RADAR on

Drug Benefits

Business Strategies and Analysis for Health Plans, Employers, PBMs and Pharma Companies

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Providers Lobby Regulators to Block 'White Bagging'

Hospital groups are lobbying regulators at the federal and state levels to restrict the practice of "white bagging" in physician-administered specialty pharmacy dispensing. Practitioners and pharmacists argue that the practice, which is driven by vertically integrated insurer-PBM-specialty pharmacy combinations like UnitedHealth Group's Optum and Anthem, Inc.'s IngenioRx, is a danger to patients with severe conditions, but it's not clear whether regulators have the ability to block the practice.

The American Hospital Association (AHA) on Feb. 4 sent a letter to CMS asking the agency to review UnitedHealth's "specialty pharmacy coverage policies" and specifically called out "certain white bagging," arguing that the practice degrades quality of care, disrupts the 340B Drug Pricing Program and could even be a danger to patients. Meanwhile, in connection with a Feb. 18 meeting of the California State Board of Pharmacy, several provider groups called for the board to stop white bagging. The meeting was billed as "informational" on the board's website, so it is unlikely to result in immediate action.

The California Hospital Association (CHA), California Medical Association (CMA) and several notable hospitals including the University of California Health system argued in public comments and letters that white bagging poses a risk to patients.

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Brand Products Offer More Options for Heart Failure Treatment

Treatment for heart failure still relies significantly on tried-and-true generic drugs, but new brand-name entrants — including Novartis' Entresto (sacubitril/valsartan) and Amgen's Corlanor (ivabradine) — are important additions to prescribers' clinical arsenals against the high-mortality condition, industry insiders say.

In fact, a newly approved expanded indication for Entresto, plus more products recently approved and in the pipeline, could shift the balance more toward brand-name drugs in heart failure treatment, the insiders say.

"Generic heart failure drugs, including beta blockers, ACE inhibitors, and ARBs [angiotension receptor blockers] have historically been used and continue to be the backbone of therapy," says April Kunze, Pharm.D., senior director of clinical program development for Prime Therapeutics. "However, in the past few years, additional treatment options have become available. Entresto is now recommended as a first-line treatment option in patients with an ejection fraction <= 40%."

Novartis said Feb. 16 that its heart failure drug Entresto won an expanded indication from the FDA to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. "Benefits are most

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clearly evident in patients with left ventricular ejection fraction (LVEF) below normal," the drugmaker said.

The label also states that LVEF is a variable measure and clinical judgment should be used in deciding which patients to treat, according to Novartis. The label expansion will enable physicians to offer Entresto to a wider range of patients, the company added.

Prime Therapeutics currently prefers Entresto on formulary, and the PBM "will evaluate if clinical guidelines update its place in therapy for HFpEF [heart failure with preserved ejection fraction] given the recent expanded approval," Kunze says.

Currently, Prime recommends that plans remove prior authorizations for Entresto in order to encourage its use, Kunze says. According to a poster that the PBM presented at the Academy of Managed Care Pharmacy Nexus 2020 virtual event last October, Prime members adherent to Entresto therapy for a year had reduced medical visits and expenditures, with savings totaling $6.7 million when comparing patients' treatment costs to their costs prior to starting Entresto. To perform the study, Prime analyzed integrated medical and pharmacy claims data for 658 commercially insured members, and found average savings of $10,177, or 22%, per patient. In addition, hospitalizations decreased 63.3% and emergency room visits decreased 43.9%, while office visits and pharmacy costs rose, according to the study.

"Entresto represents an advancement in heart failure therapy that is being recognized as the new standard of care, given the strong data and reflection in the American College of Cardiology/American Heart Association/Heart Failure Society of America treatment guidelines," says Mesfin Tegenu, CEO and chairman of RxParadigm, a pharmacy benefit cost management start-up focused on providing tools and transparency.

Entresto is recommended for use as an alternative to ACE inhibitor or ARB therapy and also can be used in combination with other heart failure medications, Tegenu tells AIS Health. "In the Phase III PARADIGM-HF trial, Entresto demonstrated a 20% relative risk reduction in cardiovascular death or heart failure hospitalization compared to [ACE inhibitor] enalapril. Of note, hypotension and angioedema were more common in Entresto than enalapril."

Therapies Must Address Root Causes

Tegenu says that heart failure therapy needs to reduce morbidity and mortality while managing the underlying causes of the condition. Standard initial treatment focuses on an ACE inhibitor or an ARB and beta blocker, as well as a diuretic, if needed, Tegenu says. "Hydralazine plus a nitrate is an alternative option if an ACE inhibitor or angiotension receptor blocker is not tolerated, and recommended for African American patients," he says, adding that all of these are available as generics.

