

DRUG BENEFIT NEWS

News, Data and Business Strategies for Health Plans, Employers, PBMs and Pharma Companies

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Pending 340B 'Mega-Guidance' Could Limit Contract Pharmacies, Duplicate Discounts

Pharmaceutical manufacturers, covered entities and other stakeholders in the 340B Drug Pricing Program are once again sweating it out as an expected "mega-guidance" spends its third month at the Office of Management and Budget (OMB). Industry insiders say the pending guidance could, among other things, finally place some limits on the wildly expanding contract pharmacy arrangements that may lead to duplicate discounts being paid by manufacturers to 340B entities and commercial and/or Medicaid plans.

HHS's Health Resources and Services Administration (HRSA) last summer was supposed to issue a "mega-reg" that would address contract pharmacy arrangements and other aspects of the program that have been repeatedly called into question by the Government Accountability Office (GAO), the HHS Office of Inspector General (OIG) and interest groups (*DBN 7/25/14, p. 1*). But due to ongoing litigation around HRSA's "interpretive" version of a separate 340B rule on orphan drugs (*DBN 11/7/14, p. 7*), that rule was withdrawn from consideration in November 2014. At the time, HRSA said it would issue proposed guidance for notice and comment in 2015 to "address key issues raised by various stakeholders committed to the integrity of the 340B program" (*DBN 11/21/14, p. 8*) and in May submitted an "omnibus guidance" to OMB for review.

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Three Years Later, Jury's Still Out on Growing Category of Anti-Obesity Drugs

A recent report from AdverseEvents, Inc. highlighting the downstream medical costs associated with newly reported adverse events linked to anti-obesity drugs concludes that Belviq (lorcaserin) may be the least risky/costly treatment of three relatively new prescription agents in this category. But without data to prove the long-term clinical benefits of these drugs or allay ongoing concerns about cardiovascular and other risks associated with them, insurers for the most part remain reluctant to cover prescription weight-loss therapies.

After a 13-year dry spell for weight-loss drug approvals after the high-profile withdrawals of two agents due to major cardiovascular concerns, Belviq and Qsymia (phentermine and topiramate) were approved in 2012 as adjuncts to a reduced calorie diet and increased physical activity for overweight and obese adults (*DBN 8/24/12, p. 1*). Contrave (naltrexone HCl and bupropion HCl) joined the growing category in September 2014 (*DBN 10/24/14, p. 8*) followed by the injectable diabetes treatment Victoza (liraglutide), which received FDA approval in December for the treatment of obesity under the name Saxenda.

The AdverseEvents report, *FOIA Report Update: RxCost Comparison of Anti-Obesity Drugs*, posted June 26, takes into account more than 2,300 new primary suspect cases relating to 18 drugs, including Belviq, Contrave and Qsymia, which had 1,060, 179 and 153 new case reports through June 1, respectively. The report suggests that based on the true costs associated with the management of serious adverse events reported in

the real world, Belviq may be the least risky/costly treatment of the three relatively new prescription agents on the market and Qsymia is the most risky/costly option.

Saxenda and Xenical were not included in the analysis since AdverseEvents currently has case reports for these drugs only through September 2014 and plans to include them in a future analysis.

Through Freedom of Information Act (FOIA) requests, AdverseEvents obtained data through June 1, 2015, and compared the downstream medical costs of adverse drug reactions associated with Contrave, Belviq and Qsymia. The report evaluated the costs of 186 total primary suspect cases for Contrave since its September 2014 approval, and 1,515 cases for Qsymia and 1,751 cases for Belviq since their 2012 approvals.

For example, of the top five most costly and serious on-label adverse events for Qsymia, 16 reported cases of nephrolithiasis resulted in a total RxCost of \$146,640 (calculated as RxCost per adverse event multiplied by the number of primary suspect cases).

Using its proprietary RxCost algorithm to calculate downstream medical costs associated with adverse event/drug combinations, the company determined that Qsymia has the highest "true" cost per prescription of \$3.31, compared with \$2.60 and \$2.03 for Contrave and Belviq, respectively. Previous RxCosts per prescription for Belviq and Qsymia were 97 cents and \$1.44, respectively, said AdverseEvents.

