve to opioids are limited to a 7-day supply and a 90 MME QVT edit.

- For opioid combination products: Patients 17 and under naïve to opioids are limited to a 3-day supply limit and a 50 MME QVT edit. Patients 18 and older naïve to opioids are limited to a 7-day supply and a 50 MME QVT edit.

See **Attachment 8** for an example of how the edit looks on the Caremark claims system and **Attachment 9**, which provides information on how often the edit was issued in 2020.

*BCBSA Response*

The OIG recommendation to limit naïve patients to a 3-day limit for all ages for both IR and opioid combination drugs would have a significant and possibly detrimental impact on Plan members suffering serious pain.

The Plan currently limits adults to a 7-day supply and children to a 3-day supply of IR opioid and combination drugs. BCBSA estimates that more than 134,000 members would be impacted by the imposition of a 3-day limit for all naïve patients irrespective of age. Such a limit could result in needless suffering and inadequate acute pain relief for adult patients with legitimate need for access to pain relief for more than three days due to surgery or other painful acute situations. BCBSA would need to discuss this recommendation and the potential impact on members with the OPM contracting officer before implementing it.

BCBSA will consider implementing the recommendation of a POS 50 MME/day non-QVT edit for IR opioid combination drugs for all ages, subject to discussions with the OPM contracting officer.

We appreciate the opportunity to provide our response to this Draft Audit Report and we request that you consider this feedback when updating the OPM Final Audit Report.

Sincerely,

[redacted]
Managing Director, FEP Program Assurance

Attachments


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