RADAR on Drug Benefits
Business Strategies and Analysis for Health Plans, Employers, PBMs and Pharma Companies

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Trump's Importation Program May Have Small Reach for Now

Amid an ongoing outcry against rising drug costs, the Trump administration introduced two importation pathways to reduce what U.S. residents pay for drugs. Although industry insiders tell AIS Health the pathways likely will have no effect on drug costs over the next few years, they suggest partnering with states already working on reimportation schemes to build experience with such programs.

HHS Secretary Alex Azar on July 31 announced two pathways to help U.S. residents pay less for pharmaceuticals. Under the Safe Importation Action Plan, the first pathway would allow states, wholesalers and pharmacists to propose to HHS demonstration projects for importing certain drugs from Canada. Proposals would have to ensure no additional risk to health and safety and must result in "significant cost savings." However, this pathway would exclude biologics such as insulin, infused drugs and injectables, among other categories.

Under the second pathway, drug manufacturers could import non-U.S. countries' versions of their drugs into the United States; manufacturers would need to validate that the drug manufactured outside the United States is the same as the FDA-approved version and that the drug would be sold under a new National Drug Code, potentially making it less costly to U.S. residents.

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PBMs Lean Into Care Management for Chronic Conditions

Though PBMs are most known — and lately, heavily scrutinized — for the influence they have on prescription drug costs, some firms are increasingly focused on offering high-touch condition management services that give them a more active role in patient care.

For the Berwyn, Pa.-based specialty PBM AscellaHealth, LLC, that means harnessing a variety of resources to help better manage treatment for hemophilia, a notoriously expensive disease state.

Not only does the PBM leverage its specialty pharmacy network to obtain the best prices for hemophilia clotting factor — which helps blood clot normally for patients with the rare bleeding disorder — but it also uses technology to monitor medication dispensing in real time and provides clinical interventions when necessary, explains Mike Baldzicki, AscellaHealth's executive vice president of growth and strategy.

"Managing cost and quality kind of go hand in hand in this regard," adds Dea Belazi, the PBM's CEO.

Meanwhile, a much larger industry player — CVS Health Corp. — is expanding its Transform Diabetes Care program, which helps members of its PBM, Caremark, control their diabetes by providing technology-enabled, personalized support and coaching focused on improving medication adherence and controlling blood-sugar levels.

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CVS says it's offering such services to meet client demand.

"Employers, health plans and other payors increasingly are looking for help in improving quality of care while reducing treatment costs for their members with complex, chronic diseases," Tracey Noe, senior director of corporate communications for CVS, tells AIS Health.

While care-management programs are hardly a new concept in the health care industry, "the new part, I would say, is putting the PBM at kind of the center of these programs," says Ashraf Shehata, a principal in KPMG's health care life sciences advisory practice and the firm's Global Healthcare Center of Excellence.

Particularly for companies like CVS — which has a payer, providers, a retail pharmacy chain and a PBM under its umbrella — "it is really a great example of the PBM being kind of the tip of the spear for this new enterprise," he says.

Belazi, meanwhile, says AscellaHealth is seeing interest in its hemophilia-management services even from stop-loss insurance carriers when they get high cost-cases that range from $450,000 to $1 million for one patient.

Asked why hemophilia is so costly to treat and challenging to manage, Baldzicki notes that it has had an "interesting disease progression" in the last five to eight years. People with the disorder are now living longer, and young adults with the disease are also engaging in activities — like hiking or playing basketball — that were previously unheard of for hemophiliacs, so "we're seeing an increase in muscle bleeds," he says. Numerous pharmaceutical products are being launched to treat hemophilia — and coming with larger price tags.

Critically, though, the firm is "not just looking at this as another disease to manage as a pharmacy benefit manager," Baldzicki says. "You simply can't apply the same tactical and utilization management techniques as you would with [hepatitis C]…or even cancer — it's a totally different market."

To design its program, AscellaHealth tapped the National Hemophilia Foundation as a subject matter expert to align the PBM's condition-management practices to what's clinically appropriate and what works best for patients, Belazi says. The PBM also uses a technology platform that enables it to gain greater visibility into "what's actually being prescribed versus dispensed" to hemophilia patients, as well as when they log their infusions, according to Baldzicki.