"There are still risks with these drugs, so long-term monitoring of this post-market data is vital for plan sponsors looking to cover this set of drugs," advises Bob Kyle, chief product officer with AdverseEvents. But given the history of obesity drugs such as Meridia and Fen-Phen that were pulled from the market in 2010 and 2007, respectively, the post-market safety data that AdverseEvents has seen for the three new obesity drugs is "encouraging so far," he remarks.

AdverseEvents' recommendation is that plan sponsors consider covering these new obesity drugs, particularly the "safest option" Belviq, on a limited basis for obese patients after diet and exercise regimens have failed. "Because of the obesity epidemic in the U.S., and the litany of additional health issues that this causes, we think that more treatment options are needed and there are no safety concerns that should block plans from providing coverage for treatments like Belviq on a limited basis," asserts Kyle.

Plans Are Skeptical of Long-Term Effects

According to a recent Action Brief from the National Business Coalition on Health, only 20% of plans cover an FDA-approved weight-loss drug. Craig Mattson, R.Ph., senior director of formulary development for Prime Therapeutics LLC, says the Blues plan-owned PBM continually monitors all approved weight-loss drugs for their safety and efficacy, while the vast majority of commercially insured employers still exclude them from coverage. "They lack proven long-term clinical outcomes and return on investment," he tells *DBN*. "In other words, patients appear to gain back weight as soon as they stop taking the medication."

The average weight loss for patients taking Belviq in clinical trials ranged from 3% to 3.7% over those taking a placebo, while Qsymia trials demonstrated an average weight loss of 6.7% when using the recommended daily dose and 8.9% with the highest dose. Clinical trials showed patients taking Contrave lost at least 5% of their body weight.

If modest weight loss is achieved at best, plan sponsors should consider whether covering a drug for which there are no known health benefits other than weight loss is worth the investment, suggests Jim Carlson, Pharm.D., vice president for professional pharmacy services at OmedaRx. "If we knew that losing 5% or so of your weight really reduced your risk of development of diabetes and complications associated with that or lowered your risk of hypertension or heart disease, and the rate of improvement of health benefits was higher than the rate of decline of your health associated with the side effects of the drug, then that's a benefit that you want to pursue," he asserts.

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“But none of the obesity drugs have actually been shown to improve health outcomes, such as cardiovascular events (e.g., heart attack, stroke) or cardiovascular deaths of patients. There is some evidence that they decrease weight in the short term, blood pressure and blood glucose control. However, this does not always translate into improvements in the health of the patient,” he continues. “In addition, we don’t know what the long-term harms are associated with the drugs. So for these manufacturers to actually show a health benefit along with these drugs is incredibly difficult, because the weight loss is so modest that it would take a huge study to show any kind of health benefit and it would also take a pretty good-sized study to show the harms associated with the drugs.”

The manufacturers of Belviq, Contrave and Qsymia are all required to conduct various postmarketing studies, including ones on cardiovascular outcomes. Belviq maker Eisai Inc. in February 2014 said it had begun recruiting and enrolling patients for the five-year CAMELLIA-TIMI 51 outcomes trial to evaluate the effect of long-term treatment with the drug vs. placebo on the incidence of major adverse cardiovascular events and new onset type 2 diabetes in obese and overweight patients with cardiovascular disease or cardiovascular risk factors. Earlier this year, Qsymia maker Vivus, Inc. said it was discussing “potential cost-saving measures” related to its own planned cardiovascular outcomes trial with the FDA. A spokesperson tells *DBN* the company is “not in a position at this time to provide an update.” A trial for Victoza/Saxenda, meanwhile, is ongoing.

Plans Favor Lifestyle Changes Over Drugs

For now, plan sponsors are likely to favor a “non-pharmacological” approach, suggests Mattson. “Historically, the benefits of weight loss drugs — beyond lifestyle modification with diet and exercise — have not provided significant efficacy, when balanced with their risks,” he asserts. “Most employers’ primary approach to addressing obesity and overweight is through health and wellness programs, recognizing that weight loss can be achieved with a comprehensive lifestyle modification program that combines diet, physical activity and behavior therapy. These initiatives have a higher probability of long-term success.”

