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I. Introduction

The Centers for Medicare & Medicaid Services recently issued a final rule that it claims will strengthen the agency's ability to stop fraud before it happens by keeping unscrupulous providers out of federal health insurance programs.

The Association for Accessible Medicines recently released a white paper called “Access Denied: Why New Generics Are Not Reaching America's Seniors.” The paper addresses new data on the treatment of generic medicines in Medicare Part D, which may be resulting in beneficiaries paying more for their medicines even if less expensive, FDA-approved generics and biosimilars are available.

The Centers for Medicare & Medicaid Services recently issued a press release noting that, “Consistent with the direction of President Trump's recent Executive Order on Strengthening and Improving Medicare for Our Nation's Seniors, the Centers for Medicare & Medicaid Services announced today that seniors will have access to more high-quality Medicare Advantage and Part D prescription drug plans in 2020.”

A recently published Kaiser Family Foundation analysis found that, between the years 2016 and 2017, the list prices for most of the top Medicare Part D drugs by total spending increased as much as nine times the rate of inflation, which was 1.7%. These findings suggest that recent Congressional proposals targeting such increases could generate savings for Medicare and Part D enrollees.

A recent Kaiser Family Foundation analysis found that millions of current enrollees in stand-alone Medicare Part D prescription drug plans will face premium and other cost increases in 2020 unless they switch to lower-cost plans during the open enrollment period that began Oct. 15 and ends on Dec. 7, 2019.

II. Government and civil Part D legal actions and legislation

Senator Brown and other Democrats introduce bill allowing HHS to negotiate drug prices for government programs such as Part D

U.S. Senator Sherrod Brown (D-OH) and Congressman Lloyd Doggett (D-TX) recently introduced legislation that would “address the prescription drug affordability crisis.”

Their proposed Medicare Negotiation and Competitive Licensing Act would authorize the Secretary of Health and Human Services (HHS) to negotiate drug prices and, if drug companies refuse to negotiate in good faith, it would enable the Secretary to issue a competitive, compulsory license to another company that is willing and able to produce the medication as a generic.

Senator Brown is the lead sponsor of the bill in the Senate. The original cosponsors of the bill in the Senate are Senators Amy Klobuchar (D-MN) and Tammy Baldwin (D-WI).

Congressman Doggett is the lead sponsor of the bill in the House of Representatives. His original co-sponsors of the bill in the House are Representatives Peter Welch (D-VT) and Elijah Cummings (D-MD).

According to Senator Brown, “The purpose of medicine is to help people, not to line the pockets of Big Pharma executives. Our bill would call Big Pharma's bluff and demand prescription drug companies offer fair prices, or be boxed out.”

A press release from Senator Brown's office states that, in the past, pharmaceutical companies have used threats to maintain the highest profits of any industry. They have also made threats against negotiations bills, stating that if they were forced to negotiate more competitive prices, they would simply refuse to sell its drugs to people on Medicare.

The Brown-Doggett bill includes a provision addressing pharmaceutical companies that refuse to agree to a reasonable price on a given medication. In such an event, the Secretary of HHS could issue this competitive, compulsory license to another company that will offer the drug at a price that's fair to Medicare beneficiaries and taxpayers.

Representative Doggett also commented on the legislation, stating that, “Let's cut prices so that patients don't have to cut pills in half. Our proposal responds to an American problem, rampant prescription price gouging, with an American solution—negotiation and competition. We repeal and replace the Republican-imposed law prohibiting negotiation and empower the use of generic competition to lower prices. While there is no wonder drug to eliminate price gouging, the cure begins by making patients' health and security nonnegotiable. We call on President Trump to follow the advice of Candidate Trump; let's start saving billions through ‘bidding.”’

Senator Klobuchar noted that, “Medicare is one of the largest drug purchasers in the country. It should not be restricted from negotiating the best deal with drug manufacturers. Americans deserve better. I have fought for years to unleash the bargaining power of seniors on Medicare and this bill offers another important step towards lowering the skyrocketing cost of prescription drugs.”

Senator Baldwin also commented on the proposed legislation, stating that, “We have a broken system in Washington that prohibits the federal government from negotiating lower prescription drug prices for older Wisconsinites. I have long championed efforts to allow the government to negotiate directly with pharmaceutical corporations to get better prices on lifesaving medicines instead of increasing drug company profits. President Trump campaigned in 2016 on lowering the cost of prescription drugs, including by allowing Medicare to negotiate drug prices. It's time for the President to work with Congress to pass this reform and help lower out-of-pocket costs for seniors.” [FN1]

Department of Justice announces $122.6 million settlement with three drug makers accused of False Claims Act violations involving Medicare payments of drug copays

The Department of Justice recently announced that three pharmaceutical companies have agreed to pay a total of $122.6 million to resolve allegations that they each violated the False Claims Act by illegally paying the Medicare or Civilian Health and Medical Program (ChampVA) copays for their own products through supposedly independent foundations that the companies used as mere conduits.

The three companies involved in the settlement are Jazz Pharmaceuticals plc (Jazz), Lundbeck LLC (Lundbeck), and Alexion Pharmaceuticals Inc. (Alexion).

When a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may have to make a partial payment, which may take the form of a copayment, coinsurance, or a deductible (“copay”). Congress included copay requirements in the Medicare program as a way to curb health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs.

The Anti-Kickback Statute prohibits a drug company from offering or paying, directly or indirectly, any remuneration (including money or any other thing of value) to induce Medicare patients to purchase the company's drugs. This ban also applies to the payment of patients' copay obligations.

According to Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division, “Pharmaceutical companies undercut a key safeguard against rising drug costs when they create assistance funds to serve as conduits for the companies to subsidize the copays of their own drugs. These enforcement actions make clear that the government will hold accountable drug companies that directly or indirectly pay illegal kickbacks.”

Jazz and Lundbeck also each entered into five-year corporate integrity agreements (CIAs) with the OIG as part of their respective settlements. These CIAs require the companies to implement measures, controls, and monitoring designed to promote independence from any patient assistance programs to which they donate. Moreover, the companies agreed to implement risk assessment programs and to obtain compliance-related certifications from company executives and Board members.

These investigations were conducted by the Justice Department's Civil Division and the U.S. Attorney's Office for the District of Massachusetts. The investigations were done in conjunction with the Department of Health and Human Services, Office of Inspector General, the Federal Bureau of Investigation, and the Department of Veterans Affairs, Office of Inspector General.

U.S. Attorney Andrew E. Lelling also commented on the settlement, noting that, “We are committed to ensuring that pharmaceutical companies do not use third-party foundations to pay kickbacks masking the high prices those companies charge for their drugs. This misconduct is widespread, and enforcement will continue until pharmaceutical companies stop circumventing the anti-kickback laws to artificially bolster high drug prices, all at the expense of American taxpayers.”

Gregory E. Demske, Chief Counsel to the Inspector General, noted that, “These kickback schemes harm Medicare and the public. OIG CIAs, such as those with Jazz and Lundbeck, are designed to reduce future risks to patients and taxpayer-funded programs. OIG decided not to require a CIA with Alexion because it made sweeping and fundamental organizational changes following the bad conduct. The changes included hiring a new eight-member executive leadership team and changing half of the members of its Board of Directors. In addition, 40 percent of Alexion's employees are new and the company relocated its corporate headquarters.”

The allegations against Jazz involved Xyrem, a narcolepsy medication with Gamma Hydroxybutyrate (GHB), a central nervous system depressant and controlled substance. Jazz allegedly asked a foundation to create a fund that would pay the copays of Xyrem Medicare patients and that the foundation agree to establish a “Narcolepsy Fund,” to which Jazz became the sole donor.

The government also alleged that, in conjunction with establishing this fund, Jazz made Medicare patients ineligible for Jazz's free drug program and instead referred Xyrem Medicare patients to the foundation, allowing Jazz to generate revenue from Medicare and induce purchases of the drug, instead of continuing to provide these patients with free drugs. Jazz also raised the price of Xyrem by over 150 percent from 2011 through the end of the relevant time period.

Lundbeck sells Xenazine, the only drug that was approved to treat chorea associated with Huntington's disease until a generic version became available until 2015. The government claims that Lundbeck was the sole donor and made millions in payments to a fund at a foundation that ostensibly provided financial support only for patients with Huntington's Disease. Lundbeck also allegedly referred Xenazine patients with many other conditions to this foundation, which then paid the Xenazine copays for these unapproved uses from its Huntington's Disease fund.

In June 2014, after the foundation determined that its Huntington's Disease fund would no longer pay the copays of patients taking Xenazine for non-Huntington's disease uses, Lundbeck agreed to repurpose some of its prior donations to the Huntington's Disease fund to a “general fund” at the foundation for the purpose of paying these patients' Xenazine copays. The drug maker then made subsequent “unrestricted” payments to the foundation with the understanding that the foundation would use these payments to pay Xenazine copays for these same patients.

Alexion sells Soliris, a very costly drug which, from Jan. 1, 2010, through June 30, 2016, was indicated for certain uses to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The government alleged that Alexion made donations to a “Complement-Mediated Disease” (CMD) fund at a foundation to pay the Medicare copay obligations of patients taking Soliris and to induce those patients' purchases of Soliris. [FN2]

Astellas and Amgen agree to pay $125 million to resolve Medicare copay kickback allegations brought by Justice Department

The Department of Justice recently announced that Astellas Pharma US Inc. (Astellas) and Amgen Inc. (Amgen) have agreed to pay a total of $124.75 million to resolve allegations that they each violated the False Claims Act by illegally paying the Medicare copays for their own products through supposedly independent foundations that the companies used as mere conduits.

When a Medicare beneficiary obtains a prescription drug covered by Medicare, the beneficiary may be required to make a partial payment, also known as a copayment, coinsurance, or a deductible (“copay”).