Platform Prevents Stockpiling, Waste

If, for example, a member infuses two times one day, "we capture that in real time with an alert, and then we have our clinical teams along with our pharmacies in our network to kind of jumpstart that intervention in terms of what's going on with that patient — and start doing the necessary reach-outs that are needed for intervention to make sure the patient is not only dosing correctly, but [to log] if they had some type of event that made them bleed a little more than usual," he says.

AscellaHealth's platform also allows it to "make sure the patient's getting not just enough medication, but also enough to handle that one-off bleed that might happen because they're hiking tomorrow or what have you," Belazi adds. Further, the PBM works closely with dispensing pharmacies to ensure they're not just sending large volumes of factor every week or every month to patients, which could lead patients to stockpile clotting factor and create waste, he adds.

Both Baldzicki and Belazi say the PBM's program is intended to complement providers' work rather than replace it, and they note that the tools

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AscellaHealth offers give physicians themselves more insight into what's happening with their hemophilic patients.

"We've not gotten significant pushback around this," Belazi says. Change can be difficult, "but for the most part, especially the patient interest, and obviously the cost savings associated with [the program], is definitely very high."

CVS Expands Diabetes Care Program

Technology also plays a key role in CVS Caremark's Transform Diabetes Care Program, which it first launched in 2017. The program "uses advanced analytics to identify unique improvement opportunities for enrolled members and leverages the company's Health Engagement Engine to enable more effective outreach by identifying and prompting personalized counseling opportunities," according to CVS.

Members who enroll in the program get free, personalized support and coaching to help improve medication adherence, better track and control A1C levels and support healthy lifestyle behaviors — services that are available at CVS pharmacies, MinuteClinic locations and by telephone. Members are also offered a glucometer that shares their blood glucose levels with a pharmacist-led team via a health cloud, "enabling the team to identify potential issues and intervene with one-on-one coaching."

CVS says more than half of members with uncontrolled diabetes who enrolled in the program have moved to a controlled status, and members have improved HbA1c by an average of 1.2 percentage points. On July 30, the company said it was "building on this success" and expanding the Transform Diabetes Care Program to focus on prevention and early identification of diabetes as well as hypertension, which is twice as common in diabetes patients as the regular population.

CVS's proprietary analytic engine identifies members with prediabetes, as well as those with hypertension, through pharmacy, medical and laboratory data, according to the company. Once enrolled in the expanded program, members with prediabetes will receive a connected digital scale, a CDC-approved app-driven prevention program and health coaching with experts across a range of specialties, like nurses, dietitians, and exercise and behavioral therapists. Those with hypertension will get a connected blood pressure cuff, along with an app-based hypertension management program and coaching support. "These connected devices automatically capture the member's readings in a personal profile that they can access securely online, on any device," Noe points out.

Programs Are 'Good Revenue Opportunity'

In general, she says, CVS is "thinking beyond the traditional PBM — creating integrated programs that leverage the latest innovations in digital health, connected devices and one-on-one, high-touch personalized support to help patients better manage chronic conditions and head off potentially high health care costs."

Both AscellaHealth's hemophilia management program and CVS's diabetes care program align with larger trends Shehata says he's seeing in the PBM space. For one, firms are increasingly integrating traditional medication therapy management with connected medical devices "to help create a much more visible data and information stream around people's ability to successfully accomplish their medication regimen," he says.

In addition, "this is also now being driven at the benefit design level," he says. "These programs are not just offered to everybody — they're clearly going to be positioned as a buy-up for the commercial market," and therefore are a good revenue opportunity for PBMs.

It's also possible that such programs might help justify the high cost of certain specialty drugs, he says, because high-touch care models can achieve better clinical results for treatments that require complex regimens. "You're going to probably see, potentially, drug manufacturers that are willing to kind of step into this and work with the PBMs — and of course their related health entities — to administer these types of more complex systems," Shehata adds.

Read about CVS's program expansion at https://bit.ly/2KkpOFx. Contact Belazi and Baldzicki via Nicole Dufour at ndufour@cpronline.com and Shehata via Peter Settles at psettles@KPMG.com. ✧

by Leslie Small

CVS Earnings Win Tempered by PBM Segment Non-Renewals

CVS Health Corp. reported strong earnings for the second quarter of 2019 across all its business segments, including the Caremark PBM. However, the company said it expects to lose a net $7.4 billion in PBM business for 2020, driven in part by Centene Corp.'s decision to move its PBM business to RxAdvance, in which Centene holds a 35% ownership stake.