Aetna, Inc., meanwhile, has taken the lead in testing the benefits of these drugs as part of an overall weight-loss management program (*DBN* 1/24/14, p. 1). Members enrolled in the program can receive Qsymia or Belviq at a preferred brand copay once Aetna applies prior authorization criteria that are consistent with the drugs’ approved use in overweight or obese patients. The insurer is measuring improvement in overall health outcomes, productivity and medical costs, and has said it expects to

see a short-term cost savings from members’ improved control of diabetes, as well as a decline in the number of members opting for bariatric surgery. Data and outcomes are still forthcoming, says an Aetna spokesperson.

Contact Carlson via Debbie Mackay at debbie.mackay@omedarx.com, Kyle via Sharon Miller at sharon@adverseevents.com and Mattson at Karen Lyons at klyons@primetherapeutics.com. ♦

Be on the lookout for a new series of reports from AIS and AdverseEvents on The Cost and Impact of Adverse Events. The first book in the series will compare seven anti-inflammatory medications.

Gilead Switches Gears With New Limits on Hep C Patient Assistance

After making patient assistance for hepatitis C therapies Sovaldi (sofosbuvir) and Harvoni (ledipasvir/sofosbuvir) broadly accessible to patients who met certain criteria, Gilead Sciences, Inc. has begun to limit the use of its Support Path program, which includes a \$5 copay coupon as well as a patient assistance program (PAP) that provides the drugs at no charge for eligible patients.

Sovaldi came to market in December 2013 at a per-patient cost of \$84,000 for a 12-week course, or \$95,000 when used with ribavirin and interferon. By comparison, the same length of treatment with Harvoni, which was approved in October 2014, has a pre-discount price of roughly \$94,500. Once AbbVie Inc.’s competing product, Viekira Pak (ombitasvir, paritaprevir and ritonavir tablets; dasabuvir tablets) received FDA approval in December 2014, however, Gilead began cutting deals with health plans and PBMs to gain exclusive or preferred formulary positioning for its hepatitis C drugs (*DBN* 1/9/15, p. 1).

In a July 1 letter addressed “Dear Community Partner,” Gilead Vice President of Managed Markets Coy Stout explained that Support Path was initially available post-launch to “virtually all patients who met financial and other program requirements,” but Gilead observed that despite the discounts it implemented for its hepatitis C therapies “across different payer groups...some payers have continued to restrict access.”

As a result, Gilead decided it was “necessary to establish more specific guidelines for patient eligibility” and as of July 1, stopped allowing insured patients “who do not meet their payer’s coverage criteria” to access the PAP. This could include patients whose insurers restrict access to the drugs by preferring or exclusively covering another product on formulary such as Viekira Pak, limiting coverage to a maximum treatment duration, denying subsequent treatment after a patient has failed therapy or

requiring step therapy. Patients covered by Medicare Part D and other government health care programs are not eligible for the coupon program or PAP.

Gilead explained that its Support Path program was “designed to help patients in the U.S. with high co-pays or who lack adequate insurance access [to] Sovaldi or Harvoni” and “provides assistance to patients who are uninsured or who need financial assistance to pay for the medicine.”

The drugmaker emphasized that it estimates this change will impact a “very small number” of patients. “Gilead continues to support open access to hepatitis C therapies — with prescribing decisions made by a physician in partnership with his or her patient,” wrote Stout. “We believe that payers should take the responsibility to provide coverage for their insured patients based on the treatment decisions of their healthcare providers.”

PBMs Are Unfazed by the Change

MedImpact Healthcare Systems, Inc. was not surprised by the move. A spokesperson says the PBM had considered a program for clients that involved the use of “copay assistance options to get a significant discount for these high cost drugs.” But MedImpact’s legal department cautioned the company not to go through with it “because they feared manufacturers would react and shut down the copay assistance programs.”