Congress included copay requirements in the Medicare program, in part, to curb health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration (including money or any other thing of value) to induce Medicare patients to purchase the company's drugs. This prohibition extends to the payment of patients' copay obligations.

Astellas, which has agreed to pay $100 million to resolve the government's allegations, sells Xtandi, an androgen receptor inhibitor (ARI) used to treat certain prostate cancer. None of the other major drugs to treat the condition is an ARI. The government alleged that, in May 2013, Astellas asked two foundations about the creation of copay assistance funds to cover the copays for Medicare patients taking ARIs, but not for other types of prostate cancer drugs. In July 2013, both foundations opened ARI-only copay funds, and Astellas was the sole donor to both funds. The government alleged that Astellas knew that Xtandi would likely account for the vast majority of utilization from each fund, and Medicare patients taking Xtandi received nearly all of the copay assistance from the two ARI funds. The government further alleged that, during the time that the ARI funds were open, Astellas promoted the existence of the ARI funds as an advantage for Xtandi over competing drugs in an effort to persuade medical providers to prescribe Xtandi.

Amgen, which has agreed to pay $24.75 million to resolve the government's allegations, sells the secondary hyperparathyroidism drug Sensipar and the multiple myeloma drug Kyprolis. Amgen acquired Kyprolis as part of its acquisition of Onyx Pharmaceuticals Inc. in 2013.

The government alleged that, in late 2011, Amgen stopped donating to a foundation that provided financial support to patients taking any of several secondary hyperparathyroidism drugs and approached a new foundation about creating a “Secondary Hyperparathyroidism” fund that would support only Sensipar patients. Amgen allegedly worked with the new foundation to determine the fund's coverage parameters and, in November 2011, the foundation launched a “Secondary Hyperparathyroidism” fund with Amgen as its sole donor. Until June 2014, the fund covered only Sensipar. Amgen allegedly made payments to the fund even though the cost of these payments exceeded the cost to Amgen of providing free Sensipar to financially needy patients. The government contends that, by enabling the fund to cover the copays of Medicare beneficiaries, Amgen caused claims to be submitted to Medicare and generated revenue for itself.

The government also alleged that Amgen's predecessor, Onyx, asked a foundation to create a fund that ostensibly would cover health care related travel expenses for patients taking any multiple myeloma drug, but which was actually used almost exclusively to cover travel expenses for patients taking Kyprolis. Kyprolis must be infused at certain health care facilities. The government alleged that Onyx was the sole donor to this travel fund and that Amgen, after integrating Onyx into its operations in 2015, continued to donate to the fund. The foundation also operated a second fund that covered copays for multiple myeloma drugs, including Kyprolis. While this latter fund had multiple donors, the government alleged that, for 2013, Onyx received data from the foundation on the fund's anticipated and actual expenses for coverage of Kyprolis copays, which it used to tailor its donations to the fund to just the amount needed to cover the copays of Kyprolis patients.

According to Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division “When pharmaceutical companies use foundations to create funds that are used improperly to subsidize the copays of only their own drugs, it violates the law and undercuts a key safeguard against rising drug costs. These enforcement actions make clear that the government will hold accountable drug companies that directly or indirectly pay illegal kickbacks.”

United States Attorney Andrew E. Lelling also commented on the cases, stating that, “According to the allegations in today's settlements, Astellas and Amgen conspired with two copay foundations to create funds that functioned almost exclusively to benefit patients taking Astellas and Amgen drugs. As a result, the companies' payments to the foundations were not ‘donations,’ but rather were kickbacks that undermined the structure of the Medicare program and illegally subsidized the high costs of the companies' drugs at the expense of American taxpayers. We will keep pursuing these cases until pharmaceutical companies stop engaging in this kind of behavior.” [FN3]

III. CMS and HHS news

CMS proposes policy changes for prescription drug programs starting in 2020; focus of changes on lowering prices

The Centers for Medicare & Medicaid Services (CMS) recently proposed polices for 2020 intended to strengthen and modernize the Medicare Part C and D programs. According to CMS, the proposal would ensure that Medicare Advantage and Part D plans have more tools to negotiate lower drug prices.

CMS is also considering a policy that would require pharmacy rebates to be passed on to seniors to lower their drug costs at the pharmacy counter.

HHS Secretary Alex Azar noted that, “President Trump is following through on his promise to bring tougher negotiation to Medicare and bring down drug costs for patients, without restricting patient access or choice.”

Secretary Azar further noted that, “By bringing the latest tools from the private sector to Medicare Part D, we can save money for taxpayers and seniors, improve access to expensive drugs many seniors need, and expand their choice of plans. The Part D proposals complement efforts to bring down costs in Medicare Advantage and in Medicare Part B through negotiation, all part of the President's plan to put American patients first by bringing down prescription-drug prices and out-of-pocket costs.”

Many of the tools addressed in the CMS recent proposal have been developed in the commercial health insurance marketplace, resulting in lower costs for patients.

CMS Administrator Seema Verma commented on the proposed changes, noting that, “In designing today's proposal, foremost in the agency's mind was the impact on patients, and the proposal is yet another action CMS has taken to deliver on President Trump and Secretary Azar's commitment on drug prices. Today's changes will provide seniors with more plan options featuring lower costs for prescription drugs, and seniors will remain in the driver's seat as they can choose the plan that works best for them. The result will be increasing access to the medicines that seniors depend on by lowering their out-of-pocket costs.”

Private plan options for receiving Medicare benefits are increasing in popularity. Nearly 37 percent of Medicare beneficiaries are expected to enroll in Medicare Advantage in 2019, and Part D enrollment is also increasing year-over-year as well. Premiums in both Medicare Advantage and Part D are projected to decline next year.

The recently proposed changes by CMS include:

• Providing Part D plans with greater flexibility to negotiate discounts for drugs in “protected” therapeutic classes, so beneficiaries who need these drugs will see lower costs;

• Requiring Part D plans to increase transparency and provide enrollees and their doctors with a patient's out-of-pocket cost obligations for prescription drugs when a prescription is written;

• Codifying a policy similar to the one implemented for 2019 to allow “step therapy” in Medicare Advantage for Part B drugs, encouraging access to high-value products including biosimilars; and

• Implementing a statutory requirement, recently signed by President Trump, that prohibits pharmacy gag clauses in Part D.

CMS is also considering a policy that would ensure that enrollees pay the lowest cost for the prescription drugs they pick up at a pharmacy, after taking into account back-end payments from pharmacies to plans. [FN4]

CMS releases Fact Sheet for Part D Payment Modernization Model

On January 18, 2019, the Centers for Medicare & Medicaid Services (CMS) released a “Part D Payment Modernization Model Fact Sheet.”

In January 2020, CMS and Medicaid Innovation (Innovation Center) will begin the Part D Payment Modernization model “to test the impact of a revised Part D program design and incentive alignment on overall Part D prescription drug spending and beneficiary out-of-pocket costs.”

The model is intended to reduce Medicare expenditures while preserving or enhancing quality of care for beneficiaries. The model is open to eligible standalone Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PDs) that are approved to participate.

According to CMS, the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs called on HHS to increase competition, improve negotiation, create incentives for lower list prices and reduce out-of-pocket costs. This model is intended to advance President Trump's stated commitment to lower prescription drug prices. Medicare beneficiaries, Part D plans, and CMS are predicted to all benefit from a more aligned system.

This voluntary, five-year model tests the impact of a modernized Part D payment structure that creates new incentives for plans, patients, and providers to choose drugs with lower list prices in order to address rising federal reinsurance subsidy costs in Part D. Eligible standalone Prescription Drug Plans and Medicare Advantage-Prescription Drug Plans that are approved to participate in the model will take two-sided risk for CMS's federal reinsurance subsidy (80 percent of catastrophic phase liability). This will allow for performance-based payments to plan sponsors or payments to CMS based on spending.

CMS will also provide participants with additional programmatic tools, including a Part D Rewards and Incentives program, to increase engagement between plans and their enrollees and to promote better enrollee understanding of their Part D benefit, out-of-pocket costs, and clinically equivalent therapeutic options. Ultimately, CMS expects that testing a modernized Part D payment structure will maintain or improve beneficiaries' access to affordable and necessary covered Part D prescription drugs.

Several risk-abating mechanisms were included in the original Part D benefit design included to ensure Medicare beneficiaries had access to a robust choice of Part D plans. These mechanisms include the direct subsidy risk corridors, risk adjustment, and federal reinsurance in the catastrophic phase of the benefit. This structure has allowed CMS to implement and administer a market-based Part D program.

CMS claims, however, that “Over time, however, pharmaceutical innovation and patent expirations have led to a bifurcation in Part D prescription drug utilization and spending.”

The percentage of Part D prescriptions filled with generic medications is higher than ever. Overall Part D spending has almost doubled from 2010 to 2016, increasing from $77.5 billion in total spending to $146.1 billion. In evaluating the reasons for this trend, the high list price of new specialty and branded medications for cancer, Hepatitis C, rheumatoid arthritis, and other conditions has led to a six-fold increase in Part D catastrophic phase spending relative to 2006. This is due, in part, to the fact that the list price determines both beneficiary out-of-pocket costs and where enrollees are in their Part D benefit.

Through this model, CMS is testing the impact of a modernized Part D payment structure that increases and better aligns Part D plan sponsor liability with the costs paid for by CMS and Medicare beneficiaries. This model will potentially allow CMS to address the high list price of drugs covered by Medicare Part D and evaluate the impact on cost and quality for Medicare beneficiaries.