The RxAdvance move will cost CVS's Caremark division around $3.6 billion. That amounts to a little less than one-third of CVS's total non-re-

newals for 2020, the company estimates.

Despite those non-renewals, CVS has had what it described as a strong 2020 PBM selling season, with 90% to 91% of contracts completed for 2020 and gross new business of $3.8 billion, compared with $3.2 billion previously announced for next year, Derica Rice, executive vice president, CVS Health, and president, CVS Caremark, said during the company's Aug. 7 earnings call. "We're beginning to get bids for 2021," Rice added.

In addition, Centene's transition to RxAdvance is moving more slowly than expected, leading CVS "to be able to retain some business" in the near term, Rice said. He noted that "operationally, we continue to have a very, very high service level," which has contributed to the PBM's bottom line.

PBM Saw Strong Growth in Mail Service

The PBM generated "strong performance on overall scripts and strong growth in mail service — especially in Maintenance Choice offerings," and "higher rebates earned in the quarter, which are a function of procurement activities and improvements in formulary compliance," added Eva Boratto, executive vice president and CFO.

The company also cited "recent policy advancements," including the Trump administration's decision to withdraw a proposed rule that would have overhauled the prescription drug rebate system in Medicare Part D, as potential tailwinds for its PBM and other business segments.

Total pharmacy services segment revenues rose 4.2% year-over-year in the second quarter from 2018's second quarter, and total claims rose 4% year-over-year to 489 million, from 470.1 million, the company said. Adjusted operating income for the business unit rose 9.7% to reach $1.296 billion in the second quarter.

Key revenue growth drivers in the pharmacy services segment included brand name drug inflation along with increased total pharmacy claims volume, the company reported. This was partially offset by "continued price compression" and an increased generic dispensing rate, which hit 88.5% for the quarter. Specialty revenue increased by 9.7% year-over-year from 2018, according to the company.

> **Frankly we don't see CVS with much risk from an intellectual standpoint.... but this may not matter as states/cities need funding from deep-pocketed entities to combat the [opioid] crisis.**

CVS upgraded its full-year total revenue forecast for its pharmacy services business by $110 million to a range of $137.4 billion to $138.95 billion, with adjusted operating income expected in a range of $5.06 billion to $5.12 billion and total claims in a range of 1.95 billion to 1.97 billion.

The company said it expects synergies worth roughly $400 million to accrue this year from its five-year pact with Anthem, Inc. to help the insurer launch its new PBM, IngenioRx.

In 2020, those synergies will be worth roughly $800 million, and by 2021 they should be worth roughly $900 million, the company said. The IngenioRx integration "to date has gone flawlessly," CVS President and CEO Larry Merlo said.

Overall, CVS posted second-quarter adjusted earnings per share of $1.89, which was above the consensus expectations of 19 to 20 cents a share and above the company's quarterly guidance of $1.68 to $1.72 per share. Second-quarter adjusted revenues came in at $63.4 billion, up 35.8% year-over-year, and adjusted operating income was $4.03 billion, up 55.2% year-over-year, both above expectations.

CVS also raised its total earnings per share guidance range for the year, with Merlo telling conference call attendees that "all of our businesses [are] performing at or above expectations."

Reimbursement Pressures Remain a Risk

Analysts generally cheered the quarter's results. "CVS' second quarter results were above our expectations, with both the retail and pharmacy services segments demonstrating upward momentum," said Moody's vice president Mickey Chadha, who did note that overall 2019 operating income will be lower than what Moody's originally had expected, "and challenges – particularly reimbursement pressures – remain."

Evercore ISI's Ross Muken and Michael Newshel agreed in their Aug. 7 investor note that "all segments delivered upside" and "the company is making progress on a number of innovative new programs/technologies."

However, they did note some potential downside risk associated with potential pharmacy liability for opioid misuse: "Frankly we don't see CVS with much risk from an intellectual standpoint (they didn't create demand and all Rx came from a licensed physician), but this may not matter as states/cities need funding from deep-pocketed entities to combat the crisis."