"While the initial goals of therapy focus on reducing symptoms, improving functional status and decreasing hospitalization, treatment progression will depend on patient-specific scenarios," Tegenu says. For example, if a patient continues to have persistent symptoms despite taking the maximum targeted dose of initial therapy, then the addition of an aldosterone antagonist should be considered, given the long-term outcome benefit in patients with heart failure, he explains.

Tegenu says that Entresto, which has an average retail price of around $600 per month, typically is placed on formularies as a preferred brand drug. Meanwhile, Amgen's Corlanor can be beneficial in reducing heart failure-associated hospitalization for patients with symptomatic (NYHA Class II-III) stable chronic heart failure with a left

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ventricular ejection fraction of less than or equal to 35% who are receiving a maximal tolerated targeted dose of a beta blocker and in sinus rhythm with a heart rate of 70 beats per minute or greater at rest, Tegenu says.

Meanwhile, Prime prefers Corlanor on formulary, Kunze says, noting that treatment guidelines recommend it as an add-on to standard therapy in patients who continue to have an elevated heart rate (70 beats per minute or higher) despite treatment with a beta blocker.

"The target for Colanor is to slow down heart rate," Tegenu explains, adding that Corlanor typically is placed on formularies as a preferred or non-preferred brand, and may be started when the patient is not being adequately controlled on optimally dosed beta blocker therapy. "It is important to keep in mind that only roughly 25% of patients studied in the randomized controlled SHIFT trial were on optimal doses of beta-blocker therapy," Tegenu says. "Unlike the well-proven mortality benefits of beta-blocker therapy, Corlanor is not considered a substitution for beta-blocker therapy and should be considered for additional therapy following the maximal tolerated targeted dose of a beta-blocker." The average retail price for Corlanor is $558.65 for a one-month supply, according to GoodRx.

Entresto and Corlanor represent advances in treatment for chronic heart failure, Tegenu says. "Both therapies were poised to change the landscape of treatment for patients with heart failure, given their unique mechanisms of action," he says.

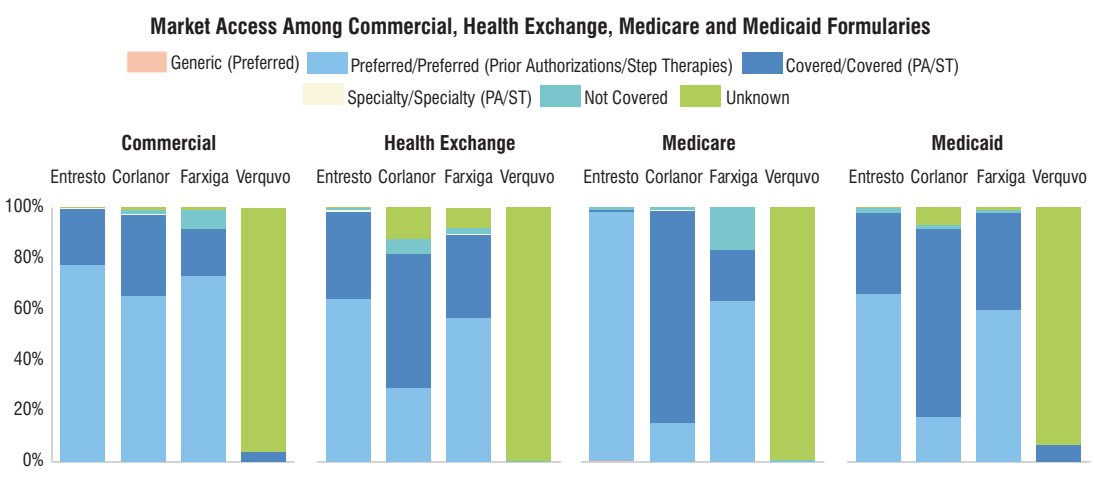
"Entresto has been considered an advancement in therapy as represented in the clinical guidelines," Kunze says. "Corlanor has failed to gain much market share given its prescribing limitations."

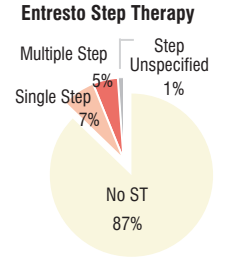
In addition, there are more therapies on the horizon. Merck's Verquvo (vericiguat), a soluble guanylate cyclase (sGC) stimulator, was approved by the FDA on Jan. 20 to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and ejection fraction less than 45%.

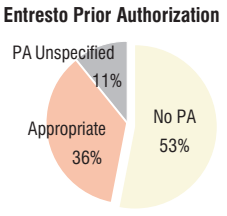
Current Market Access to Chronic Heart Failure Medications

by Jinghong Chen

The FDA recently expanded the label of Novartis' Entresto (sacubitril/valsartan) to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. It became the first and only FDA-approved drug for both heart failure with reduced ejection fraction (HFrEF) and heart failure with preserved ejection fraction (HFpEF) in patients whose left ventricular ejection fraction (LVEF) is below normal levels. For chronic heart failure treatments, the majority of insured people have plans that put them under the preferred/preferred (prior authorization and/or step therapy) tiers and covered/covered (PA/ST) tiers, as of February 2021. Most payer pharmacy benefit formularies do not require step therapy or prior authorization for Entresto.