The voluntary, five-year (CY 2020-2024) Part D Payment Modernization model aims to promote a decrease in total Part D program spending in the following two ways: (1) Creating new incentives for plans, patients, and providers to choose drugs with lower list prices to better manage catastrophic phase federal reinsurance subsidy spending by introducing two-sided risk to align payment incentives for plan sponsors with their enrollees and CMS; and (2) Providing programmatic flexibilities, including Part D Rewards and Incentives programs, to ensure Medicare beneficiaries are able to maintain affordable access to the prescription drugs that they need.

CMS will be releasing a Request for Applications (RFA) for eligible standalone PDPs and MA-PDs to participate in plan year 2020, the first year of the model. As part of a competitive application process, the model will accept applications from eligible Part D plan sponsors nationally.

If a Part D sponsor chooses to apply with a standalone PDP in a Part D region, the Part D sponsor must include all standalone PDPs in that Part D region. If a Medicare Advantage Organization (MAO) chooses to apply with an MA-PD, the MAO must include all of the eligible MA-PD plan benefit packages (PBPs) offered in or across the Part D region(s) that the MA-PD serves.

CMS will review plan sponsors' applications for participation and only accept applications to the extent the model still ensures a competitive Part D market and CMS preserves the ability to evaluate the impact of the model.

CMS is maintaining all current Part D bid, payment, and reconciliation processes, including the application of risk corridors. Plans will continue to bid a prospective federal reinsurance amount, which will be fully reconciled as per current law. The direct subsidy amount will be reconciled per the existing direct subsidy Part D risk corridors, including the current 15 percent plan liability in the catastrophic phase. Payment, risk adjustment, and reconciliation processes will still apply to each subsidy consistent with current law. [FN5]

CMS announces proposed changes designed to maximize competition among Medicare Advantage and Part D plans and to address opioid crisis

The Centers for Medicare & Medicaid Services (CMS) recently released proposed changes that are intended to take significant steps in continuing the agency's efforts to maximize competition among Medicare Advantage and Part D plans. These proposals are predicted to increase plan choices and benefits and include important actions to address the opioid crisis.

According to CMS Administrator Seema Verma, “CMS is committed to modernizing Medicare and our top priority is to ensure that seniors have more choices and affordable options in receiving their Medicare benefits. Medicare Advantage enrollment is at an all-time high as more and more seniors are choosing to enroll in private Medicare health and drug plans, and we need to maximize competition by providing plans the flexibility to meet patients' needs.”

CMS is also proposing new action to combat the nation's opioid crisis. CMS is encouraging Part D plans to provide lower cost sharing for opioid-reversal agents. CMS' overutilization policies have resulted in a 14 percent decrease in the share of Part D beneficiaries using opioids between 2010 and 2017 (36.3 percent to 31.3 percent), with the largest decrease from 2016 to 2017 (5 percent). [FN6]

CMS finalizes updates intended to lower costs for Part D patients

The Centers for Medicare & Medicaid Services (CMS) recently finalized updates that are intended to take significant steps in continuing the Trump administration's efforts to increase competition among Medicare Advantage and Part D plans so that patients can receive higher quality care at lower costs. CMS contends that these changes will increase plan choices and benefits, and include important actions to address the opioid crisis.

According to CMS Administrator Seema Verma “Today's changes give plans the ability to be innovative and offering benefits and services that address social determinants of health for people with chronic disease. With Medicare Advantage enrollment at an all-time high, plans need greater flexibility in offering benefits that they focus on preventing disease and keeping people healthy.”

In addition to expanding opportunities for choice and providing flexibility in offering supplemental benefits, these payment and policy updates include actions that help combat the nation's opioid crisis. In a recent announcement, CMS encouraged Part D plans to provide at least one opioid-reversal agent on a lower cost-sharing tier. CMS' overutilization policies have resulted in a 14 percent decrease in the share of Part D beneficiaries using opioids between 2010 and 2017 (36.3 percent to 31.3 percent), with the largest decrease from 2016 to 2017 (5 percent).

A press release from CMS notes that, “Medicare Advantage remains a popular choice among beneficiaries and has high satisfaction ratings. Average Medicare Advantage premiums are at their lowest in six years, Part D premiums are at their lowest in three years, and plan choices have increased. Today's announcement builds in additional flexibilities that will continue to increase choice and competition among Medicare health and drug plans.” [FN7]

CMS announces new policy addressing opioids

In early 2018, CMS published a roadmap outlining its efforts to address the national opioid epidemic. The roadmap detailed its three-pronged approach, which included prevention of new cases of opioid use disorder (OUD), expanding access to treatment for patients who have already developed OUD, and using data from across the country to better target its prevention and treatment activities.

CMS notes that, “prescription opioids provided by physicians can also contribute to the crisis when not used carefully. As Medicare pays for a significant amount of prescription opioids, we strive to ensure appropriate stewardship of these medications that can provide a medical benefit but also carry a risk for our beneficiaries.”

As part of its prevention efforts, CMS has introduced Medicare Part D opioid safety policies intended to reduce prescription opioid misuse while preserving medically necessary access to these medications. The new opioid policies include improved safety alerts at the pharmacy for Part D beneficiaries who are filling their initial opioid prescription or who are receiving high doses of prescription opioids. Medicare drug plans will perform additional safety checks by sending pharmacies an alert to review certain opioid prescriptions before they are filled. Safety alerts may arise under the following scenarios:

• Possible unsafe amounts of opioids. The pharmacist or Medicare drug plan may need to perform a closer safety review of the prescription with the prescribing doctor if a Part D beneficiary receives opioid prescription(s) that exceed a certain amount.

• First prescription fills for opioids. Part D beneficiaries may be limited to a 7-day supply or less for acute pain if they haven't recently taken opioids (such as within the past 60 days). The limit is based on medical best practices that show that the risk of developing an opioid use disorder increases after 7 days of use. This policy is not intended for current users of prescription opioids.

• Use of opioids and benzodiazepines at the same time. These medications can be dangerous when taken in combination.

If the prescription cannot be filled as written, including the full amount on the prescription, the pharmacist will give the beneficiary a notice explaining how they or their doctor can contact the plan to ask for a “coverage determination,” which is a decision about whether or not the plan will cover the drug. The beneficiary or his or her doctor may also ask the Part D plan for an exception to its rules before the beneficiary goes to the pharmacy so the beneficiary can know in advance whether the prescription is covered.

According to CMS, “It's important to note that these new policies are not “one size fits all,” and are deliberately tailored to address distinct populations of Medicare Part D prescription opioid users. These interventions do not apply to residents of long-term care facilities, beneficiaries in hospice, palliative, or end-of-life care, and beneficiaries being treated for active cancer-related pain.”

The new policies also allow Part D plans to implement drug management programs to help beneficiaries use opioids and other frequently abused medications safely. If a beneficiary receives opioids from multiple doctors or pharmacies, the beneficiary may need to receive their medications from specific doctors or pharmacies to ensure appropriate care coordination. The Part D plan would send

the beneficiary a letter if it is going to limit their access to these medications under its drug management program. The beneficiary and doctor will have the right to appeal such decisions.

CMS notes that, “The new Medicare Part D opioid policies encourage collaboration and care coordination among Medicare drug plans, pharmacies, prescribers, and patients, in order to improve opioid management, prevent opioid misuse, and promote safer prescribing practices. CMS continues to be committed to addressing the opioid crisis and helping our beneficiaries use prescription opioid pain medications more safely.” [FN8]

CMS announces final rule for Part D and Medicare Advantage; focus of rule on transparency for plan sponsors

On May 16, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that, according to CMS, “modernizes and improves the Medicare Advantage and Part D programs. These changes will ensure that patients have greater transparency into the cost of prescription drugs in Part D and will also enable Medicare Advantage plans to negotiate better prices for physician-administered medicines in Part C.”

Current Part D policy requires sponsors to include on their formularies all drugs in six categories or classes: 1) antidepressants; 2) antipsychotics; 3) anticonvulsants; 4) immunosuppressants for treatment of transplant rejection; 5) antiretrovirals; and 6) antineoplastics; except in limited circumstances.

Under current policy, Part D sponsors are only permitted to impose prior authorization and step therapy requirements for beneficiaries initiating therapy (i.e., new starts) for 5 of the 6 protected classes, with no prior authorization or step therapy allowed for antiretrovirals. The final regulatory provision codifies this existing policy, which has been in effect since 2006.

CMS did not finalize the proposed exceptions that would have allowed Part D sponsors to: 1) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period, or 2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market.

In an attempt to “accelerate the use of electronic Real Time Benefit Tools (RTBT)” in the Part D program, CMS is now requiring that each Part D plan adopt one or more RTBTs that are capable of integrating with at least one prescriber's ePrescribing system or electronic health record (EHR), no later than January 1, 2021. RTBTs have the capability to inform prescribers when lower-cost alternative therapies are available under the beneficiary's prescription drug benefit, which could potentially improve medication adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket costs.

Effective January 1, 2021, CMS will require the Part D Explanation of Benefits that Part D plans send members to include drug price increases and lower cost therapeutic alternatives. This information will inform Medicare beneficiaries about possible ways to lower their out of pocket costs by considering a lower cost medication.

There is now an official prohibition against gag clauses in pharmacy contracts. This provision implements the statutory requirement that restricts Part D sponsors from prohibiting or penalizing a pharmacy from disclosing a lower cash price to an enrollee. According to CMS, this provision supports the President's initiative to help lower out-of-pocket costs of prescription drugs for Medicare beneficiaries by helping inform them about lower cost alternatives.

