Drugmakers, PBM’s, Payers Point Fingers on High List Prices for Insulin Medications

The rising cost of insulin, which is placing the drug out of reach for some patients, is driven by factors that include innovative new therapies and the lack of a generic alternative, stakeholders say. But underneath lies a dispute between pharmaceutical manufacturers, PBM’s and payers involving insulin list prices, rebates and the way in which drug prices are set — and those players blame each other for the problem.

“The prices for drugs are set by one group: the drugmakers,” says Pharmaceutical Care Management Association (PCMA) President Mark Merritt. A class-action lawsuit filed by a group of people with diabetes in January against insulin manufacturers Sanofi U.S., Novo Nordisk Inc. and Eli Lilly and Co. would seem to back up this argument (DBN 2/3/17, p. 8).

But that’s not true, say drug manufacturers. Eli Lilly, for example, says that “changes in insurance benefit design have increased the cost of insulin for some people.” Lilly says it has been working on options to make insulin affordable for people who have no drug coverage and thus pay full retail prices and for those with high deductibles, and in fact it rolled out such a program in January (DBN 12/23/16, p. 7).

So who’s really to blame for the problem with insulin? It’s all of the above, says Irl Hirsch, M.D., an endocrinologist and expert in insulin pricing at the University of Washington. “Everyone wants to point the finger at everyone else. But the bottom line is, everybody is at fault.”

continued on p. 7

Harvard Pilgrim Inks Two Value-Based Deals for Specialty Drugs Enbrel, Forteo

One health insurer continues to forge ahead with value-based arrangements in the hope of improving patient outcomes and reducing costs for two specialty drugs. Harvard Pilgrim Health Care, Inc. said Feb. 22 it had signed outcomes-based contracts with Amgen Inc. for its anti-inflammatory treatment Enbrel (etanercept) and Eli Lilly and Co. for its osteoporosis medication Forteo (teriparatide). Experts maintain that as health care costs continue to rise, payers will continue to seek out innovative management strategies such as these sorts of deals.

The contracts have slightly different approaches, according to the Wellesley, Mass.-based health plan, which has 2.7 million customers. The Enbrel deal, which is for two years, is focused on outcomes as determined by an “effectiveness algorithm” that factors in “six criteria, including patient compliance, switching or adding drugs, dose escalation and steroid interventions that can serve as a global measure of the positive impact on Harvard Pilgrim members,” says the plan in a press release. And although Enbrel has FDA approval for the treatment of five conditions, the contract is pertinent to only those Harvard Pilgrim members with rheumatoid arthritis. The insurer maintains that this “is the only outcomes-based contract of its kind in the market for the treatment of moderate to severe rheumatoid arthritis.”
“Historically, only about a third of patients on Enbrel and others in this class meet all six criteria,” said Harvard Pilgrim Chief Medical Officer Michael Sherman, M.D., in a prepared statement. “By linking the ultimate cost of this drug to its real-world clinical efficacy, this agreement truly puts patients at the center of focus.” For rheumatoid arthritis, patients self-inject 50 mg of Enbrel once per week. According to website GoodRx, one carton of four
50 mg SureClick autoinjectors costs more than $4,500 with a free coupon. The anti-inflammatory therapeutic class consistently ranks as one of the top categories of overall spend among PBMs reporting these data (DBN 2/17/17, p. 4).

“Payers are increasingly interested in outcomes-based contracts for pharmaceuticals that compose a significant portion of spend and those that are competitive categories,” says Dan Mendelson, president of Avalere Health. “Because outcomes-based contracts can leverage data, real-world experience is being used to pay for results.”

The second deal will measure patient adherence to Forteo, which is injected subcutaneously daily for two years. The medication is used in men and postmenopausal women with osteoporosis who are at high risk of fractures. When patients don’t follow the dosing regimen, this puts them at a higher risk of breaking bones. Forteo’s recommended dose is 20 mcg injected daily. GoodRx lists the price of one prefilled pen that contains 28 daily doses as approximately $2,800 with a free coupon.

