White Paper

The Impact of the Affordable Care Act's Maximum Out-of-Pocket Limit

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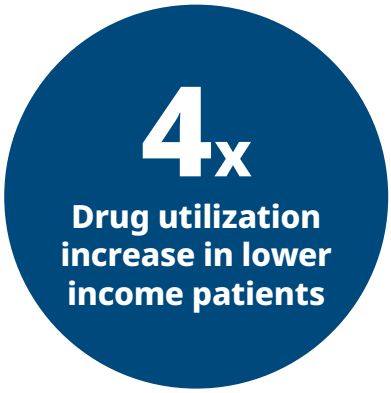
Introduction and findings

The Affordable Care Act (ACA) was a healthcare reform law enacted in March 2010 with the aim of making health insurance more affordable, expanding Medicaid, and supporting innovative models for care delivery. Although much has been written about the overall changes due to the ACA, little has been published about the impact of one of its key provisions: the requirement of compliant health plans to limit cost sharing for beneficiaries by setting an annual maximum for out-of-pocket (OOP) costs.

The current study analyzed the impact of ACA's maximum OOP limit on privately insured patients and found it lowered patient OOP costs and increased patient drug utilization. Specifically, the percentage of patients who reached their OOP limit tripled from 5% before the ACA went into effect to 15% afterwards. Also, the proportion of branded prescriptions free to the patient (zero-dollar copays) increased by 59% relative to pre-ACA levels, an effect that was stronger in disease areas with high-priced products. Furthermore, once patients reached their OOP limit, their branded drug consumption increased 12% and generic consumption grew 7%. Finally, lower income patients benefited the most, with their drug utilization increasing four times as much as seen in higher income patients.

"The percentage of patients who reached their OOP limit tripled from 5% before the ACA went into effect to 15% afterwards."