CMS solicited comments on a policy that would re-define negotiated price as the baseline, or lowest possible, payment to a pharmacy. The negotiated price for a drug is the price reported to CMS at the point of sale, which is used to calculate beneficiary cost-sharing and generally adjudicate the Part D benefit. Although CMS is not implementing this policy for 2020, the agency claims that it “appreciates the over 4,000 comments that were received on this potential policy approach. CMS will continue to carefully review these comments as we continue to consider policies that would lower prescription drug costs, address challenges that independent pharmacies face, and improve the quality of pharmacy care.” [FN9]

Health and Human Services Secretary Alex Azar commented on the final rule, noting that, “The improvements we are making to Medicare Advantage and Medicare Part D deliver on the promises in the President's blueprint to provide more negotiating tools and more transparency for patients. They are significant steps toward a Medicare program, a drug pricing marketplace, and a healthcare system where the patient is at the center and in control.”

CMS Administrator Seema Verma also commented on the final rule, stating that, “Under President Trump's leadership, CMS is delivering on price transparency, because patients have a right to know the cost of their healthcare services before they receive them. Today's rule requires Part D plans to adopt tools that provide clinicians with information that they can discuss with patients on out-of-pocket costs for prescription drugs at the time a prescription is written.”

Verma continued, noting that, “By empowering patients with information on the cost of their prescription drugs, today's rule will ensure that pharmaceutical companies have to compete on the basis of price. This effort builds on new requirements for hospitals to disclose chargemaster prices and other agency initiatives to promote price transparency.” [FN10]

CMS projects continued decrease in basic premium for Part D drug plans; announces redesign of Medicare Plan Finder

The Centers for Medicare & Medicaid Services (CMS) recently announced that, for the third straight year, the average basic premium for Medicare Part D prescription drug plans is projected to decrease.

Over the last three years, average Part D basic premiums have decreased by 13.5 percent, from $34.70 in 2017 to a projected $30 in 2020. These savings over that period amount to approximately $1.9 billion in premium costs. Furthermore, enrollment in the Part D program has increased 12.2 percent since 2017.

In addition to the premium savings for beneficiaries over the last three years, the continued decline in Part D bid amounts over the past three years is estimated to save taxpayers nearly $6 billion in the form of lower Medicare premium subsidies.

According to HHS Secretary Alex Azar. “President Trump has listened to what American patients and seniors want, and he has promised to protect what works and fix what's broken in American healthcare. Medicare Part D plans continue to be extremely popular, and the President is delivering improvements to Part D, offering plans more ways to provide low-cost options and delivering patients more transparency on drug prices. With premiums in Part D now projected to decline for 2020, President Trump is delivering on his promise to protect seniors and put patients in control.”

CMS Administrator Seema Verma also commented on the recent announcement, noting that, “Under President Trump's leadership, CMS has been taking action to lower the cost of prescription drugs, and we are seeing the results of our actions. At a time when healthcare costs are going up, the Trump Administration is delivering lower costs to seniors. Part D plans are having to prove their value to beneficiaries – the actions that CMS has taken to strengthen the Medicare prescription drug program are working to drive down costs for seniors.”

Over the years, CMS has attempted to modernize the Part D program by providing beneficiaries the opportunity to choose among plans with greater negotiating tools adopted from the private market and by providing patients with increased transparency on prescription drug prices.

CMS takes the position that, “Increasing competition and strengthening negotiations are key pillars of President Trump's Blueprint to reduce prescription drug prices, and CMS will continue to implement the President's Blueprint to ensure that American seniors can access the prescription drugs they need at an affordable price.”

Improvements to the Medicare Part D program that CMS has recently made include:

• Providing more information on out-of-pocket costs for prescription drugs to beneficiaries by requiring Part D plans to adopt tools that provide clinicians with information that they can discuss with patients on out-of-pocket drug costs at the time a prescription is written.

• Implementing Part D legislation signed by President Trump to prohibit “gag clauses,” which keep pharmacists from telling patients about lower-cost ways to obtain prescription drugs.

• Requiring the Explanation of Benefits document that Part D beneficiaries receive each month to include information on drug price increases and lower-cost therapeutic alternatives.

• Providing beneficiaries with more drug choices and empowering beneficiaries to select a plan that meets their needs by allowing plans to cover different prescription drugs for different indications, an approach used in the private sector.

• Reducing the maximum amount that low-income beneficiaries pay for certain innovative medicines known as “biosimilars,” which will lower the cost of these innovative medicines for these beneficiaries.

• Allowing certain generic drugs to be substituted onto plan formularies more quickly during the year, so beneficiaries immediately have lower cost sharing for these drugs.

• Increasing competition among plans by removing the requirement that certain Part D plans have to “meaningfully differ” from each other, making more plan options available for beneficiaries.

The upcoming annual Medicare Open Enrollment period for 2020 begins on October 15, 2019, and ends on December 7, 2019. During this period, Medicare beneficiaries can choose health and drug plans for 2020 by comparing their current coverage and plan quality ratings to other plan offerings. They can also simply choose to remain in traditional Medicare.

For the first time in ten years, CMS is redesigning Medicare Plan Finder, the website for Medicare plan selection. This redesign is intended to allow beneficiaries to more easily compare options and choose the plan that best meets their needs. CMS anticipates releasing the premiums and costs for specific Medicare health and drug plans for the 2020 calendar year in mid-to-late September. [FN11]

OIG report finds Medicare Part D still paying millions for drugs already paid for under the Medicare Hospice Benefit

In 2012, OIG issued a report to the Centers for Medicare & Medicaid Services (CMS) finding that, during 2009, Medicare Part D paid for prescription drugs that likely should have been paid for by hospice organizations under the Medicare Part A hospice benefit. OIG matched Part A and Part D data to identify occurrences when Part D paid for drugs for beneficiaries who were receiving hospice care at the same time. OIG then recently conducted an audit to follow up and expand on the previous audit.

The objective of the OIG was to determine whether the Medicare Part D program paid for drugs during 2016 that should have been paid for by hospice organizations under the Medicare Part A hospice benefit.

The audit covered $422.7 million in Part D total costs for prescriptions filled while beneficiaries were receiving hospice care. OIG selected a stratified random sample of 200 Part D records and contacted hospice organizations to find out if they should have paid for the drugs.

Hospices should pay for all drugs used to treat a beneficiary's terminal illness and related

conditions. Part D should not pay for drugs if they are covered under the Part A hospice

benefit. The hospice conditions of participation state that “drugs and biologicals related to the palliation and management of the terminal illness and related conditions . . . must be provided by the hospice while the patient is under hospice care” (42 CFR § 418.106).

In this recent audit, OIG found that Medicare Part D paid for drugs during 2016 that hospices should have paid for under the Medicare Part A hospice benefit. Based on sample results, OIG estimated that the Part D total cost was $160.8 million for drugs for which hospice organizations should have paid.

Furthermore, although hospices told OIG that the hospices should not have paid for the drugs associated with the remaining $261.9 million of the $422.7 million total cost, a review of CMS communications with hospices and sponsors between 2012 and 2016 indicated otherwise: Hospice organizations or hospice beneficiaries likely should have paid for many of these drugs, not Part D.

According to OIG, CMS must do more to avoid paying twice for the same drugs. It should work directly with hospices to ensure that they are providing drugs covered under the hospice benefit.

OIG also recommended that CMS develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit. Such a strategy, according to OIG, would save at least an estimated $160.8 million a year in Part D total costs. These savings would potentially be significantly higher when factoring in drugs that hospices said they were not responsible for providing. CMS should also work with Part D sponsors and seek whatever authorities are necessary to develop proper controls.

In written comments on the OIG draft report, CMS stated that its current efforts “will address the issue and help ensure there is no disruption in beneficiary access.” CMS also indicated that it will “continue to engage in meaningful activities to reduce duplicate payment in this area, such as ensuring hospice providers are proactively educating beneficiaries on covered services and items (including drugs) and Part D drug plan sponsors are appropriately applying prior authorization criteria and coordinating with hospice providers on drug coverage issues.”

The OIG openly disagreed with CMS's assertion that its current activities will adequately address the issue and continued to recommend that CMS develop controls to stop the duplicate hospice drug payments.

In explaining why OIG disagrees with CMS's argument relating to addressing this issue, the OIG noted that, “Specifically, in 2012 we reported that duplicate payments occurred during 2009. In this current report, we identified millions of dollars in duplicate payments that still occurred in 2016 despite previous recommendations.”

The OIG also stated that, “Therefore, it appears that CMS's activities to reduce duplicate payments in this area have not been effective. We continue to recommend that CMS develop a strategy to stop the duplicate hospice drug payments that includes working with Part D sponsors and seeking whatever authorities are necessary to develop proper controls.” [FN12]

IV. General Part D News

Report calls on government to address issues in Part D program

A recently released report addressing the Medicare Part D program found that the program is quite popular, but poses challenges to beneficiaries that result in increased out-of-pocket costs and limited access for millions of beneficiaries.

The study, called “Navigating Medicare Part D: Approaches to Addressing Beneficiary Affordability and Access Challenges,” was commissioned by Medicare Access for Patients Rx (MAPRx). MAPRx is a coalition consisting of more than 55 patient, family caregiver, and health professional organizations committed to strengthening and protecting Medicare Part D.

According to Stevan W. Gibson, president and CEO of the Lupus Foundation of America, which founded the MAPRx coalition in 2005, “This report makes it clear that Part D needs to be strengthened. Policymakers should work toward solutions that address out-of-pocket costs and access. There is a lot of work still to be done to improve Medicare Part D for our seniors and those living with chronic conditions like lupus. We look forward to improving the program now and in the years to come.”