Cigna Corp., meanwhile, says it does not expect the changes being implemented by Gilead to have much of an effect on its commercially insured members. The insurer on July 17 posted its first “real world” data on the use of Harvoni, indicating that 98.4% of Cigna Pharmacy Management customers treated with Harvoni for hepatitis C genotype 1 achieved a sustained virologic response for 12 weeks (SVR12) after the completion of treatment.

Cigna attributed the results to its “connected care approach,” which involves clinical management to ensure safety and appropriateness, comprehensive counseling for customers regardless of their pharmacy choice and a preferred drug approach including the development of an outcomes-based incentive program with Gilead. Cigna added that customers who used the Cigna Specialty Pharmacy achieved 99.3% SVR12.

“At Cigna, we’re helping people get the most out of their medications — this means improved health and improved affordability. Cigna’s coverage policy and the use of Harvoni and Sovaldi as the preferred drugs for treating hepatitis C are helping us to achieve those objectives for our customers and clients, and, therefore, there should not be any significant impact to our commercial customers connected with changes to Gilead’s patient assistance program,” suggests Christopher Bradbury,

senior vice president for integrated clinical and specialty drug solutions.

Express Scripts Holding Co., which has Viekira Pak as the exclusive genotype 1 hepatitis C treatment option on its National Preferred Formulary, declined to comment on the new Gilead strategy. “Separately, Express Scripts remains committed to making the hepatitis C therapy class as affordable as possible for payers, and as accessible as possible for patients,” added spokesperson David Whitrap.

For more information, contact Bradbury via Karen Eldred at karen.eldred@cigna.com and Whitrap at dwhitrap@express-scripts.com. ✧

With User Fees Up for Renewal, Will Cures Make it to the Table?

As the recently passed U.S. House of Representatives version of the 21st Century Cures Act goes to the Senate for review, one of the questions looming over this large and evolving piece of legislation is how the initiative will be funded. Controversial proposals such as a Medicare Part D funding offset that was opposed by the Pharmaceutical Care Management Association were removed prior to the July 10 House vote. But Avalere Health LLC suggested during a recent panel briefing that Cures funding may factor into recently initiated discussions around the renewal of the Prescription Drug User Fee Act (PDUFA) and other user fee programs that support FDA activities.

“The user fees...are going to be incredibly important for next year,” asserted Avalere Senior Vice President Gillian Woollett during the July 17 panel briefing, “FDA: Prescribing Value,” held in Washington, D.C. “And the question is how much of Cures becomes part of user fee legislation, if you have must-pass user fees and you have a lot of aspirations under Cures and user fees are the way you pay for things.”

Enacted in 1992, PDUFA authorized the FDA to collect fees from companies that produce certain human drug and biological products, in order to expedite the drug approval process. The FDA now has three other fee programs: the Medical Device User Fee Act, which will renew for the third time in 2017, and the Generic Drug User Fee Act and the Biosimilar User Fee Act, both established in 2012.

PDUFA user fees have experienced a dramatic increase compared to the rate of inflation since their inception, observed Woollett, who leads Avalere’s FDA Regulatory Strategy and Policy Practice. In 2013, PDUFA fees collected by the FDA exceeded \$2.75 million, representing an increase of 1,600% from 1993, compared with a 63% rise in inflation during that time.

Each user fee program is authorized by Congress for a five-year period; PDUFA is one of the few pieces of health legislation that is considered “must-pass” because of its central role in funding FDA activities, explained Avalere. PDUFA V, the current reauthorized version of PDUFA, expires on Sept. 30, 2017. The FDA kicked off the reauthorization process in May and held its first public meeting on the subject on July 15.

Meanwhile, the House on July 10 passed the 21st Century Cures Act (H.R. 6) by a vote of 344-77. Among other things, the bill would increase National Institutes of Health funding by \$8.75 billion over five years, boost FDA funding by an additional \$550 million and provide ways for the FDA to approve drugs faster than it does now, such as by “allowing patient experience data to be considered in the risk-benefit assessment of a new drug...[and] allowing the FDA to rely upon data previously submitted for a different purpose to expedite the development of certain drugs.”