Mendelson contends that “payers are particularly interested in outcomes-based contracts in classes where there are quality measures that affect their payments. Osteoporosis management is the basis of a Medicare Advantage star rating — so even if it isn’t a large total spend for a particular plan, it can be a financial driver.”

According to the health insurer, “The contract rewards improvement in persistence in medication use as compared to the baseline level of adherence seen in the Harvard Pilgrim population. If meaningful improvements to Forteo persistence are realized in Harvard Pilgrim’s patients, Lilly will reduce the cost of the drug for Harvard Pilgrim. Harvard Pilgrim will work with its pharmacy network and Eli Lilly to drive improvements in patient persistency.”

As reported by AIS Health about how these stakeholders will drive patient persistence, as well as other aspects of both contracts, Harvard Pilgrim declined to comment.

Deals Add to Existing Contracts

Harvard Pilgrim certainly is not new to these sorts of deals. Last June it unveiled a deal with Novartis through which the insurer would receive a discount if Entresto (sacubitril/valsartan) does not demonstrate an agreed-upon level of reduction in hospitalizations for congestive heart failure (DBN 7/8/16, p. 1). At the same time, it said it had struck a deal with Eli Lilly for the manufacturer’s next-generation diabetes drug Trulicity (dulaglutide). Harvard Pilgrim will pay a lower net cost for the drug if fewer of its members reach hemoglobin A1c levels of less than 8% compared with those taking other GLP-1 receptor agonists. Conversely, if the drug outperforms competing therapies, the insurer will pay a higher net cost. Entresto and Trulicity are now preferred treatments on the insurer’s formulary.

And in 2015, Harvard Pilgrim announced a pact with Amgen that includes a pay-for-performance guarantee around the PCSK9 Repatha (evolocumab) (DBN 11/20/15, p. 2). That deal provided for an “enhanced discount” in the form of an additional rebate if the reduction in low-density lipoprotein cholesterol (LDL-C) levels for Harvard Pilgrim members is less than what was observed in clinical trials.

Asked about the different structures of the most recent deals, Mendelson tells AIS Health that “outcomes-based contracts with plans are specifically tailored to the objectives of the parties. Custom algorithms are derived
to ensure that these objectives are being met and that both parties can monitor progress.”

A *Boston Globe* article on the new arrangements says, “The insurer said it spends about $30 million a year on Enbrel now and about $2 million a year on Forteo.” Asked about potential savings for Harvard Pilgrim based on this information, Mendelson says that “plans can often drive better economics in categories such as osteoporosis if they improve quality measures. The value to the plan depends on a range of factors.”

Last June, Avalere released the results of its March 2015 survey of 42 health plans representing 161 million covered lives. More than half of respondents said they had high or very high interest in entering into outcomes-based contracts in the areas of hepatitis C (63% of respondents), oncology (53%), rheumatoid arthritis (41%) and multiple sclerosis (35%). Of lesser interest were contracts in the areas of inflammatory bowel disease (23% high or very high interest), HIV (20%), hemophilia (12%) and growth deficiency (5%).

“We’re seeing a lot of interest in these types of pricing arrangements among our clients,” Josh Golden, area senior vice president, client development at Arthur J. Gallagher & Co.’s Solid Benefit Guidance consulting arm, tells AIS Health. “Most plan sponsors understand that the current system of formulary-driven rebates can result in a misalignment of incentives within the supply chain. They’re genuinely excited about the idea of connecting the price of a drug more closely to its value or effectiveness. That said, there is still the question of whether these various incentives will be fully passed-through to the payers. As we’ve seen with rebates and other manufacturer incentives, channel intermediaries are often in a position to intercept and retain these revenue streams. So financial transparency will be a critical factor in the success of these types of arrangements.”