The MAPRx coalition calls on the current Administration and Congress to address the following issues relating to Part D beneficiaries:

• Increased out-of-pocket costs, including a shift to coinsurance (beneficiaries pay a percentage of the cost of the prescription versus a fixed copay), which can significantly increase out of pocket costs;

• Lack of an annual out of pocket (OOP) cap on costs to beneficiaries – unlike other insurance, both public and commercial, there is no limit on what beneficiaries may be required to pay for their prescription drugs throughout the year;

• An out-of-pocket cliff, which if not addressed by Congress early in 2019, will result in beneficiaries paying $1,200 more out of pocket in 2020 before reaching the catastrophic coverage phase of the benefit. This cliff will increase the catastrophic threshold from $5,100 in 2019 to $6,350 in 2020;

• Failure to pass along manufacturer rebates to beneficiaries at the point of sale, which currently prevents patients with prescription drug needs from benefiting from reduced drug prices negotiated by manufacturers and health plans;

• Adverse tiering for chronically ill beneficiaries, such as utilization of specialty tiers that entail high cost sharing for Medicare beneficiaries (as much as 33%) who rely on drugs for multiple sclerosis, rheumatoid arthritis, multiple myeloma and many other conditions;

• Restrictions on the ability of beneficiaries to request specialty tier exceptions and the usage of non-preferred brand tiers;

• Utilization management practices, such as step therapy that require a patient to first take a drug (and fail on that drug) before moving to taking the drug originally prescribed by their doctor;

• Lack of easy-to-navigate resources explaining plan options and patient opportunities to submit appeals and exceptions; and

• Narrow formularies that have fewer prescription drug options for low-income subsidy beneficiaries. [FN13]

Trump Administration proposes to lower drug costs for Part D beneficiaries by targeting rebates

U.S. Health and Human Services Secretary Alex Azar and Inspector General Daniel Levinson recently proposed a rule intended to lower prescription drug prices and out-of-pocket costs by encouraging manufacturers to pass discounts directly on to patients and bringing new transparency to prescription drug markets.

According to Secretary Azar, “Every day, Americans—particularly our seniors—pay more than they need to for their prescription drugs because of a hidden system of kickbacks to middlemen. President Trump is proposing to end this era of backdoor deals in the drug industry, bring real transparency to drug markets, and deliver savings directly to patients when they walk into the pharmacy.”

The HHS proposal would expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans, and Medicaid managed care organizations.

It would also create a new safe harbor for prescription drug discounts offered directly to patients, as well as fixed fee service arrangements between drug manufacturers and PBMs. The proposal would also provide a new level of transparency to a system “that has been shrouded in secrecy for decades.”

Under the proposed rule, prescription drug rebates that currently amount to 26 to 30 percent of a drug's list price may be passed on directly to patients and reflected in what they pay at the pharmacy counter. By encouraging negotiated discounts that are reflected in cost-sharing methods like co-insurance, used for many expensive drugs in Medicare Part D, the proposal is projected to provide the greatest benefits to seniors with high prescription drug costs.

The proposal would also address the most significant incentive drug manufacturers cite in raising their list prices every year, which is supposedly the pressure to provide larger rebates. This rule provides a clear pathway for drug companies instead to compete to have the lower price and out-of-pocket cost to the patient.

This proposal is intended to complement efforts in progress laid out in the President's “American Patients First - PDF” blueprint, including requiring the disclosure of list prices in television ads, increasing negotiated discounts in Medicare, banning pharmacy gag clauses, adopting real-time prescription benefit tools, and boosting low-cost generic and biosimilar competition.

Secretary Azar further noted that, “This historic action, combined with other administrative and legislative efforts on prescription drug pricing, is a major departure from a broken status quo that serves special interests and moves toward a new system that puts American patients first. Democrats and Republicans looking to lower prescription drug costs have criticized this opaque system for years, and they could pass our proposal into law immediately.”

Azar also stated that, “This proposal has the potential to be the most significant change in how Americans' drugs are priced at the pharmacy counter, ever, and finally ease the burden of the sticker shock that millions of Americans experience every month for the drugs they need.”

The government contends that the current rebate-driven system “is part of an unacceptable status quo characterized by high prices and backdoor deals.”

According to HHS, rebates reward ever-increasing list prices. Everyone in today's system, including PBMs and Part D plans, negotiate rebates as a percentage of list price. When list prices rise, industry players benefit and taxpayers and the patients paying for the drug pay the price. This proposal is intended to counteract the incentives behind rising list prices. Drug companies would no longer be able to cite their rebate contracts as an excuse to keep raising list prices.

The government also contends that replacing safe harbor protections for opaque rebates with transparent discounts is expected to lead to lower Part D spending for Medicare beneficiaries as a whole. This prediction is based on the fact that the projected reductions in out-of-pocket costs are larger than potential increases in premiums. By removing the incentives that reward list price increases, patients who have out-of-pocket costs based on list prices will save. [FN14] [FN15]

Kaiser Family Foundation releases report addressing out of pocket spending on specialty drugs in 2019

The Kaiser Family Foundation (KFF) recently released a report called “The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019.”

The KFF analysis drew on data from Medicare's Plan Finder website to calculate expected annual 2019 out-of-pocket costs for 30 specialty tier drugs used to treat four health conditions—cancer, hepatitis C, multiple sclerosis, and rheumatoid arthritis. For each drug, the study authors calculated the median annual out-of-pocket cost across all plans that cover the drug, based on coverage in stand-alone prescription drug plans (PDPs) and costs at a pharmacy in zip code 21201, located in Baltimore, Maryland.

KFF used one zip code to represent PDP costs nationally because most PDPs are offered on a national or near-national basis (including 24 of the 25 PDPs in the 21201 zip code). Moreover, it is common for PDPs to use the same formulary and the same specialty tier coinsurance rate in all regions. Because of this fact, KFF suggests that its findings are broadly applicable to a majority of PDP enrollees nationwide.

The report found that median annual out-of-pocket costs for Part D beneficiaries in 2019 for 28 of the 30 studied specialty tier drugs range from $2,622 for Zepatier (for hepatitis C) to $16,551 for Idhifa (for leukemia), based on a full year of use. Furthermore, two of the 30 drugs are not covered by any plan in the KFF analysis in 2019.

The report also found that, for the 28 studied specialty tier drugs covered by some or all plans in the analysis, the share of out-of-pocket costs that an enrollee would incur in the catastrophic phase in 2019 ranges from 13 percent for Zepatier to 86 percent for Idhifa (based on a full year of utilization). 61 percent of expected annual out-of-pocket costs for these 28 drugs in 2019 would occur in the catastrophic phase, on average, which represents $5,444 in out-of-pocket costs in the catastrophic phase alone.

Not all specialty tier drugs are covered by all Medicare Part D plans. Only drugs that are in one of the six protected classes (such as cancer drugs) are covered by all plans. For the 14 specialty drugs in the KFF analysis that are not covered by some or all plans in 2019, the median total annual cost when not covered ranges from $26,209 for Zepatier to $145,769 for Gleevec.

In 2019, annual out-of-pocket costs are approximately 12 percent higher than in 2016 for 8 of the 10 specialty tier drugs analyzed in both 2016 and 2019 and covered by plans in both years. For these drugs, median annual out-of-pocket cost increases varied from $224 for Copaxone (a multiple sclerosis drug) to $2,923 for Revlimid (a cancer drug). Two of the 10 drugs—Harvoni and Sovaldi, both used to treat hepatitis C—had annual out-of-pocket costs slightly lower in 2019 than in 2016. This reduction in costs was potentially due to the entry of competitor products since the end of 2015, as well as other factors related to changes in the benefit design and the limited duration of treatment.

Because of the complete closure of the Part D coverage gap for brand-name drugs, Part D enrollees will likely pay lower annual out-of-pocket costs for selected specialty tier drugs below the catastrophic threshold in 2019 compared to 2016. However, they may face higher costs above the catastrophic threshold. For example, the rheumatoid arthritis drug Humira shows a decrease in median out-of-pocket costs below the catastrophic threshold by $99 between 2016 and 2019 (from $3,155 to $3,057), but an increase above the catastrophic threshold increased by $705 over this same period (from $1,709 to $2,414).

One of the conclusions of the report was that, “Medicare Part D enrollees without low income subsidies can expect to pay thousands of dollars out of pocket for a single specialty tier drug in 2019. For many specialty tier drugs, the majority of these costs will occur in the catastrophic phase of the benefit.”

The report further noted that, “Part D enrollees taking high-cost specialty tier drugs often incur significant costs in the catastrophic coverage phase of the benefit because the catastrophic threshold is not an absolute limit on out-of-pocket spending. For the 28 specialty tier drugs in our analysis covered by some or all plans, the share of annual out-of-pocket costs that would be incurred in the catastrophic phase in 2019 ranges from 13 percent for Zepatier to 86 percent for Idhifa; for 19 of these drugs, enrollees can expect to pay more than half of their annual out-of-pocket cost in the catastrophic phase. On average across these 28 specialty drugs, 61 percent of annual out-of-pocket costs occur above the catastrophic threshold in 2019, which translates to $5,444 in out-of-pocket costs in the catastrophic phase alone.”

The KFF analysis focused on 30 specialty tier drugs, 12 of which were from its original 2016 analysis, and an additional 18 drugs that were approved by the FDA in 2016, 2017, and 2018 (through November) for the four health conditions in the analysis and which are covered by Medicare Part D, as verified by the 09/14/18 version of the 2019 Medicare Part D formulary reference file.

For 19 of the 30 specialty tier drugs in the analysis, the dosage, form, and quantity of the medication used per month were taken from the defaults offered by the Medicare Plan Finder. For the 11 remaining drugs, the Plan Finder dosage, form, and/or quantity did not match the dosage and administration recommendations in the prescribing information for each drug available from the FDA. As such, KFF modified the Plan Finder dosages, forms, and/or quantities accordingly. [FN16]

CBO predicts higher Part D premiums and more federal spending in response to drug rebate proposal by Trump administration

According to a recently released report from the Congressional Budget Office (CBO), the Trump administration's plan to end legal protections for drug rebates in a move to potentially reduce costs would actually increase Part D premiums and federal spending.