As the FDA and policymakers carry out the reauthorization process and evaluate the structure and performance goals for the PDUFA program, Woollett suggested certain issues will take priority, such as new breakthrough pathways — which she said have “proven disproportionately popular” — as well as patient-focused activities. During the last round of PDUFA negotiations, the FDA was tasked with initiating the Patient-Focused Drug Development program to better incorporate patient feedback throughout the drug development and regulatory review processes.

In a joint statement issued July 15 by the Pharmaceutical Research and Manufacturers of America (PhRMA)

and the Biotechnology Industry Organization (BIO), leaders from the trade associations expressed their support for patient engagement in the drug development process.

“In PDUFA VI, the biopharmaceutical industry will advance and support policies that scientifically integrate the patient perspective in innovative drug development and regulatory decision-making, enhance the FDA’s scientific expertise and tools, and promote long-term stability of the PDUFA program while ensuring the Agency can recruit and retain a highly-skilled workforce,” remarked PhRMA Vice President of Science and Regulatory Advocacy Sascha Haverfield, Ph.D., and BIO Senior Vice President of Science Policy Kay Holcombe.

Regarding the impact of PDUFA reauthorization to payers, Woollett suggested that it’s all about timing. “The predictability of the review is really, really important,” she said, referring to the six or 10-month review deadlines that drugs are given depending on their priority status. “The actual cost of the user fee per se is not a major part of the development of cost, but the timing of when one can expect decisions is very, very important to the [drug] sponsors and it’s very, very important then to the payers how they anticipate the availability of the newer products.”

Negotiations will likely carry into 2016, with final user fees determined well after the presidential elections and the pending approval of the 21st Century Cures Act, added Avalere.

For more information, contact Amy Martin Vogt for Avalere at amartinvogt@gymr.com. ✧

Preparing for Super Statins: Strategies to Mitigate the Coming PCSK9 Cost Explosion

- How much of the potential high price of PCSK9s is likely to be offset by rebate negotiations or claims controls?
- What potential scenarios exist for adoption of these agents once they become available? What impact is this likely to have on health plan pharmaceutical costs?
- What are the financial implications for the key PBM players, including purchasing incentives, rebating and formulary management?
- How will the strategies already being laid out by the large PBMs impact other competitors and health plans negotiating for coverage? And how much of the value that PBMs negotiate in price is likely to trickle down to health plans and other clients?

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Heat Is on HRSA for 340B Guidance

continued from p. 1

Speaking at the 340B Coalition Annual Conference held July 13-15 in Washington, D.C., HRSA Office of Pharmacy Affairs (OPA) Deputy Director Michelle Herzog updated attendees on the progress of various agency initiatives, but gave little detail as to what will be in the guidance other than that it will address “pretty much” all areas that HRSA is not authorized to address in rulemaking, such as contract pharmacy arrangements and patient definition.

The 340B program, which is managed by HRSA, was established in 1992 to allow qualifying nonprofit entities such as disproportionate share hospitals and critical access hospitals to purchase covered outpatient drugs at deeply discounted rates and thus stretch limited resources to expand care to vulnerable patients. But manufacturers and members of Congress have questioned whether the program is functioning as it was intended to, and suggested that the growing use of contract pharmacies may lead to duplicate discounts being paid by manufacturers to 340B entities as well as other payers.