Contact Chadha via spokesperson Stephanie Leavitt at Stephanie.leavitt@moods.com and Muken and Newshel at rossandmike@evercoreisi.com. ✧

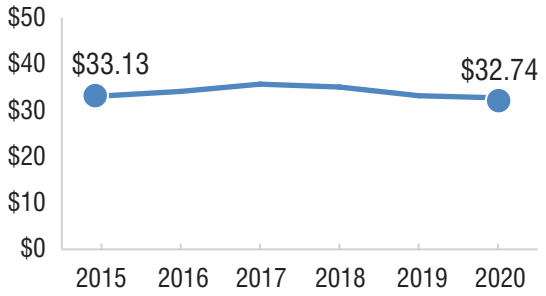
by Jane Anderson

Average Medicare Part D Base Beneficiary Premium Declines for Third Straight Year

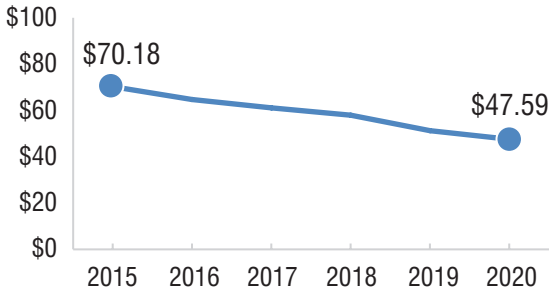
by Jinghong Chen

CMS said on July 30 that the Part D base beneficiary premium for 2020 will be $32.74, down from $33.19 in 2019, and the *de minimis* amount is $2. The Part D national average monthly bid amount also dropped slightly, from $51.28 in 2019 to $47.59 in 2020. Regional low-income premium subsidy amounts fluctuated over the past six years, but all states are projected to see a decrease in 2020.

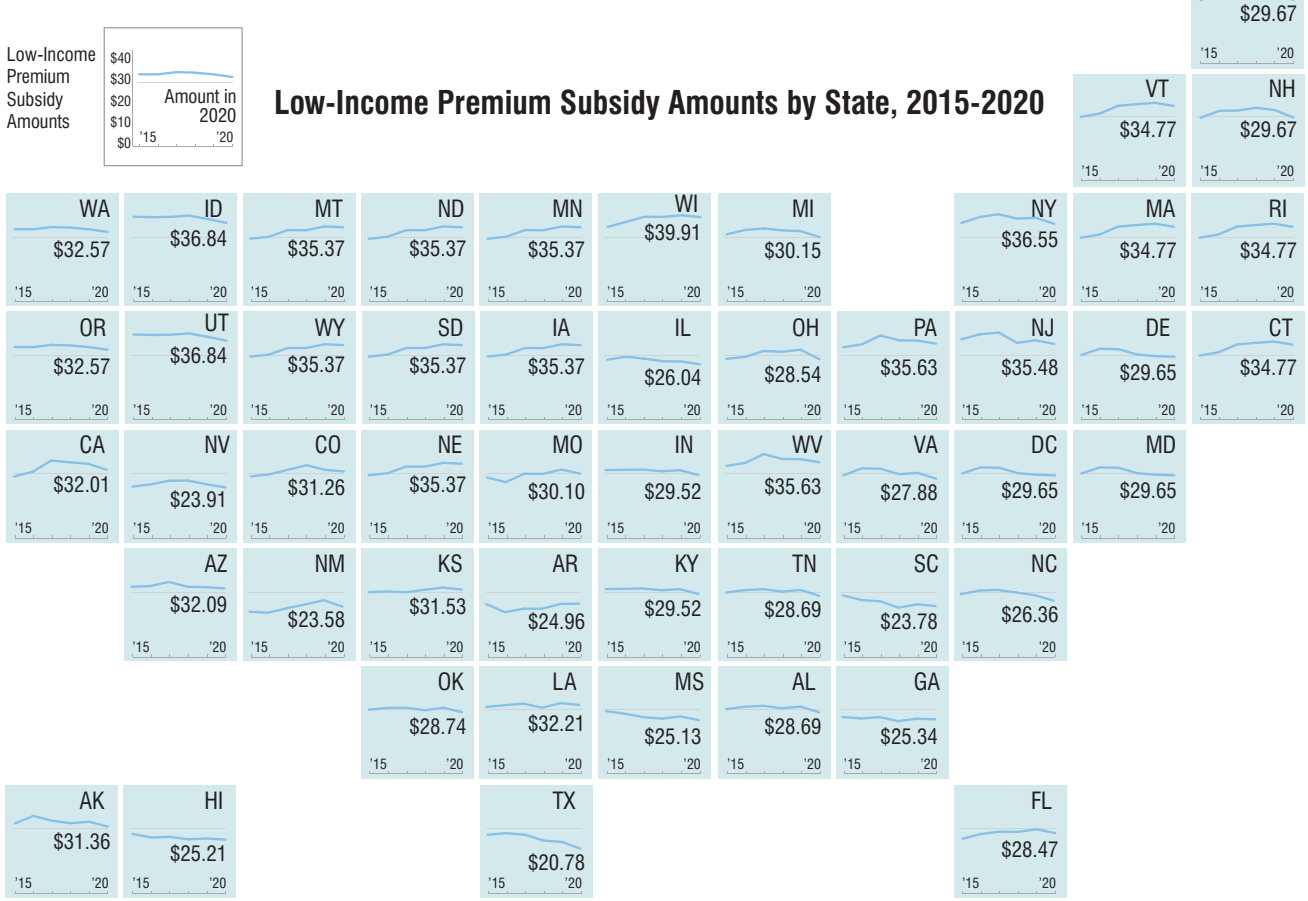
Part D Base Beneficiary Premium, 2015-2020