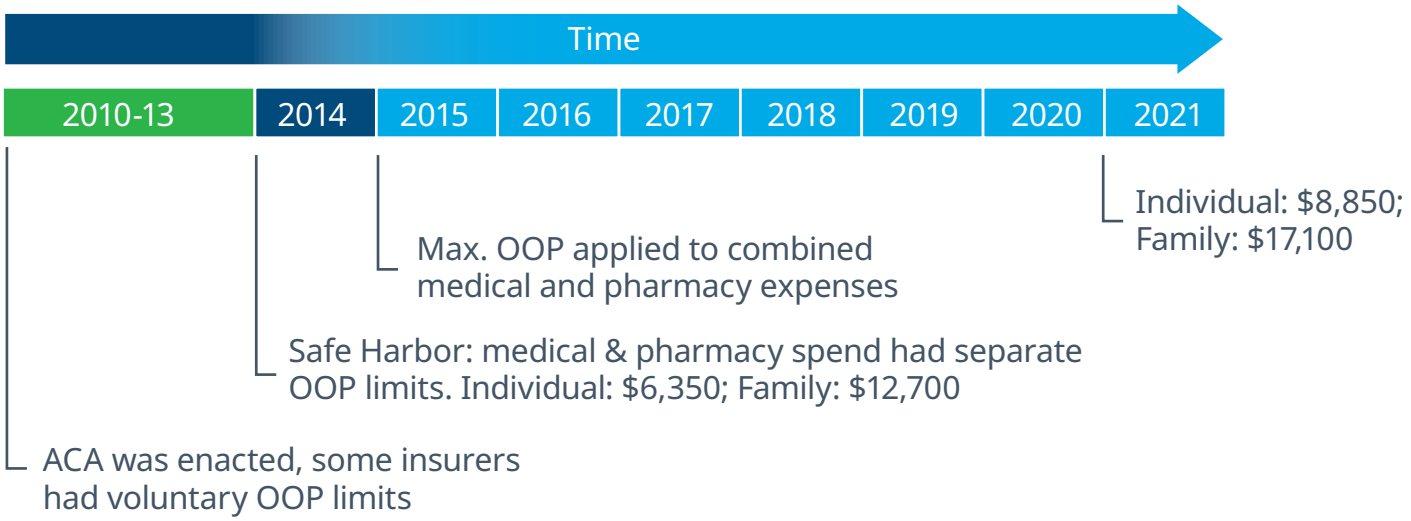


Origins

Starting in 2014, the ACA established a maximum for OOP limits for private insurance plans. When insured patients reach an OOP limit their treatment costs become zero, which helps protect patients with severe medical conditions from high costs. Although the ACA's maximum OOP limit applied to all private plans, at first glance it appears many beneficiaries would have been unlikely to be affected by it. For example, in 2013 73% of covered workers were already enrolled in a plan with an OOP limit of $5,999 or less,[1] which was a lower, more stringent limit than the ACA's $6,350 limit. Furthermore, fewer than 1% of private group insurance beneficiaries had OOP costs higher than $6,350 in 2013.[2] Also, policymakers had previously implemented maximum OOP limit legislation for government sponsored plans: Medicaid has had an OOP limit of 5% of family income for decades, and in 2011 Medicare Advantage plans were required to have an OOP limit for services covered under Medicare Part A and B, but not for Part D.

Nonetheless, an additional component of the ACA provisions was that the OOP limit applied jointly to medical and pharmacy expenditure, and this part of the legislation was more likely to have a wider impact on patients. For example, in 2009, 85% of beneficiaries in PPOs with an OOP limit had plans that didn't count prescription drug spend towards meeting the OOP limit.[3] Note that regulators gave insurance companies a "safe-harbor" year in 2014, delaying this part of the regulation to give insurance companies time to combine their medical and pharmacy systems.

Fig. 1. How the ACA's maximum OOP limit was implemented



How the ACA maximum OOP limit was implemented

The ACA's maximum OOP limit was implemented in two phases for private insurance: separate maximums for pharmacy and medical benefits in 2014, and a single, combined maximum in January 2015, as illustrated in Figure 1. Each year, the maximum OOP limit is set by The Department of Health and Human Services to account for inflation in healthcare costs.

HOW MANY MORE PATIENTS REACHED THEIR OOP LIMIT?

To determine the impact of the maximum OOP limit, three time periods were studied: 2012-13, prior to the maximum OOP limit; the "safe-harbor" phase in 2014; and the second phase from 2015 to 2018 when the combined pharmacy and medical maximum for OOP limits was implemented. For the current study, the impact of these changes on the pharmaceutical market was measured using the proportion of prescriptions paid for by private insurance that were purchased with a zero-dollar copay. This statistic is a salient outcome that affects insurers, manufacturers, and patients alike: "free to the patient" prescriptions. *See Analysis Methods and Data on page 10 for further details.*

In 2012-13, only 15.9% of branded prescription volume corresponded to a zero-dollar copay, which rose to 19.5% in 2014 and to 25.3% in 2016, the second year of the combined maximum for OOP limits, as shown in Figure 2. From 2013 to 2016, the volume of branded scripts with a zero-dollar copay saw a relative increase of 59% and an absolute increase of almost 10 percentage points. Details of the analysis are provided in *Analysis Methods and Data*.