The CBO anticipates that the proposed rule would “result in pharmacies' charging beneficiaries' prices for prescription drugs that reflect the discounts that pharmacy benefit managers (PBMs) negotiate with manufacturers.”

The CBO estimates that implementing the rule as proposed would increase federal spending by about $177 billion over the 2020–2029 period. Spending for Medicare would increase by approximately $170 billion and spending for Medicaid would increase by approximately $7 billion.

CBO projects that the proposed rule would increase mandatory spending by a total of $89 billion over the 2020–2029 period. The rule was proposed by the Office of Inspector General of the Department of Health and Human Services (HHS) on January 31, 2019. It would eliminate the existing safe harbor for rebates paid by pharmaceutical manufacturers to health plans and PBMs in Medicare Part D and Medicaid managed care beginning January 1, 2020.

That current safe harbor protects those parties from liability or penalty in specific situations defined in regulations implementing the anti-kickback statute, which prohibits offering or accepting payments to induce use of services reimbursable under federal health care programs. Removing this safe harbor would effectively make it illegal for a drug manufacturer to pay rebates to a health plan or PBM in those programs in return for coverage or preferred treatment of the manufacturer's drug under the PBM's plan. The rule would replace that safe harbor with two new ones: (1) one related to upfront discounts for prescription drugs; and (2) the other to service fees.

The proposed rule would apply to transactions involving Part D plans in Medicare and managed care organizations (MCOs) participating in state Medicaid programs. When announcing the rule, HHS indicated that its intention was for manufacturers to lower their list prices, replace rebates with discounts, or do both.

Under the rule, PBMs could continue to negotiate discounts in return for covering certain medications or giving those medications preferential placement on their formulary (a list of prescription drugs preferred by an insurance plan), but the discounts could not take the form of a rebate paid by the manufacturer to the PBM. Instead, all discounts would need to be directed to the pharmacy and reflected in the final price charged to beneficiaries. Manufacturers could offer discounts to beneficiaries either by reducing their list price or by making a payment to the pharmacy of the full amount of the negotiated discount (referred to as a chargeback). Under the current system, a Part D beneficiary's cost-sharing obligation is related to the list price of the drug (that is, it does not reflect the rebates paid by the manufacturer to the PBM or plan).

Under the system envisioned by HHS, a beneficiary's cost-sharing obligation for a prescription drug for which the manufacturer currently provides a rebate under the safe-harbor rules would instead be based either on a lower list price or on a post-chargeback price. The proposed rule deals only with safe-harbor provisions under the purview of HHS's Inspector General and does not incorporate guidance from the Centers for Medicare & Medicaid Services (CMS) for prescription drug programs in Medicare and Medicaid.

CBO consulted with stakeholders and outside experts to understand the likely effects of implementing the rule as proposed. Based on these consultations, CBO concluded that the new proposed safe harbors would lead to pharmaceutical manufacturers withholding some of the discounts they previously negotiated that could no longer be used under the rule, especially those based on whether a PBM met targets for the share of prescriptions filled with a manufacturer's drug. Specifically, manufacturers would likely withhold approximately 15 percent of the amounts they currently rebate to PBMs in Part D and they would negotiate discounts approximately equal to the remaining 85 percent.

CBO predicted that, instead of lowering list prices, manufacturers would offer the renegotiated discounts in the form of chargebacks.

CBO also estimated that the direct effect of implementing the proposed rule would be to increase federal spending on Part D premiums by about $170 billion over the 2020–2029 period. That increase results from manufacturers' withholding 15 percent of current-law rebates, increases in federal subsidies for premiums, changes in the annual thresholds at which beneficiaries' cost sharing requirements and other program rules change, and the costs of implementing the chargeback system.

CBO also predicted increases in premiums. Under current rules, plans may use manufacturers' rebates to reduce premiums for all beneficiaries. If those rebates were no longer paid directly to plans, Part D premiums would rise. Because the government subsidizes 74.5 percent of the basic beneficiary premium, higher premiums would lead to larger federal subsidies, thus increasing federal spending. [FN17]

Kaiser Family Foundation publishes analysis about out-of-pocket drug costs for Part D enrollees

The Kaiser Family Foundation (KFF) recently conducted an analysis inquiring into the number of Medicare Part D enrollees who experienced high out-of-pocket drug costs in 2017.

Part D enrollees can experience high out-of-pocket costs because the Part D benefit does not include a hard cap on out-of-pocket spending. For drug costs above the catastrophic threshold, enrollees are required to pay up to five percent of their total drug costs, unless they receive low-income subsidies (LIS) that assist them with paying Part D premiums and cost sharing.

This analysis presents the latest data on out-of-pocket drug spending among Medicare Part D enrollees without the LIS who have costs above the catastrophic threshold, referred to in the analysis as “enrollees with high out-of-pocket drug costs.”

Key Findings of the analysis include:

• In 2017, one million Medicare Part D enrollees had out-of-pocket spending above the catastrophic threshold, with average annual out-of-pocket costs exceeding $3,200—over six times the average for all non-LIS enrollees;

• Treatments for autoimmune diseases, hepatitis C, and certain types of cancer were among the 10 highest-cost medications for these 1 million enrollees in 2017, with annual out-of-pocket spending per drug for each of the 10 medications averaging over $5,000; and

• Part D enrollees without low-income subsidies who had high out-of-pocket drug costs in 2017 would have collectively saved $1.4 billion if Part D had a hard cap on out-of-pocket spending that year, rather than requiring enrollees to pay up to 5% coinsurance in the catastrophic phase.

Researchers also found that, in 2017, 3.6 million Medicare Part D enrollees had total drug spending above the catastrophic coverage threshold, which equaled $8,071 in total drug costs that year. This equals 8% of the 44.6 million Medicare beneficiaries enrolled in Part D plans in 2017. Of this total, 2.6 million enrollees (72%) received low-income subsidies (LIS) to help pay their Part D plan premiums and cost sharing, but 1 million enrollees (28%) did not receive these additional subsidies and were therefore not protected against having high out-of-pocket drug costs.

Also, between years 2007 and 2015, the number of Part D enrollees without low-income subsidies who had spending above the catastrophic coverage threshold more than doubled.

On average, Part D enrollees with high out-of-pocket drug costs spent $3,214 for prescriptions in 2017. This is more than six times average out-of-pocket spending by enrollees without the LIS overall ($486), and more than 2.5 times average out-of-pocket spending by enrollees without the LIS who had spending in the coverage gap but not above the catastrophic threshold ($1,200). Enrollees without the LIS who did not have spending high enough to reach the coverage gap spent $274 out of pocket in 2017.

The analysis used Medicare Part D prescription drug event (PDE) claims data from the Centers for Medicare & Medicaid Services (CMS) Chronic Conditions Data Warehouse (CCW) for Part D enrollees between 2007 and 2017. The PDE claims data includes all prescription drug events reported by Part D plans for their enrollees in a given calendar year, and includes detailed data on spending for each event, corresponding to a single prescription drug fill, including how much was paid by plans, low-income subsidy amounts, and beneficiary out-of-pocket payments.

The claims data includes spending for Part D covered drugs, but does not include spending on Part D plan premiums, Part B covered drugs (which are typically administered in providers' offices or hospital outpatient settings), or the cost of drugs purchased outside the Part D plan. The CCW data also includes flags for several chronic conditions (27 common chronic conditions and 35 other chronic or potentially disabling conditions).

The authors calculated average out-of-pocket spending for enrollees overall and by benefit phases. The analysis focuses on beneficiaries enrolled in both stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs) who have high out-of-pocket drug costs, which we define as enrollees who have drug spending that exceeds the catastrophic coverage threshold in a given year who do not receive low-income subsidies (LIS).

The catastrophic threshold is updated annually by the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary; in 2017, the threshold amount was $8,071. The 2017 20% PDE sample includes 8.9 million Part D enrollees (44.6 million weighted), of whom 718,276 (3.6 million weighted) had spending above the catastrophic coverage threshold, including 203,332 (1.0 million weighted) who had high out-of-pocket drug costs and did not receive the LIS.

The analysis of spending by chronic condition excludes beneficiaries who did not meet coverage criteria necessary to assign conditions, including those with multiple months of Medicare Advantage enrollment. This is because the CCW variables that identify chronic conditions are defined algorithmically based on information in medical claims, which are not available for Medicare Advantage enrollees.

The analysis of chronic conditions and specific drugs associated with high out-of-pocket spending was limited to conditions and drugs with 100 (500 weighted) or more non-LIS beneficiaries with high out-of-pocket drug costs in 2017 to avoid reporting estimates based on small sample size. For specific drugs, there are two drugs that had higher average out-of-pocket costs among Part D enrollees with high out-of-pocket spending than the top drug reported (H.P. Acthar), but the number of non-LIS users of each of those drugs in the CCW PDE for 2017 was less than 20. As such, the analysis of the 10 most expensive drugs among those with high out-of-pocket costs is likely conservative because it does not include some drugs with higher out-of-pocket costs but smaller sample sizes. [FN18]

Center right think tank issues proposals to reform Part D program, focusing on out of pocket caps

The American Action Forum (AAF) identifies itself as a “center-right” think tank on economic, domestic, and fiscal policy issues.

AAF's proposal from last year to reform the Medicare Part D program has recently gained attention. The organization recently released a paper that further discusses some of those ideas from its proposal and provides more analysis. A summary of its observations include:

• In setting an out-of-pocket (OOP) cap, the primary trade-off to consider is how many beneficiaries should receive financial protection versus how much premiums should be increased: the lower the OOP cap, the higher the premiums.