Part D National Average Monthly Bid Amount, 2015-2020



Low-Income Premium Subsidy Amounts by State, 2015-2020



SOURCE: CMS. Visit https://go.cms.gov/2arFZfX. Infographic compiled by AIS Health.

Importation Is a Long Way Off

continued from p. 1

The Trump administration has been working to reduce drug prices at a time when the cost of insulin has nearly tripled between 2002 and 2013 and CAR T-cell treatments such as Novartis' Kymriah (tisagenlecleucel) cost $475,000 for a single use. But other Trump administration initiatives have fallen apart over the past month. A judge blocked an HHS rule requiring that manufacturers disclose drug prices in TV ads from taking effect, and the administration abandoned a proposal targeting drug rebates.

What do health plan executives need to worry about with these two pathways? Not much, at least not in the next couple of years. That's according to Jigar Thakkar, Pharm.D., a managing director at FTI Consulting, where he advises health care clients on pharmacy strategy.

"There are so many hurdles that this isn't something that's going to happen tomorrow or in the next year or two," says Thakkar. The hurdles include passage of legislation to allow biologics such as insulin to be imported and the ability of drugs imported from other countries to be tracked according to FDA-TRACK, the FDA's agency-wide performance system that monitors drugs during their journey from manufacturer to distributors to pharmacies.

Expect Resistance From Canada

Another significant hurdle is pushback from the Canadian Medical Association, the Canadian Pharmacists Association and other interest groups in Canada. Bloomberg News reported that the Canadian Medical Association and 14 other groups sent a letter to Canada Health Minister Ginette Petitpas Taylor protesting the Trump administration's moves.

"Hospital and community pharmacies in Canada are resourced to serve the Canadian public," wrote signatories to the letter. "They are not equipped to support the needs of a country 10 times its size without creating important access or quality issues."

> **"There are so many hurdles that this isn't something that's going to happen tomorrow or in the next year or two.**

The interest groups' representatives also wrote: "Encouraging Americans to look for cheap Canadian imports could also spur the growth of illegal online pharmacies misrepresenting themselves as licensed Canadian pharmacies — as it is, 600 new illegal pharmacy sites launch every month."

Canadian Supplies 'Would Be Exhausted'

Deb Devereaux, senior vice president of pharmacy at Gorman Health Group, isn't optimistic about the success of the first pathway where drugs would be imported to the United States from Canada. "The bottom line is the Canadian drug supply would be exhausted in 16 months with all the U.S. states trying to avail themselves of Canadian drugs."

Devereaux is confident Canadian lawmakers will pass legislation to prevent the import of drugs from Canada to the United States.

Bharat Rao, Ph.D., a principal at KPMG in the health care practice, applauds the Trump administration's efforts to reduce prescription costs for U.S. residents. Still, he describes the first pathway as "kicking it to the states" rather than causing systemic change that will reduce the cost of drugs in the United States.

Another hurdle to the first pathway is privacy laws such as HIPAA, he says, which U.S.-based health plans must adhere to. Health plan executives should be mindful of patient privacy, because there could be a data breach where notification is required. "It's unlikely that a Canadian [entity] is going to sign up for that," says Rao.