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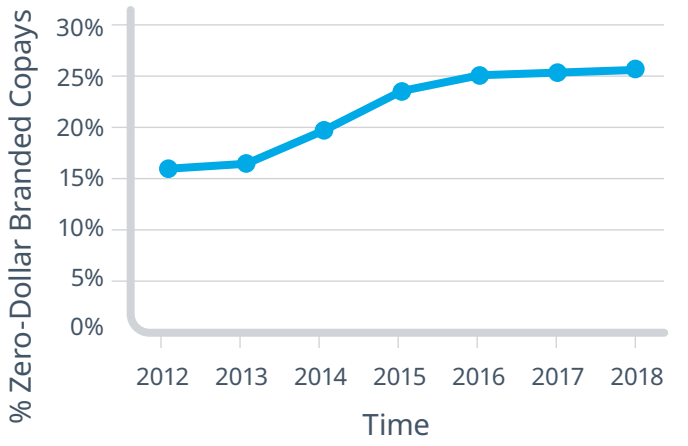
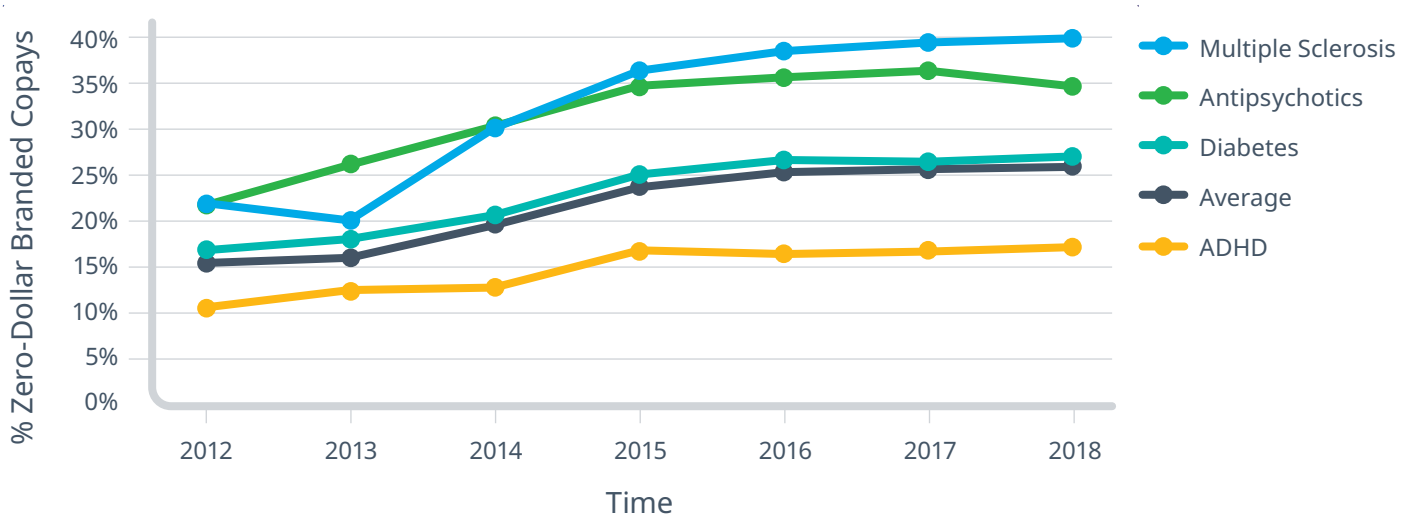
Fig. 2. Percent of branded prescriptions with a zero-dollar copay dispensed to privately insured patients



Given that prior to 2014, fewer than 1% of covered workers had more than $6,350 in OOP costs and 73% already had an OOP limit, it is surprising to see a 4-percentage point increase in zero-dollar scripts between 2013 and 2014. However, patients who are prescribed and fill branded medications face much higher healthcare costs than the average covered worker. Because of this, the direct effect of this portion of the ACA on the branded pharmaceutical market was larger than may have been expected.

The second phase beginning in 2015 also had a substantial impact: by 2016, when the rate appears to have stabilized, the proportion of scripts with no OOP costs had increased an additional 6 percentage points. Additional longitudinal patient analysis confirmed that almost all of this increase in zero-dollar branded prescriptions was due to patients reaching their OOP limit more often and earlier in the plan year (results not shown).

Fig. 3. Proportion of zero-dollar copay branded prescriptions by therapeutic area and year.

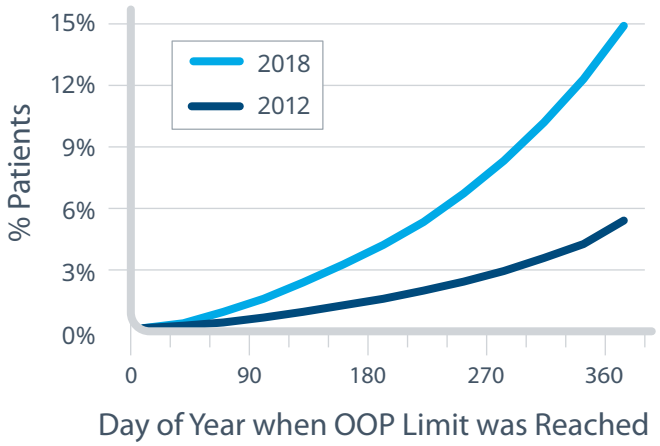


The impact of the maximum OOP limit varied substantially by therapeutic area, with largest impact in therapeutic areas where patients had high cost exposure. For instance, in the multiple sclerosis market, zero-dollar copay prescriptions increased 18 percentage points with most of the impact taking place between 2013 and 2014, as illustrated in Figure 3. This may be due to the high cost of multiple sclerosis pharmaceutical products. On the other hand, for the diabetes market, more of the impact occurred between 2014 and 2015 potentially due to high medical costs associated with diabetes and its comorbidities (the American Diabetes Association has estimated that almost half of the $16,752 in average medical expenditure per year for diabetes patients comes physician office visits and inpatient care[4]). Meanwhile some therapeutic areas, like ADHD, were not as heavily affected, possibly because ADHD patients are less likely to have high OOP costs in other disease areas.