**Some Challenges Exist**

According to Mendelson, “There are three central challenges in establishing strong outcomes-based contracts: accessing robust data (clinical and lab) on which to base assessments of real-world usage, determination of accurate algorithms and establishing interventions to improve performance (e.g., compliance). Depth of experience in establishing these contracts is key — particularly knowing when and how physician and patient behaviors can and can’t be changed is key....It’s harder to change patient behavior than clinician behavior.”

Avalere itself recently unveiled an arrangement that should help Boehringer Ingelheim Pharmaceuticals, Inc. and Eli Lilly construct value-based deals with payers for their diabetes drug Jardiance (empagliflozin) *(DBN* 2/3/17, p. 5).

“Momentum for value-based contracts is increasing rapidly as plans have a better handle on their data and are more interested in using the information they have to make better purchasing decisions,” Mendelson says. “We are presently working on over a dozen value-based contracts, and I expect that they will become a standard way of contracting over the next few years.”

Contact Golden at Josh_Golden@ajg.com and Mendelson through Frank Walsh at fwalsh@messagepartner-spr.com. ♦

**GOP ACA Replacement Would Kill Essential Benefits, Pharmacy Tax**

Curtailing or eliminating essential health benefits — as would occur in legislation proposed by House Republicans as the replacement for the Affordable Care Act (ACA) — would mean policies no longer would need to cover drug benefits at all, stakeholders say.

The ACA mandates that health insurance cover 10 essential benefits, which include at least one prescription drug in each therapeutic category. This requirement has made drug coverage universal among those who have health insurance through the ACA.

But the House GOP’s proposed “repeal and replace” bill, unveiled March 7, would eliminate essential health benefits as of Dec. 31, 2019. That means beginning in 2020, insurers wouldn’t have to provide drug coverage — or any other essential benefit, including maternity coverage and mental health coverage — as part of every policy offered.

States still would be free to mandate categories of coverage and could require drug coverage if they chose. Therefore, more robust coverage that includes prescription drugs could be mandatory in some states, while other states would allow insurers to sell policies without any drug coverage.

In states that don’t require drug coverage to be part of every policy, insurance products that do include drug coverage likely would be much more expensive, as was the case prior to the advent of the ACA. Policies also could cover some types of drugs — for example, generics — while exempting more expensive categories like biologics.

The legislation “once again leaves millions of people in America with chronic illness and disease at the mercy of insurance companies,” says Ron Pollack, executive director of consumer advocacy group Families USA.

However, President Donald Trump has endorsed the concept of allowing states more flexibility on health care policies sold within their borders, which indicates he

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Web addresses cited in this issue are live links in the PDF version, which is accessible at DBN’s subscriber-only page at http://aishealth.com/newsletters/drugbenefitnews.
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would support eliminating the ACA’s essential benefits provision.

Trump, in his Feb. 28 address to a joint session of Congress, also took aim once again at the high cost of prescription drugs, saying lawmakers should “work to bring down the artificially high price of drugs and bring them down immediately.”

However, the GOP replacement for the ACA fails to address drug costs, notes Deutsche Bank analyst George Hill. “We suspect that while drug price reform is out of the regulatory crosshairs in the near term, a long editing process begins before the bills can be voted on and signed into law.”

Likewise, Stifel analyst Tom Carroll said Trump’s statements on drug costs “would have an effect, if they (1) mean it, and (2) can actually get it done. Drug pricing has clearly been in the purview of this administration. They have discussed the need to lower drug prices repeatedly, and have flirted, albeit vaguely, about possibly allowing large purchasers (read: Medicare) to use their buying power to negotiate a better deal.” But, he warns, “Many think this makes all the sense in the world, which is why it probably won’t happen.”

**Bill Would Kill Tax for Brand Drugs**

The GOP bill does eliminate the Branded Prescription Drug Fee, a provision included in the ACA that taxes pharmaceutical manufacturers based on their share of the brand-name prescription drug market. The tax cost drugmakers an estimated $3 billion in 2016, and is set to bring in $4 billion in 2017 and $4.1 billion in 2018, according to the Internal Revenue Service.