In terms of timing, he doesn't expect significant movement on either pathway until after the 2020 presidential election. Still, Rao doesn't rule out the political will of President Donald Trump, who could drive his administration to partner with a state such as Florida, which passed a law allowing it to import drugs from Canada. (Florida joins Colorado and Vermont, which have passed similar laws.)

Regarding the second pathway, where drug manufacturers could import their drugs from another country into the United States, Rao also sees the possibility of a short-term success. That is, if the Trump administration, to achieve a political win, provides financial incentives for pharmaceutical companies to encourage their participation.

U.S. Won't See Changes For Years

But Rao doesn't foresee fundamental changes to the way U.S. residents pay for drugs for at least five years. He points to two possible wild cards that could change his calculation: Either the Democratic or the Republican party takes over both houses of Congress and the White House, or Trump uses his political will to force a change.

Amid this uncertainty, what can health plan executives do? Rao suggests kicking off a small pilot project with a state like Florida that has already passed laws to allow importation from Canada. Before participating in a pilot project, he advises executives to study the appropriate regulations, assess the

role of the FDA in the project and determine the liabilities if, for example, a breach of patient information occurs.

In addition, health plan executives typically negotiate three-year contracts with PBMs with the option to update specifics each year in response to market conditions, says Brian Anderson, a principal at Milliman where he advises clients on pharmacy benefits.

That's important to keep in mind, as any strategy moves related to the two new pathways would need to be integrated with those timeframes.

Contact Anderson at brian.anderson@milliman.com and Devereaux at ddevereaux@gormanhealthgroup.com. ✧

by Aine Cryts

Despite Initial Uncertainty Over Rebates, 2020 Part D Bids Are 'Business as Usual'

Both the Medicare Part D base beneficiary premium and the Part D national average monthly bid amount declined in 2020, according to data released by CMS on July 30. That makes 2020 the third straight year that the base premium is set to decline, a trend that one expert says is partially driven by what's happening with the national average reinsurance amount.

The average reinsurance amount — essentially what the government pays when Part D plan members are in the catastrophic phase of their benefit — went up by "double digit percentages" for several years but has flattened out more recently, says Shelly Brandel, a principal and consulting actuary in the Milwaukee office of Milliman, Inc. Brandel calculates the figure will be $80.80 for 2020.

Around 2014 and 2015, pricey new products on the market like Gilead Sciences, Inc.'s breakthrough hepatitis C drug, Harvoni (ledipasvir/sofosbuvir), had a significant impact on reinsurance costs, Brandel explains. "Now the utilization and costs for some of those drugs is coming down, so that has an impact on reinsurance."

Changes to the defined standard benefit in Part D have also affected reinsurance amounts, but another key factor is that drug manufacturer rebates and other forms of direct and indirect renumeration (DIR) — such as pharmacy price concessions — have been increasing over time.

"When carriers put together their bids, a portion of that DIR flows into the reinsurance amount, so that has a dampening impact on reinsurance trends," she says.

Asked why rebates and DIR have been increasing, Brandel points to the fact that Part D sponsors are getting more concessions out of drug manufacturers. And, "preferred pharmacy networks have become very prevalent, especially for Prescription Drug Plans," she says.

Earlier this year, the Trump administration's proposal to stop shielding rebates from antikickback laws threatened to add considerable complexity and uncertainty to the annual Part D process. But CMS ended up advising Part D plan sponsors to assume the status quo when submitting their 2020 bids, and the administration later scrapped its proposed rule *(RDB 7/11/19, p. 8)*.

The Part D national average monthly bid amount for 2020 ended up being $47.59, according to CMS, down from $51.28 in 2019 (see infographic, p. 5). Brandel says that $3.69 year-over-year decrease is "roughly in line" with changes in bid amounts in the last few years, although in 2019 the bid amount decreased more than average.

"After a lot of uncertainty initially — early in the bidding process — at the end of the day, there wasn't a lot changing with respect to prior years," she says. In other words, the 2020 Part D bids were "business as usual," according to Brandel.

The 2020 base beneficiary premium will be $32.74 — down from $33.19 in 2019 — and the *de minimis* amount for next year is $2. In a press release, CMS attributed the steady decline in Part D premiums to "increased competition and strengthened negotiations" in the program. One program improvement the administration points to is its decision to allow Part D plan sponsors the option to implement indication-based formulary designs beginning in 2020 *(RDB 9/14/18, p. 8)*.