• Requiring drug manufacturers to pay rebates in coverage phases beyond just the catastrophic phase will more evenly spread the burden across manufacturers and drug classes, but may weaken the incentive not to increase prices, relative to AAF's original proposal, depending on the discount rates required. It may also provide financial savings to more beneficiaries.

• Implementing this proposal in combination with the administration's proposed “rebate rule” could lead to even higher premium increases. Further, a lower OOP cap would be required to keep the overall spending that occurs before catastrophic coverage at roughly the same level, which in turn would keep expected manufacturer rebates roughly equal.

AAF's proposal seeks to address some problems that currently exist in the Medicare Part D program. For example, insurer liability is very limited in the catastrophic phase. As such, they have little incentive to keep beneficiaries out of that final phase. Moreover, drug makers have no incentive to keep their prices down. The result of this dynamic means that the government is paying more of Part D's cost in the catastrophic phase, the government's overall costs are rising, and some beneficiaries are paying very high costs (even in the catastrophic phase).

AAF's proposal addresses these issues by increasing insurer liability in the catastrophic phase, moving the required manufacturer rebates to the catastrophic phase, and placing a cap on beneficiaries' out-of-pocket (OOP) liability.

Determining where to set the OOP limit is a question of balancing how many beneficiaries should be protected from high OOP costs (and the level of protection that should be provided) against the need for premiums not to increase dramatically. Premiums will rise as the OOP limit drops, all other factors remaining equal. Milliman conducted an analysis in July 2018 modelling OOP maximums between $2,500 and $4,000. At $4,000, the cost of the premium increase is expected to be $60.9 billion less over 10 years relative to what it would be under a $2,500 OOP cap.

Under the current system, beneficiaries reaching the catastrophic coverage phase in 2020 will spend an estimated $2,650 in OOP costs before reaching that phase. As a result, setting the cap at $2,500 provides a comparable threshold to the current system while also providing financial relief to all beneficiaries reaching catastrophic coverage (as well as some who are currently just below the threshold). While premiums are still expected to rise with a $2,500 cap, insurers know the importance of premiums to beneficiaries when selecting a plan and will likely try to mitigate increases through various means, including increased utilization management tools.

Some also favor providing a monthly OOP cap to assist beneficiaries (especially those on a fixed income) facing a very high OOP cost in a single month, potentially reaching the annual OOP cap by January or February. There are two different ways a monthly OOP cap may be applied. A cap that limits OOP expenses in a given month could lead to some manipulation. For example, a beneficiary, upon learning that he will reach the monthly limit, may try to fill all other medications he is prescribed or multiple doses of a medicine before the month's end. Another option is a monthly cap that limits OOP spending for a single month but allows any amount over the monthly cap to still be due in following months, similar to an installment payment plan. For example, if a beneficiary has an OOP liability of $2,000 one month, but a $500 monthly cap is imposed, the beneficiary would pay the $2,000 over the course of four months.

An OOP cap (either annual or monthly) could be indexed just as the various coverage phase limits are currently: increasing at the average rate of per capita cost growth in the program.

One feature of AAF's proposal is that it sets the manufacturer's liability in the catastrophic phase at nine percent. It found nine percent to be the percentage that would be budget-neutral for the pharmaceutical industry as a whole over the 10-year period considered, relative to current projections, based on Milliman's model prior to any assumed behavioral changes.

In explaining this proposal, AAF noted that, “Of course, the intent of the proposal is to change behavior; specifically, it seeks to reduce the prices paid for drugs. Accordingly, modeling showed the expected impact of AAF's proposal if it induced a 5 percent reduction in spending on non-specialty brand-name drugs, achieved through a combination of price reductions and increased plan management of high-cost drugs. Analysis by Milliman found that such a change would reduce the rebates drug manufacturers pay, relative to the baseline scenario, by $1.6 billion over 10 years.[1] It is important to note, however, that a reduction in rebates owed does not necessarily translate to higher revenue for drug companies: Again, those projected reductions in rebates are based on an assumption that prices and spending on drugs is reduced. In other words, drug manufacturers would only owe less in rebates if overall program spending is reduced, essentially allowing them to share in the savings.” [FN19]

CMS announces new enforcement authorities intended to reduce fraud in federal health care programs such as Medicare

The Centers for Medicare & Medicaid Services (CMS) recently issued a final rule that it claims will strengthen the agency's ability to stop fraud before it happens by keeping unscrupulous providers out of federal health insurance programs.

According to CMS, this rule “marks a critical step forward in CMS' longstanding fight to end “pay and chase” in federal healthcare fraud efforts and replace it with smart, effective and proactive measures.” It is part of the Trump Administration's effort to safeguard taxpayer dollars and protect the integrity of the Medicare and Medicaid programs upon which millions of Americans rely.”

The final rule, Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-FC), creates several new revocation and denial authorities to increase CMS' efforts to stop waste, fraud, and abuse. A new “affiliations” authority in the rule allows CMS to identify individuals and organizations that pose an undue risk of fraud, waste, or abuse based on their relationships with other previously sanctioned entities. For example, a currently enrolled or newly enrolling organization that has an owner or managing employee who is “affiliated” with another previously revoked organization can be denied enrollment in Medicare, Medicaid, and CHIP. If the organization in question is already enrolled, it can have its enrollment revoked because of the “problematic affiliation.”

CMS Administrator Seema Verma commented on the new rule, noting that, “For too many years, we have played an expensive and inefficient game of ‘whack-a-mole’ with criminals – going after them one at a time -- as they steal from our programs. These fraudsters

temporarily disappear into complex, hard-to-track webs of criminal entities, and then re-emerge under different corporate names. These criminals engage in the same behaviors again and again."

Administrator Verma also noted that, "Now, for the first time, we have tools to stop criminals before they can steal from taxpayers. This is CMS hardening the target for criminals and locking the door to the vault. If you're a bad actor you can never get into the program, and you can't steal from it."

The rule also includes other authorities intended to improve CMS' fraud-fighting capabilities. Similar to the affiliations component, these authorities provide a basis for administrative action to revoke or deny, as applicable, Medicare enrollment if:

• A provider or supplier circumvents program rules by coming back into the program, or attempting to come back in, under a different name (e.g. the provider attempts to "reinvent" itself);

• A provider or supplier bills for services/items from non-compliant locations;

• A provider or supplier exhibits a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, services or drugs; or

• A provider or supplier has an outstanding debt to CMS from an overpayment that was referred to the Treasury Department.

The newly announced rule also gives CMS the ability to prevent applicants from enrolling in the program for up to three years if a provider or supplier is found to have submitted false or misleading information in its initial enrollment application.

The rule also expands the reenrollment bar that prevents fraudulent or otherwise problematic providers from re-entering the Medicare program. CMS can now block providers and suppliers who are revoked from re-entering the Medicare program for up to ten years. In the past, revoked providers could only be prevented from re-enrolling for up to three years. Furthermore, if a provider or supplier is revoked from Medicare for a second time, CMS can now block that provider or supplier from re-entering the program for up to 20 years.

These new authorities and restrictions become effective November 4, 2019. They are intended to ensure that the only providers and suppliers that will face additional burdens are "bad actors," defined by CMS in a press release as "those who have real and demonstrable histories of conduct and relationships that pose undue risk to taxpayers, patients and program beneficiaries."

CMS also claims that, "This new rule ushers in an important new era of smart, effective, proactive and risk-based tools designed to protect the integrity of these vitally important federal healthcare programs we rely on every day to care for millions of Americans," and Administrator Verma notes that, "Every dollar that is stolen from federal programs is a dollar that will never contribute to paying for an item or service for seniors and eligible people who need them."

According to CMS, the Trump Administration's program integrity activities saved Medicare an estimated $15.5 billion in Fiscal Year (FY) 2017, for an annual return on investment of $10.8 to $1. The 2018 Medicare fee-for-service (FFS) improper payment rate was 8.12%, the lowest since 2010. This translates to about $4.5 billion less in estimated improper payments from 2017. For Medicaid, in FY 2018 CMS recovered $10.5 billion in FFS improper payments. An improper payment is defined as any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements. [FN20]

White paper addresses lack of "first generics" and biosimilars in Part D formularies; suggests that consumers pay more for prescription drugs than they should

The Association for Accessible Medicines (AAM) recently released a white paper called "Access Denied: Why New Generics Are Not Reaching America's Seniors." The paper addresses new data on the treatment of generic medicines in Medicare Part D, which may be resulting in beneficiaries paying more for their medicines even if less expensive, FDA-approved generics and biosimilars are available.

AAM represents the manufacturers and distributors of finished generic pharmaceuticals and biosimilars, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry.

AAM defines "first generics" as medicines approved by FDA as the first competitor to the brand. The organization believes these drugs face "increasing challenges to patient adoption" based on the fact that fewer than 50% of Medicare Part D plan formularies automatically include first generics immediately after launch and for up to three years after launch.

Christine Simmon, AAM Senior Vice President for Policy and Executive Director of its Biosimilars Council, commented on this issue, noting that, "New, discounted generics are a critical public health priority, but when they are delayed onto the Part D plan formularies, America's seniors pay more out -of-pocket for their prescription drugs. It doesn't add up."

Ms. Simmon further stated that, "We urge the Administration to use its existing authority to require automatic coverage of first generics onto generic tiers, and create a dedicated specialty generics/biosimilars tier, saving the health care system billions annually and ensuring seniors get the full value of generic and biosimilar medicines."

AAM argues that, in addition to depriving patients access to more affordable medicines, this practice "threatens the long-term sustainability of the generic and biosimilars industry." The biosimilars industry, according to AAM, is responsible for delivering $293 billion in savings for the U.S. health care system in 2018 alone, despite industry-wide price deflation for 36 of the past 38 months.