Another way of quantifying the impact of the maximum OOP limit is to study the proportion of patients hitting an OOP limit. Each year, this proportion starts at zero in January and increases until it reaches a peak at the end of December, as shown in Figure 4. In 2012, two years before the ACA came into effect, only about 5% of patients reached an OOP limit (of course, some patients had no OOP limit at all). In 2018, several years after the ACA was implemented, this figure had tripled to almost 15% of patients hitting an OOP limit.

Each calendar year there is an increase in the percent of patients with $0 copays, followed by a drop in January when the vast majority of private plans reset. This became more pronounced after the ACA changes of 2014 and 2015 and is market wide. It has become an integral part of the healthcare landscape for patients, manufacturers, and insurers.

Fig. 4. Percent of patients reaching their OOP limit



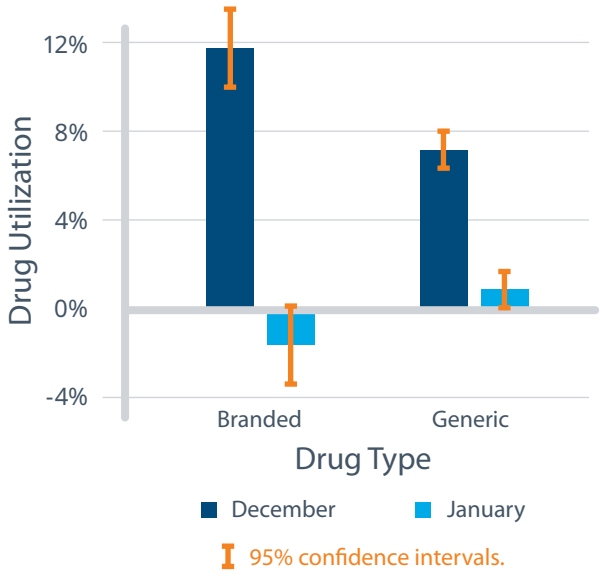
DID PATIENTS INCREASE DRUG UTILIZATION AFTER REACHING THEIR OOP LIMIT?

Almost three times as many patients now reach their OOP limit each plan-year as a result of the ACA's implementation, thus it is more important than ever to understand how these patients behave when they reach this limit. Although basic economic theory predicts patients will use more pharmaceutical products when prices decrease, this is a dynamic decision-making process for patients with doctors, pharmacies, and insurers acting as intermediaries, so the question is worth careful analysis. The data showed that patients increased branded drug utilization by 11.8% in the last month of the year after reaching their OOP limit, controlling for how much utilization they had in the earlier part of the year (Figure 5). This raises the question of whether there was a corresponding decrease in the following January when prices return to standard insurance pricing. That is, were patients simply stockpiling? The data showed a much smaller decrease in the following January, indicating that overall utilization was increasing as a result of the OOP limit rather than patients stockpiling free product in December to use in January when their plan-year reset.

The data also showed patients increased their utilization of generic medications by 7.2% in December after reaching their OOP limit (Figure 5), an increase that was smaller than for branded products potentially due to generic medications being cheaper than branded drugs (at full price and in most benefit designs).

One thing that health industry insiders often forget is how complicated and obfuscated the American healthcare system is, and studies have shown that consumers do not make rational choices in healthcare.[5] An additional analysis was performed to test whether patients who reach their OOP limit in multiple years learned from the experience, but the data showed no statistically significant evidence of such behavior.