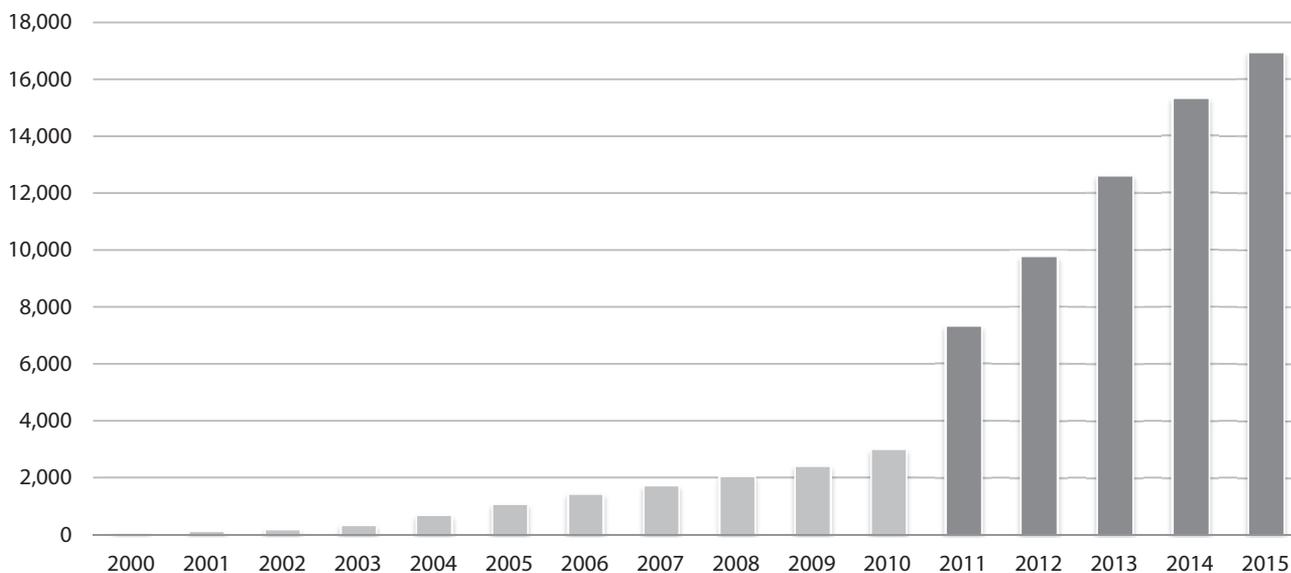
“It’s been a very challenging year for HRSA and for OPA as a whole, from the orphan lawsuit to possible regulations, now guidance,” said Herzog. “We have seen this as a tremendous opportunity; while it has presented challenges, it has also given us the opportunity to take a

look at our priorities and where we want to go in moving the 340B program forward. Program integrity is of the highest priority in HRSA and OPA.”

The House Energy and Commerce Committee in May had circulated draft language to reform the 340B program in the 21st Century Cures Act that was passed by the House on July 10 (see story, p. 4). That language was ultimately removed, but sources suggest it provided a glimpse into future legislative tweaks to the program. For example, it would have expanded HRSA’s limited authority to issue regulations and enforce 340B program requirements, placed new requirements on contract pharmacy agreements and clarified the patient eligibility definition. The language reflected many of the concerns raised at a House Energy and Commerce Committee hearing in March, including testimony from GAO and OIG that HRSA’s current patient definition guidance does not account for the complexity of contract pharmacy arrangements (*DBN 4/3/15, p. 6*).

A 2014 research paper issued by Berkeley Research Group (BRG) on behalf of the Pharmaceutical Research and Manufacturers Association of America estimated that more than 3.8 million prescriptions will be filled by contract pharmacies for managed Medicaid beneficiaries in 2016. If all of these prescriptions are filled at a 340B price, total chargebacks (i.e., the amount of money that would be repaid to a manufacturer in the instance of a

Total Number of 340B Contract Pharmacies, 2000–2015



NOTE: Data show contract pharmacies as of July of each year.

SOURCE: Avalere Health LLC (2000-2012); Pembroke Consulting, Inc. (2013-2015). For additional analyses, visit www.drugchannels.net.

duplicate discount) on these prescriptions will exceed \$475 million.

“The fact that duplicate discounts continue to exist hurts all stakeholders in the 340B program. The fact that these duplicate discounts exist *and* that there is a prohibition against duplicate discounts hurts the integrity of the 340B program. The mere presence of them demonstrates that historically and on an ongoing basis covered entities continue to have challenges being compliant within the 340B program,” remarks the paper’s author, Aaron Vandervelde, managing director with the BRG health analytics group.