The conservative Tax Foundation argues that this tax is rising drug prices: “Of course, it is always difficult to pinpoint specific causes of price movements — especially because of the extensive effects of the Affordable Care Act on other aspects of the pharmaceutical market — but the relatively high price growth of branded drugs is evidence that the Branded Drug Prescription Drug Fee has contributed to higher drug prices overall,” the group says.

Overall, it’s not clear whether the GOP bill has the support it will need to pass the House and Senate, since it’s likely to cause significant declines in insurance coverage, says Evercore ISI analyst Michael Newshel. “The key unknown at this point is whether President Trump forcefully gets behind the House and pressures Senate Republicans or takes a more passive approach to the process as he has to date,” Newshel adds.

Contact Pollack at (202) 347-2417, Hill at George. hill@db.com and Newshel at Michael.newshel@evercoreisi.com.

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**California Bill Would Require Disclosure of PBM Rebates**

California PBMs would be required to get state licenses and to disclose their rebates as part of a bill under consideration by California lawmakers.

The proposal, which comes at a time when PBMs’ roles are under increased scrutiny both on the state level and nationally, also would develop requirements for PBMs to meet in order to be licensed. PBMs now are not regulated at all in California.

“This lack of oversight coupled with a lack of transparency regarding business operations has generated numerous questions,” says the bill’s sponsor, state Rep. Jim Wood (D). “In order to address questions that have been raised about whether the industry fully discloses how much it is actually saving insurer and employer clients and what portion of those savings are actually passed along to consumers, the Legislature needs to address this issue through the regulation of PBMs.”

The bill would require PBMs to disclose:

- **The percentage of all oral prescriptions and self-administered drugs** that were dispensed through pharmacies affiliated with the PBM and the percentage of oral and self-administered medications dispensed through retail pharmacies;
- **The total amount of discounts or price concessions** the PBM received that was attributable to California residents whose drug benefits were managed by the PBM;
- **The amount and types of rebates, discounts or price concessions** provided to health care plans that could be attributed to patient use under those plans; and
- **The amount of the rebates, discounts or price concessions** that are passed through to enrollees and the total number of prescriptions dispensed.

It’s not clear how much support the bill, AB 315, has among California lawmakers. But it comes as other efforts intensify to place PBMs under more federal and state oversight.

**Bill Comes Amid Calls for PBM Oversight**

For example, two House members — Reps. Doug Collins (R-Ga.) and Dave Loebsack (D-Iowa) — introduced a bill March 2 (HR 1316) that would require PBMs to update their maximum allowable cost (MAC) lists for Medicare Part D, TRICARE and the Federal Employee Health Benefit Program every seven days (see brief, p. 8). Collins says this would protect local community pharmacies from selling scripts at a loss. “Because of PBMs’ failure to regularly update MAC pricing lists, the true cost of prescription drugs is hidden from employers, consumers, pharmacists, and the federal government,” he contends.
The National Community Pharmacists Association (NCPA) argued in a letter to newly installed HHS Secretary Tom Price in late February that President Trump’s plans to lower drug costs won’t work if PBMs “continue to operate in a virtual black box. The only way transparency can be achieved is to expose the pricing behaviors in which PBMs have engaged since the inception of the Medicare Part D program.” NCPA strongly supports Collins’ bill.

By contrast, the Pharmaceutical Care Management Association (PCMA) says MAC lists reduce drug prices and adds that PBMs are a cost-saving device for the health care system overall.

“PBMs reduce prescription drug costs by 30% on average,” says PCMA President Mark Merritt. “Nobody has to hire a PBM — they choose to hire a PBM because they bring costs down.”

Merritt tells AIS Health that the general public “understands it’s the drug companies” that are responsible for rising pharmaceutical costs. Nonetheless, to counter confusion about the role of PBMs in the marketplace, the association has launched a website, www.drugbenefitsolutions.com, to make PBMs’ case to policymakers and journalists, he says: “It explains how drugs are priced and what PBMs do.”