Fig. 5. Impact of reaching an OOP limit on therapy purchased in December and January



Since we have shown that the ACA increased the proportion of patients reaching their OOP limit and that once this happened patients increased utilization, we wanted to understand the impact of this provision on total pharmaceutical utilization. We estimate that the branded prescription utilization in December increased by 0.75% due to the ACA's maximum OOP limit. If we extrapolate the behavior of December patients to the entire year after accounting for the rate at which patients reach their OOP limit throughout the year, we calculate a 0.29% increase in total branded utilization as a result of this single provision in the ACA. In 2018, this would have represented an increase in pharmaceutical gross revenue of about $1.4 billion.[6]

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WHICH PATIENTS GAINED THE MOST FROM REDUCED COSTS AFTER REACHING THEIR OOP LIMIT?

The finding that patients increase utilization of both branded and generic products upon reaching their OOP limit raises the question of whether patient socioeconomic status, which may be associated with being better informed, plays a role. To explore this further, the impact of patient income on drug utilization was tested. No direct measure of patient income was available, so patients were segmented based on the income quartile of the Census Public Use of Microdata Area (PUMA) geography in which they lived.

Patients in the lowest income quartile geography increased their utilization four times as much as patients in the highest quartile geography once they reached their OOP limit, 20% versus 5%, respectively (see Figure 6). This is evidence that lower income patients benefit the most from a maximum OOP limit and that increased price sensitivity among lower income patients outweighs any information advantage that higher income patients may have. The analysis also found evidence that wealthier patients engage in product warehousing, advancing purchases from January into December. This is consistent with the notion that low-income patients struggle to pay for drugs and increase overall utilization when it is cheaper to do so, while wealthier patients are simply reducing OOP costs while maintaining their existing medication schedule.

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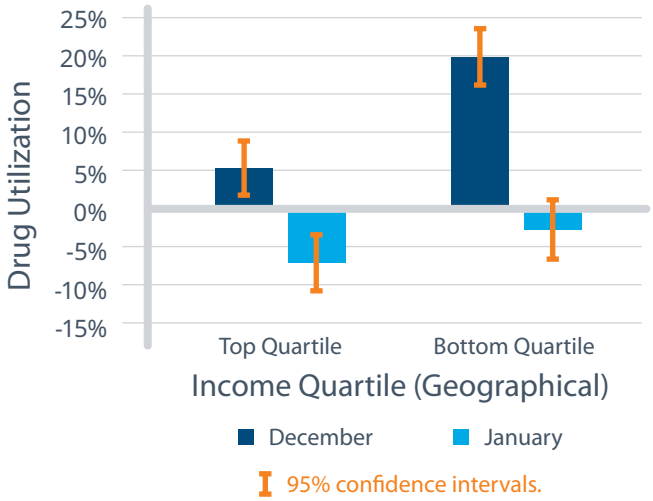
Fig. 6. Impact of reaching an OOP limit on branded products purchased in December and January by census PUMA income quartile geography



Encouragingly, this analysis is evidence that the OOP limit has substantially helped low income patients who have experienced very high OOP costs in the calendar year to fill their prescriptions at the end of the year.

Conclusions

Since the ACA was enacted in 2010 it has faced a number of legal challenges. Additionally, in 2019 the Tax Cuts and Jobs Act of 2017 rescinded the federal tax penalty for violating the individual mandate of the ACA. The current paper has for the first time estimated the impact of the ACA's maximum OOP limit, quantifying what would be at risk if this part of the ACA were to be repealed or otherwise compromised.

The current study found that branded zero-dollar copay commercial prescriptions increased by 4 percentage points between 2013 and 2014 upon the initial implementation of the law, and by an additional 6 percentage points between 2014 and 2016 upon the combining of medical and pharmacy

expenses. However, the impact varied substantially by therapeutic area. Disease areas with expensive drug products and/or high-cost patient populations saw larger effects than those with less severe comorbidities and lower costs.

The introduction of the ACA's maximum OOP limit likely accelerated the use of deductibles for pharmacy benefits. For example, the Kaiser Family Foundation's annual survey of employer health benefits found deductibles rose four times faster than premiums in 2016[7] and have continued to rise ever since. This has had several effects. First, by shifting costs from beneficiaries with the highest treatment expenses to beneficiaries in general, it may have contributed to the observed increase in the percent of beneficiaries who reached their OOP limit. Second, it increased patient awareness of the true cost of pharmaceutical products because during their deductible period, beneficiaries are exposed to the full cost of those products.