Findings include of the white paper include:

• First generics are covered on formulary approximately 10 to 25% of the time in the first year of launch, 25 to 35% in the second year after launch and 55 to 65% in the third year after launch;

• By the second year after launch, first generic net prices declined by 45 percent on average, yet plan coverage only improved by 9-13%. Plans are not proportionally responding to generic price decreases well after the first year of being on the market;

• Even three years after launch, formularies exclude coverage of first generics approximately 40% of the time; and

• When covered, first generics are placed on brand tiers more than 50% of the time, putting them on the same or similar tier as their higher-priced brand counterparts. This means patients pay the same or more for a generic than for the higher priced brand drug.

According to Simmon, “The FDA prioritizes review of first generics and has been approving generic drug applications at a record-setting pace, yet these Medicare Part D design structural flaws mean seniors and taxpayers continue to pay for high priced brand drugs. First generics are a bellwether for savings and future generic competition, and policymakers must act now to ensure America's patients have both.”

AAM states that it “is driven by the belief that access to safe, quality, effective medicine has a tremendous impact on a person's life and the world around them. Generic and biosimilar medicines improve people's lives, improving society and the economy in turn.”

Generic drugs constitute approximately 90 percent of prescriptions dispensed in the United States, but only 22 percent of total drug spending. [FN21]

Kaiser Family Foundation report finds that list prices increased as much as nine times faster than inflation for 20 of the top 25 Part D drugs

A recently published Kaiser Family Foundation (KFF) analysis found that, between the years 2016 and 2017, the list prices for most of the top Medicare Part D drugs by total spending increased as much as nine times the rate of inflation, which was 1.7%. These findings suggest that recent Congressional proposals targeting such increases could generate savings for Medicare and Part D enrollees.

The analysis found that 20 of the top 25 drugs, all of which were brand-name medications, had price increases between three and over nine times the inflation rate during that year. In some instances, increases significantly exceeded the inflation rate. These included a 15.7% increase for Lyrica, a pain medication used by 900,000 Part D enrollees; a 15.3% increase for Revlimid, a cancer drug used by 37,000 enrollees; and a 13.2% increase for Humira Pen, a medication for rheumatoid arthritis taken by 52,000 Medicare Part D enrollees.

The KFF analysis was based on data from the CMS's most recent Medicare Part D drug spending dashboard. Of the 2,879 drugs reported in 2017 in the dashboard (both brand-name and generic), the list prices of 60 percent of the drugs rose at a rate greater than inflation between 2016 and 2017.

The analysis suggested that there exists a significant potential for savings to the Medicare program if drug manufacturers limited price increases to the rate of inflation, or if they paid a rebate to the federal government. Medicare beneficiaries could also benefit from such changes because Part D cost sharing often occurs in the form of coinsurance, which is calculated as a percentage of the list price.

KFF did not analyze any specific provision in current legislation that would require drug manufacturers to pay a rebate to the federal government if their drug prices increase above the rate of inflation. The analysis was based on pricing data that does not reflect existing manufacturer rebates or discounts to plans, which are considered proprietary and are not publicly available. [FN22]

CMS issues press release praising number and quality of choices in Part D drug program

The Centers for Medicare & Medicaid Services (CMS) recently issued a press release noting that, “Consistent with the direction of President Trump's recent Executive Order on Strengthening and Improving Medicare for Our Nation's Seniors, the Centers for Medicare & Medicaid Services (CMS) announced today that seniors will have access to more high-quality Medicare Advantage and Part D prescription drug plans in 2020.”

According to CMS, most people with Medicare will have access to Medicare Advantage and Part D plans with four or more stars in 2020, and approximately 81 percent of Medicare Advantage enrollees with prescription drug coverage will be in plans with four and five stars in 2020.

CMS Administrator Seema Verma commented that, “President Trump continues to be the great protector of the Medicare program for our nation's seniors. Thanks to the President's leadership and commitment, the improvements that CMS has made to the Medicare Advantage and Part D programs means that seniors will have access to more high-quality plans. Proposals for more government in our healthcare – such as Medicare-for-All – would eviscerate the progress we've made to strengthen the program by empowering patients to make informed choices in choosing high-quality plans that best fit their needs.”

CMS also contends that more Medicare beneficiaries will have access to a greater number of high-quality stand-alone Medicare Part D prescription drug plans. In 2020, based on current enrollment, approximately 28 percent of enrollees will be in stand-alone prescription drug plans with 4 stars or higher, an increase from approximately 3 percent in 2018. Moreover, the average star rating for a stand-alone prescription drug plan has improved from 3.34 in 2019 to 3.50 in 2020.

Earlier in 2019, CMS attempted to improve the Medicare Advantage and Part D Star Ratings so that consumers can more easily identify high-value and high-quality plans. The Star Ratings methodology was enhanced to better account for differences in a plan's enrollee population.

CMS notes that “it will be easier than ever” to compare Medicare Advantage and Part D plans on Medicare.gov. CMS has launched a modernized and redesigned Medicare Plan Finder, which is the most-used tool on Medicare.gov. The Plan Finder allows users to shop and compare Medicare Advantage and Part D plans (including by total costs of estimated annual drug costs plus premiums), as well as compare costs between original Medicare, Medicare prescription drug plans, Medicare Advantage plans and Medicare supplemental insurance (Medigap) policies.

Medicare Open Enrollment began on October 15, 2019, and ends on December 7, 2019. During this period, Medicare beneficiaries can compare coverage options like Original Medicare and Medicare Advantage, as well as choose health and drug plans for 2020. [FN23]

Kaiser Family Foundation analysis finds that millions of Part D enrollees will see higher premiums and costs in 2020 if they do not switch plans this open enrollment period

A recent Kaiser Family Foundation (KFF) analysis found that millions of current enrollees in stand-alone Medicare Part D prescription drug plans will face premium and other cost increases in 2020 unless they switch to lower-cost plans during the open enrollment period that began Oct. 15 and ends on Dec. 7, 2019.

Researchers found that two-thirds of Part D stand-alone drug plan enrollees not receiving low-income subsidies, which amounts to approximately nine million enrollees, will experience higher monthly premiums if they keep their current plan in 2020.

For example, the 1.9 million enrollees without low-income subsidies in the Humana Walmart Rx plan (which is the third most popular stand-alone plan in 2019) will have their monthly premium more than double, on average, if they do not switch plans for 2020. This increase is a result of Humana consolidating this plan and the Humana Enhanced plan into a new offering named Humana Premier Rx. Current Humana Walmart Rx enrollees will be automatically enrolled in the new plan, and, unless they switch, will experience a monthly premium increase from $28 to $57.

Moreover, although premiums for other national plans are decreasing, enrollees in those plans may experience other cost increases. For example, the 2.1 million enrollees without low-income subsidies in the nation's largest stand-alone Part D plan (CVS Health SilverScript Choice) will have a $2 decrease in their average monthly premium, from $31 in 2019 to $29 in 2020. However, the annual deductible in this plan will increase from $0 in most areas in 2019 to $215 to $435 in 2020. This deductible increase will more than offset the $2 reduction in monthly premiums.

The analysis found that premiums will vary widely across plans in 2020, which is consistent with prior years. Among the 20 stand-alone Part D plans available nationwide, average premiums will range from $13 per month (Humana Walmart Value Rx) and $14 per month (WellCare Wellness Rx) to $79 per month (AARP MedicareRx Preferred) and $83 per month (Express Scripts Medicare Choice).

Based on current enrollment patterns, the estimated national average monthly PDP premium for 2020 is projected to increase by 7% to $42. The actual national average premium in 2020 may be lower if current enrollees switch to, and new enrollees enroll in, lower-premium plans during the current open enrollment period.

Other key findings in KFF's “Medicare Part D: A First Look at Prescription Drug Plans in 2020” include:

• The typical Medicare beneficiary will have a choice of 28 stand-alone drug plans next year, one more option than in 2019, and six more than in 2017;

• In 2020, nearly nine in 10 stand-alone drug plan enrollees are projected to be in plans operated by five firms: UnitedHealth, Humana, WellCare, CVS Health, and Cigna;

• There is a wide difference in cost sharing for generic and brand-name drugs, and most plans are charging the standard deductible of $435, unlike previous years. Among all stand-alone plans, median cost sharing is $0 for preferred generics and just $3 for generics, but $42 for preferred brands and 38 percent coinsurance for non-preferred drugs (the maximum allowed is 50%), plus 25 percent coinsurance for specialty drugs (the maximum allowed is 33%);

• Medicare beneficiaries receiving the Low-Income Subsidy (LIS) will have a choice of seven premium-free PDPs in 2020, on average, one more than in 2019. In 2020, nearly 20% of all LIS PDP enrollees who are eligible for premium-free Part D coverage (1.3 million LIS enrollees) will pay Part D premiums averaging $18 per month unless they switch or are reassigned by CMS to premium-free plans; and

• Forty-five million beneficiaries have prescription drug coverage through Medicare, including 20.6 million who are in stand-alone Part D plans as a supplement to traditional Medicare. The analysis provides an overview of stand-alone plans that will be available in 2020 and highlights key changes from prior years.

The analysis did not address the 17.4 million people enrolled in Medicare Advantage prescription drug plans (non-employer), the 4.6 million enrollees in employer-group only stand-alone plans, and the 2.3 million in employer-group only Medicare Advantage drug plans. Premiums and benefits data for those employer-group plans are not publicly available.

KFF also provides an updated basic resource, “An Overview of the Medicare Part D Prescription Drug Benefit,” and the recently released “How Will The Medicare Part D Benefit Change Under Current Law and Leading Proposals?” The latter publication also suggests that some Part D enrollees can expect to see their out-of-pocket drug expenses rise in 2020. [FN24]

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