Contact Merritt via PCMA spokesperson Greg Lopes at glops@pcmanet.org and the National Community Pharmacists Association at (703) 683-8200. ♦

As More States Mull Step-Therapy Laws, Article Questions Impact

Step therapy has been around for decades and is used by virtually every health insurer and PBM to control soaring prescription drug costs by requiring patients to try established, less-expensive treatments first (see table, p. 6). Clinical algorithms, used by carriers to develop prescribing guidelines, can improve patient outcomes while trimming costs, according to a recent article in the Journal of the American Medical Association (JAMA). But some models might be more focused on cost containment than on patient health, the article concludes.

Eleven states have implemented laws aimed at limiting the use of step-therapy practices that could negatively impact a patient’s condition, according to the

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American Academy of Dermatology (AAD) (see map, p. 5). Another 11 states have pending legislation. The American Medical Association (AMA) says it is tracking 24 step-therapy bills in 14 states. Several states have two bills pending, and Iowa has four, according to the AMA.

New York’s law, which was enacted Dec. 31, provides patients and doctors with an expedited process for getting exceptions to step therapy. According to an overview on AAD’s website, California’s law allows patients to avoid repeating step therapy when coverage changes. In Connecticut, health care providers can request a step-therapy override if they can demonstrate the drug regimen under step therapy has proven ineffective in the past for the patient’s condition or is expected to be ineffective. In Maryland, the insurer must allow the member to continue with an existing therapy if the doctor can show that a drug was prescribed for a patient within the past 180 days and that it is effective in treating the patient’s condition, according to data compiled by AAD’s state policy team.

“While there can be problems in the way step therapy is used, fixing it by legislation that disallows it as a tool isn’t an efficient or very pragmatic solution,” says the article’s co-author, Michael Fischer, M.D., a physician in the division of pharmacoepidemiology and pharmacoeconomics at Brigham & Women’s Hospital in Boston.

See the JAMA article at http://tinyurl.com/go299vs. For an overview of each state’s step-therapy law, visit AAD.org. Contact Fischer at mfischer@partners.org.

The above article was excerpted from the March 6 issue of DBN’s sister publication Health Plan Week. For more information, visit the MarketPlace at www.AISHealth.com.

### Drugs With Highest Use of Prior Authorization or Step Therapy in Selected Therapeutic Classes

<table>
<thead>
<tr>
<th>Product Class</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Formulary Status with Restrictions*</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Preferred</td>
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<tr>
<td>Acne</td>
<td>Onexton gel</td>
<td>Valeant Pharmaceuticals</td>
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<td>Antidepressants</td>
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<td>Allergan</td>
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<td>Boehringer Ingelheim</td>
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<td>Vanda Pharmaceuticals</td>
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<td>Asthma/COPD</td>
<td>Daliresp</td>
<td>AstraZeneca</td>
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<td>Allergan</td>
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<td>Enablex</td>
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<td>Viscosupplements</td>
<td>Monovisc</td>
<td>Anika Therapeutics</td>
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*Percentage of covered lives in 6,574 pharmacy benefit plans subject to prior authorization or step therapy protocols for indicated product at formulary tier.

SOURCE: MMIT Analytics, as of Feb. 28, 2017.
Blame Shifts for Insulin Price Hikes
continued from p. 1

Three of the six drugs that have doubled or more than doubled in price over the past five years are insulin products, according to Hirsch: Humulin R U500 (insulin human) from Eli Lilly has risen in price by 325%, Levemir (insulin detemir) from Novo Nordisk has risen by 169%, and Lantus (insulin glargine) from Sanofi has risen in price by 168%. Hirsch says the prices of different drugmakers’ insulins have risen in lockstep. Over the past 13 years, price increases for some insulin products have been close to 600%, he says.