The OOP limit, along with the high prevalence of large and increasing deductibles, are shaping the commercial pharmaceutical landscape and lead to an annual cycle of high patient OOP costs in the beginning of the calendar year and lower OOP costs as the end of the year approaches. This annual cycle underpins the strategy of many market participants. For example, it incentivizes pharmaceutical manufacturers to use coupons to help patients stay on therapy through the expensive, early part of the year in the hope that they will still be adherent to therapy once deductibles have faded and OOP limits have been reached. In response, pharmacy benefit managers (PBMs) and insurers are incentivized to ensure coupon payments do not count toward deductibles or OOP limits through accumulator programs to maintain utilization control of branded pharmaceuticals. Finally, patients increase their utilization after reaching their OOP limit.

The current study looked at the impact of the ACA's maximum OOP limit on patient OOP costs and drug utilization. It's also of interest to know how manufacturers and insurers responded to this legislation. For example, did manufacturers change the timing or magnitude of price increases, and if so, how did insurers respond? Such questions may be the basis of follow-up studies from the current authors.

In the current study, drug utilization of patients increased 7-12% once they reached their OOP limit for the year. The effect was higher for branded products than generics and was four times larger in low income geographies than high income ones. On the question of whether patients are likely to stockpile product at the end of the year and then reduce purchases in the beginning of the year once prices reset, the data found suggestions of that behavior among the highest income geographies, but the predominant observed behavior was an increase in pharmaceutical utilization in December without a commensurate decrease in January. These findings support previous studies that indicate that high out-of-pocket costs decrease adherence to medication.[8]

As the market evolves and policy changes, many factors will help shape the impact of the ACA's maximum OOP limit in the future. If cost-sharing and prices increase faster than statutory OOP limits, the annual cycle of high prices in the beginning of the

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year and low prices at year's end will grow stronger. However, if patients shift out of ACA-compliant healthcare plans in large numbers, as might happen after the repeal of the insurance mandate, the maximum OOP limit will be less impactful for market participants. In the meanwhile, policymakers and market participants should be aware of the many effects that the ACA's maximum OOP limit has had on patient cost-sharing in the U.S. healthcare system.

ANALYSIS METHODS AND DATA

To measure the impact of the maximum OOP limit, prescription volume was estimated across all pharmaceutical products found in IQVIA's Longitudinal Access and Adjudication Dataset (LAAD) reference data. This spans all U.S. pharmaceutical products, including branded and generic products, patient- and physician-administered products, and all disease areas. Because scripts can be written for different quantities of medication, script volume was weighted by days of supply. Thus, a script for a 90-day supply of a drug would have three times the weight of a 30-day supply script.

Regarding the proportion of patients reaching their OOP limit (Section 1), most but not all patients have plan years that align with the calendar year, meaning their deductibles and OOP limits reset in January.[1] Data indicating which patients were exceptions to this was not available, thus this was not taken into account in the analysis in Figure 4.

In the current study, drug utilization of patients increased 7-12% once they reached their OOP limit for the year. The effect was higher for branded products than generics and was four times larger in low income geographies than high income ones.

The impact on patient behavior due to a patient reaching his or her OOP limit was estimated as follows. In a year in which their OOP limit was reached, the change in drug utilization was measured: December utilization versus pre-December utilization. The same quantity was estimated in a year in which the patient did not reach his or her OOP limit, to establish a baseline, and the difference was calculated. The process was repeated for drug utilization in January to test for the presence of product warehousing, i.e., flat total utilization where January purchases are advanced into December.

Except where indicated, the current study looked only at branded prescriptions since generic prescriptions often have a zero OOP cost due to benefit design.

A handful of confounding effects existed in the pharmaceutical market around the time the ACA was enacted, including coupon usage, accumulator programs, an increased presence of generics, and price increases for branded products. The current study measured patient OOP costs before the use of coupons took effect. Unless an accumulator program was being used, a coupon would reduce OOP costs *for the patient* but wouldn't impact the patient reaching his or her OOP limit. An increased generic presence may have caused fewer patients to hit their OOP limit than otherwise would have done, while price increases would have had the opposite effect. The current study did not control for generics and price increases because its aim was to measure the impact of the ACA's maximum OOP limit on market conditions as they existed at the time the ACA was enacted.

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