The reasons for those challenges are complex, he tells *DBN*. For example, to ensure that pharmaceutical manufacturers are not subject to duplicate discounts, state Medicaid programs typically refer to the Medicaid Exclusion File maintained by HRSA and/or exclude claims with a specific modifier indicating that a 340B drug was used for the patient, explains Vandervelde. Because contract pharmacies are not typically included on the Medicaid Exclusion File, covered entities must rely on PBMs and managed Medicaid health plans to provide state agencies with the information necessary to identify 340B utilization.

Herzog said that HRSA is continuously working to update the Medicaid Exclusion File to help prevent duplicate discounts. But Vandervelde points out that since contract pharmacies are not subject to any statutorily defined method of identifying 340B eligible vs. non-eligible prescriptions, and prescriptions are typically identified as 340B eligible after the claim has been adjudicated, they are vulnerable to double discounts.

Guidance Could Limit Pharmacies by Distance

How the problem of duplicate discounts will be addressed in the pending guidance is unclear. Vandervelde suggests the most likely changes around contract pharmacies would involve limits on the number of contract pharmacies per covered entity or restrictions on the proximity between the contract pharmacy and the covered entity. However, it is possible that HRSA may go as far as requiring 340B contract pharmacies to exclude all Medicaid utilization, he observes.

Covered entities were initially allowed to use only one pharmacy to process 340B drug purchases, but since HRSA in 2010 issued guidance allowing contracts with multiple outside pharmacies to enhance patient access, these arrangements have grown well beyond its expectations. According to a recent analysis by Pembroke Consulting, Inc., the number of unique contract pharmacy locations has grown 37% in the last two years to 16,965, representing more than 25% of the retail, mail and specialty pharmacy locations in the U.S. (see chart, p. 6).

Duplicate discounts may also be a burden for Medicare Part D plans and commercial plans, but it depends on how their contracts with manufacturers are written, observes Vandervelde. “Many contracts include clauses that state the manufacturer will not pay a rebate to the commercial plan or the Part D plan if that utilization is a 340B drug,” he points out. “As the 340B program grows and as additional utilization occurs through contract pharmacies, the commercial plans and the Part D plans may experience a reduction in rebate revenue because those 340B claims should be excluded from their rebates. This has not gotten to be a big-dollar issue yet because although the contract pharmacy program has grown substantially over the last four to five years, it is difficult for manufacturers or the plans to identify the 340B utilization that exists.”

Will Patient Definition Be Revised?

In addition to the duplicate discounts, pharmaceutical manufacturers are concerned about what is considered a very broad patient definition, says William Sarraille, a partner in the healthcare practice group at Sidley Austin LLP. “Manufacturers for years have looked at that subregulatory definition and have concluded that it is broad enough that you could drive a truck through it,” he remarks. And despite one minor tweak, that subregulatory definition as proposed in the Cures draft would have essentially become a statutory definition, he says.

Meanwhile, HRSA has explicit regulatory authority in three areas: civil monetary penalties (CMPs), ceiling price calculation and administrative dispute resolution. The agency in June issued a proposed rule (80 Fed. Reg 34583, June 17, 2015) imposing CMPs of no more than \$5,000 on manufacturers that knowingly and intentionally charge a covered entity a price for a 340B-purchased drug that exceeds the established ceiling price (*DBN* 6/26/15, p. 8).

Sarraille says that rule has created some confusion around the distribution of specialty pharmacy drugs. “The proposed rule suggests that manufacturers have a responsibility to ensure that the 340B price is available regardless of the distribution model, and there are people within the 340B community who believe that that statement is a reference to product that is sold through specialty pharmacies,” he explains. Some manufacturers, however, argue that the distribution system referenced in the rule doesn’t apply to specialty pharmacy. He suggests this will likely be resolved through comments, which are due Aug. 17. As for the mega-guidance, Sarraille predicts it may be released in August.