PBMs say they have zero control over the cost of medications — the pharmaceutical manufacturers control prices. “We do get discounts on these products by creating formularies,” Merritt tells AIS Health. “We do what we can to get significant discounts despite the price increases.”

But the drugmakers say they have to raise prices so that they can provide the larger rebates that payers demand, Hirsch says.

Rebates Lower Costs for Some, but Not All

Eli Lilly notes that rebates lower the price for most people, but not all: “While discounts and rebates paid by manufacturers make insulin affordable for most people, they don’t directly help the uninsured or people in the deductible phase of their high-deductible plans,” Eli Lilly says. “And while some high-deductible plans exempt insulin from the deductible phase, others require people to pay most or all of the retail price until the deductible is met — meaning those people don’t fully benefit from rebates when they visit the pharmacy.”

Saying deeper discounts are to blame for price increases is “a red herring,” Merritt says. “It’s a chicken-and-egg argument,” he says. “If prices are raised, the payers are going to demand bigger discounts.” He describes the situation as “a kind of shell game drugmakers have been pushing.”

That’s basically the argument made in the class action lawsuit (Donald Chaires et al. v. Sanofi U.S. et al., No. 1:17-cv-10158), which contends that over the past five years, the three defendants have increased the publicly reported “benchmark prices of their respective drugs in an astounding and inexplicable manner.”

The lawsuit, filed Jan. 30 in the U.S. District Court for the District of Massachusetts, contends that drug manufacturers and PBMs don’t want the public to know the “spread” between reported benchmark prices and prices the PBMs pay for the drugs. It accuses the three drug manufacturers of violating the Racketeer Influenced and Corrupt Organizations (RICO) Act and multiple state consumer protection laws.

The lawsuit doesn’t name PBMs as defendants but does blame the spread between benchmark insulin prices and the real prices paid by PBMs for the high cost of insulin. PCMA said in response that PBMs work to reduce costs.

“The challenge is, the price is set by the manufacturer — just like any product, they set the price at what the market would bear,” Merritt says. “The reason they have high list prices is so they can give different discounts — a larger PBM gets a larger discount.” Members of smaller organizations don’t have the advantage of size in negotiations, and therefore often pay higher prices, he says.

Patients Are Caught in Middle

Meanwhile, patients who use insulin are caught in the middle. “I’m dealing with this on a daily basis,” Hirsch says. “People are literally spending more on insulin than on their mortgages. They have insurance, but they have $6,000 deductibles.”

There’s no generic alternative for insulin, a product that has been available for nearly a century, although a follow-on version of Lantus — Lilly’s Basaglar — launched Dec. 15 at a price 15% less than that of Lantus (DBN 12/23/16, p. 7). The oldest form of insulin, human insulin, is inexpensive, but it doesn’t work as well as newer forms, Hirsch says. Specifically, human insulin can lead to life-threatening hypoglycemia, which is responsible for 5% to 10% of all deaths in type 1 diabetes, he says. In addition, physicians trained in the last 15 years or so have little experience with this older form of insulin, which is tricky to manage, and so don’t prescribe it, he says.

Newer insulins “are incrementally better,” and their benefit is in managing blood sugar well enough to prevent hypoglycemia, Hirsch says. This is a bigger issue for people with type 1 diabetes, he says.

PBMs are addressing the problem of insulin prices by negotiating the best discounts possible and also by trying to improve care overall for people with diabetes — for example, by helping them get better treatment for comorbid conditions such as depression, Merritt says.

In one approach, Express Scripts this month launched its Diabetes Care Value Program, originally unveiled in August 2016 (DBN 9/9/16, p. 8), which it calls a comprehensive approach to improve pharmacy care while controlling plan costs for people with diabetes. The program includes a network of preferred pharmacies that will deliver on a set of quality metrics, including medication adherence, and also includes multiple insulins — instead of just one — on its national preferred formulary.
According to the PBM, the program is expected to boost the average medication adherence rate for enrolled patients by 5%, which will reduce health complications and costs. Express Scripts says avoidable complications cost $4,690 per diabetes patient per year.