"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," CMS Administrator Seema Verma said in a statement.

View CMS's Part D national average bid amounts and other data at https://go.cms.gov/2ytp61K. Contact Brandel at shelly.brandel@milliman.com.

by Leslie Small

News Briefs

✦ ***A U.S. district court ruled on July 31 that the Pharmaceutical Research and Manufacturers of America (PhRMA) can proceed with an amended lawsuit that challenges California's law requiring drug manufacturers to provide advance notice and justification for price hikes, Stat reported.*** PhRMA contends that the law — which will remain intact while litigation continues — is unconstitutional. Two days earlier, California Attorney General Xavier Becerra said the state reached settlements with Teva Pharmaceutical Industries Ltd., Endo Pharmaceuticals Inc. and Teikoku Pharma USA Inc. to resolve claims they engaged in "pay for delay" practices — when pharmaceutical firms pay generic drugmakers to delay bringing cheaper versions of branded drugs to the market. The three drugmakers will pay the state nearly $70 million. See https://bit.ly/2YL1AZ3 and https://bit.ly/311guMb.

✦ ***The fight between Amazon-owned prescription drug delivery service PillPack and industry incumbents is heating up.*** CNBC reports that Surescripts — an electronic-prescribing company owned by a coalition that includes CVS Health Corp. and Cigna Corp.-owned PBM Express Scripts — is threatening to report a third party entity called ReMy Health to the FBI, claiming it fraudulently provided PillPack with patient prescription information. Previously, Amazon threated to sue Surescripts over its alleged attempt to block PillPack from obtaining that data *(RDB 7/25/19, p. 8)*. Meanwhile, a separate CNBC article details another PillPack conflict, in which the firm claims CVS and Walgreen Co. are unfairly refusing to honor prescription transfer requests. The retail pharmacy giants contend that PillPack isn't getting proper consent from patients. See https://cnb.cx/2TcqnEd and https://cnb.cx/2yMaZVq.

✦ ***The Minnesota-based health plan Medica on Aug. 6 introduced a cap on the maximum amount that its commercial and individual market members will pay for insulin — no more than $25 for a 30-day supply.*** The policy will apply to all types of insulin covered by the affected customers' plans, and Medica notes that the move will not affect member premiums that it already filed with the state for 2020. Visit https://bit.ly/2yH98RU.

✦ ***Starting this fall, the Federal Employees Health Benefits Program (FEHBP) will tighten its rules for covering prescription opioid painkillers, the Trump administration said July 29.*** The Associated Press said the announcement was made by a senior administration official as part of a White House drug policy briefing; the official spoke on condition of anonymity under the event's media coverage rules. With some exceptions, the new policy calls for an initial prescription supply of seven days instead of up to 30 days, the official said. Three refills of seven days apiece will be allowed, and formal reauthorization from a clinician will be required every 28 days. FEHBP covers about 9 million federal workers, retirees and their families. Read the AP story at https://bit.ly/2LPwz4d.

✦ ***A new study from Humana Inc. highlights the unique benefits associated with targeted medication reviews (TMRs) for Medicare Part D members, which involve ongoing monitoring to assess a patient's medication use and identify actual or potential medication-related problems.*** The study, published in the June 2019 issue of the Journal of Managed Care & Specialty Pharmacy, found that TMR interventions were associated with statistically significant reductions in acute inpatient admissions and increases in medication adherence. Comprehensive medication reviews (CMR) — which include an annual medication review and action plan for each eligible patient — were associated with reductions in acute inpatient admissions only when the patient had a known medication-related problem. But Humana notes that the CMS star rating system "incentivizes Part D plans to focus on CMR completion and may limit investments in TMR activities." Read more at https://huma.na/2Km1T8C.

✦ ***Of the 1.2 million beneficiaries who filled a prescription for a Medicare Part D-covered cancer drug in 2017, 21% reached the catastrophic level of coverage, compared to just 8% of all Part D beneficiaries,*** according to a recent analysis by Avalere Health. Excluding beneficiaries who were in employer plans and those who qualify for low-income subsidies, patients taking a Part D cancer therapy in 2017 spent an average $5,515 out of pocket for their medications. Read more at https://bit.ly/2KnFiJ0.