Contact Sarraille at wsarraille@sidley.com and Vandervelde at avandervelde@thinkbrg.com. ✧

NEWS BRIEFS

◆ **CMS will soon begin conducting pilot audits of medication therapy management (MTM) programs for Medicare Part D insurers.** During a presentation made at CMS's annual Medicare Advantage and Prescription Drug Plan (PDP) audit and enforcement conference in Baltimore on June 16, Commander Rebecca Walden said the agency will examine the implementation of the sponsor's CMS-approved MTM program for enrollment, targeted medication reviews that must be furnished at least quarterly and comprehensive medication reviews to be done at least annually. She cautioned that the pilot audit protocols are still in development and thus subject to change. CMS intends to conduct them during the first week of formulary audits for Part D plans; sponsors with MTM programs will get a letter from CMS six weeks before the pilot audits detailing what the agency will ask for.

◆ **The Novartis heart failure drug Entresto (sacubitril/valsartan) could potentially be more costly in the long term than its Valeant Pharmaceuticals International, Inc. competitor Vasotec (enalapril maleate),** according to a new report by AdverseEvents, Inc. Novartis recently entered into talks with health care purchasers about performance-based pricing for Entresto to offset some costs (*DBN 7/10/15, p. 1*). The AdverseEvents study said that while Entresto had a shorter list of adverse events than Vasotec — 28 for Entresto vs. Vasotec's 146 — Entresto's increased risk of falls and possible risk of developing Alzheimer's disease could make Entresto more costly. Additionally, one of Entresto's components, Diovan (valsartan), has a higher RxCost, an AdverseEvents algorithm used to calculate downstream medical cost, than Vasotec. These statistics could signal that the drug, while touted as cost-saving by its prevention of hospital visits, could lead to additional costs due to adverse reactions. To view the report, visit <http://tinyurl.com/ov9azs9>.

◆ **A recent National Community Pharmacists Association (NCPA) survey cites new data gathered from pharmacists receiving below-cost reimbursements from PBMs for generic drugs that have risen in price.** The survey, released July 20, builds on a previous NCPA survey regarding generic drug prices and PBM reimbursements to pharmacies (*DBN 12/5/14, p. 3*). The new survey cites multiple examples of differences between reimbursement and

acquisition costs ranging from \$180 to \$475, which NCPA said provides "new evidence to substantiate the need for federal sunshine legislation," referring to the MAC Transparency Act (H.R. 244), introduced in January by Reps. Doug Collins (R-Ga.) and Dave Loebsack (D-Iowa). To view the NCPA survey results, visit <http://tinyurl.com/pw5qvmk>.

◆ **AstraZeneca's lung cancer drug, Iressa (gefitinib), is back on the market after receiving FDA approval on July 13.** The drug originally received accelerated FDA approval in 2003 for use as a third-line agent after chemotherapy failure for a subset of non-small cell lung cancer (NSCLC) patients, conditional on a confirmatory trial. However, after the confirmatory study showed no clinical benefit, AstraZeneca withdrew Iressa from the market in 2011, except for patients who were benefiting from it. Following recent tests, however, Iressa has been approved for first-line treatment of patients with metastatic NSCLC. Contact AstraZeneca spokesperson Michele Meixell at (302) 885-6351.

◆ **Cardinal Health, Inc. on July 16 unveiled its intention to acquire medication therapy management (MTM) provider OutcomesMTM.** Cardinal Health said the acquisition would enable the company to expand its MTM services and ultimately help it adapt to a changing value-based market. Cardinal Health is not disclosing the financial details of the acquisition. For more information, visit <http://cardinalhealth.mediaroom.com/news>.

◆ **During a July 9 conference call to discuss third quarter earnings for the fiscal year that ended May 31, 2015, Walgreens Boots Alliance, Inc. Executive Vice Chairman and CEO Stefano Pessina reiterated earlier remarks that the firm is exploring acquisition targets or strategic partnerships.** "We are open to any kind of combination which could improve the value of our company and we are looking actively around us to understand which is the best option for us," said Pessina, who was named permanent CEO after serving as acting CEO since January. He added that the company is looking not just in the U.S. but in other countries. Pessina in April had hinted at possible merger and acquisition activity (*DBN 4/24/15, p. 8*). Wall Street analysts have suggested that Walgreens would benefit in the U.S. from acquiring a PBM. Contact Walgreens spokesperson Michael Polzin at (847) 315-2935.

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