As part of the program, Express Scripts is guaranteeing per-patient spending caps, which it says will limit participating plans’ diabetes drug spend to approximately half of what the industry is forecasting for commercial payers. Express Scripts will assume financial risk for drug spending in excess of the caps.

Meanwhile, some drug manufacturers are tackling the affordability problem with patient-assistance programs. For example, Eli Lilly’s insulin program, launched on Jan. 1, allows patients to access up to a 40% discount for various Eli Lilly insulins through Blink Health, a competitor of GoodRx. However, the discounts are outside of any drug coverage, so those with insurance who use the program most likely won’t be able to apply the cost to their deductibles. Sanofi and Novo Nordisk also advertise patient assistance programs for insulin products.

Contact Merritt via PCMA spokesperson Greg Lopes at glops@pcmanet.org, Hirsch via University of Washington spokesperson Brian Donohue at bdonohue@uw.edu, and Eli Lilly spokesperson Greg Kueterman at (317) 432-5195.

A group of 38 large employers known as the Health Transformation Alliance (HTA) says it will purchase prescription drugs through CVS Health Corp.’s Caremark and UnitedHealth Group Inc.’s OptumRx, according to a March 6 article in The Wall Street Journal. The companies can decide whether to participate after comparing the new deals with their existing ones. HTA CEO Robert Andrews told the Journal that the group expects at least 20 of its members to take advantage of the new contracts, which are expected to save a total of $600 million over three years. According to Seeking Alpha, six members of the group are customers of Express Scripts Holding Co., which is not included in the HTA contracts. View the Journal article at http://tinyurl.com/h5g6uy4. View the Seeking Alpha analysis at http://tinyurl.com/hqg3zo7.

Prime Therapeutics LLC said its clients’ overall drug spending rose 2.5% in 2016. The PBM said its specialty drug spend rose 13.7%, but traditional drug expenditures declined 1.7%. Total member savings were more than $2.2 billion, said the company. Visit http://tinyurl.com/j6e5ldy.

CMS fined 17 Medicare plans for allegedly failing to comply with requirements for handling prescription drug benefits. The agency imposed the largest of the civil monetary penalties — $2,498,850 — on UnitedHealth Group, Inc. for 56 of its Medicare Advantage-prescription drug and stand-alone Prescription Drug Plan contracts. In a statement to the Star Tribune, the insurer said, “We immediately addressed the findings of this planned audit, which occurred last year, and remain committed to helping our members with the care they need, when they need it.” View the CMS letters at http://tinyurl.com/zxro46x and the Tribune article at http://tinyurl.com/hhpp3ss.

Rep. Doug Collins (R-Ga.) introduced HR 1316, known as the Prescription Drug Price Transparency Act, on March 2. The legislation, which has seven co-sponsors, seeks to “amend title XVIII of the Social Security Act to provide for pharmacy benefits manager standards under the Medicare prescription drug program and Medicare Advantage program to further transparency of payment methodologies to pharmacies, and for other purposes.” The bill was referred to the House Energy and Commerce, Ways and Means, Armed Services, and Oversight and Government Reform committees. View the bill at www.congress.gov.

The Health Resources and Services Administration (HRSA) delayed the effective date of the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation from March 6 to March 21 (82 Fed. Reg. 12508). The final rule, published Jan. 5 (82 Fed. Reg. 1210), caps the civil monetary penalty for each time a manufacturer “knowingly and intentionally charges a covered entity more than the 340B ceiling price…for a covered outpatient drug” at $5,000. HRSA will begin enforcing it April 1. View the Federal Register document at http://tinyurl.com/hqqaxvy and final rule at http://tinyurl.com/hae9t7h.

Last year saw more than 800 generic drug approvals and tentative approvals, according to the FDA Office of Generic Drugs’ annual report. View the report at http://tinyurl.com/jn2bvyo.
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