NOTE: The numbers of total covered lives under commercial, health exchange, Medicare and Medicaid formularies are 171.1 million, 10.5 million, 47.5 million and 68.0 million, respectively.

SOURCE: Managed Markets Insight & Technology, LLC database as of February 2021.

Verquvo, which received a priority regulatory review from the FDA, is the first treatment approved for chronic heart failure specifically for this group of patients.

According to Merck, in its pivotal VICTORIA Phase III trial, there was a 4.2% reduction in annualized absolute risk with Verquvo compared with placebo, meaning that 24 patients would need to be treated over an average of one year to prevent one death or heart failure hospitalization.

It's still unclear how Verquvo will fit into heart failure treatment, Tegenu says: "With its recent FDA approval and lack of current support by treatment guidelines standards, Verquvo's value in heart failure therapy will need to be further evaluated." Verquvo has an average retail price of around $600 per month, according to GoodRx.

FDA Reviews Jardiance for Heart Failure

AstraZeneca's sodium-glucose co-transporter 2 (SGCT2) drug Farxiga (dapaglifozin) was approved in May 2020 by the FDA to reduce the risk of cardiovascular death and hospitalization for heart failure in adults who have heart failure (NYHA Class II-IV) with reduced ejection fraction with and without type 2 diabetes. That builds on Farxiga's earlier approvals to treat type 2 diabetes and patients with both heart failure and type 2 diabetes. Jardiance (empagliflozin) from Boehringer Ingelheim and Eli Lilly and Co. may become the second SGLT2 drug approved for chronic heart failure with reduced ejection fraction, with an expected FDA review in late 2021, Tegenu says. Jardiance currently holds FDA approval for use in diabetes.

Additional heart failure drugs are in late-phase clinical trials. Cytokinetics, Inc. is developing omecamtiv mecarbil, a novel, selective cardiac myosin activator for the potential treatment for heart failure with reduced ejection fraction. "By stimulating the cardiac myosin protein, it will allow the heart to contract and improve cardiac muscle performance," Tegenu says.

In addition, Lexicon Pharmaceuticals, Inc., is preparing to apply for FDA approval for sotagliflozin, the first dual inhibitor of both SGLT1 and SGLT2. "Sotaglifozin is anticipated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent visits for heart failure in adult patients with type 2 diabetes with either worsening heart failure or additional risk factors for heart failure," Tegenu says.

Plans Want to Prevent Readmissions

Health plans also are turning to targeted disease and care management programs to focus on preventing hospital readmission, reducing mortality and reducing costs in heart failure, Tegenu says. "Heart failure is a major health concern due to the high rates of morbidity and mortality despite optimal therapy," he says. "The prevalence, especially in the elderly population, will continue to increase over the next decades as a result of the demographic trends. Concerns for hospitalization and high readmission rates continue to plague health plans."

Targeted disease or care management programs should take a multidisciplinary approach with cardiologists, primary care physicians, nurses, pharmacists and other health care professionals, and primarily should target the high-risk symptomatic patients, Tegenu says. "Remote-monitoring congestive heart failure programs plus medication therapy management programs, where patients are closely tracked and followed post-discharge (e.g., weight, functional status, nutrition, symptom monitoring), along with patient education and interventions such as medication adherence and self-care follow-up care, are effective in the management of heart failure."

Tegenu notes that the heart failure death rate remains very high despite new treatment options: "Avoiding hospitalization and preventing readmission remain the focus in the management of heart failure," he says. "In addition, we have to manage diabetes well, since there is a strong linkage between these comorbid conditions. We have more treatment options now. If we can be more aggressive and adopt remote monitoring, medication optimization and adherence monitoring, I am optimistic that we will see improvement in the mortality rate."

View the Prime Therapeutics research on Entresto at https://bit.ly/2NmgWUj. Contact Kunze via Denise Lecher at denise.lecher@primetherapeutics.com and Tegenu at Mesfin.Tegenu@rxparadigm.com. ✧

by Jane Anderson

Learn more about MMIT's Analytics solution to understand market access and payer coverage.

States May Use ICER to Target 'Unsupported' Drug Price Hikes

As states continue their quest to lower prescription drug prices for the benefit of their budgets and residents, a small but growing number are considering legislation that would levy an 80% tax on drug price increases that the Institute for Clinical Effectiveness Research (ICER) deems "unsupported" by clinical evidence.

The new measures, which have so far been introduced in Hawaii, Maine and Washington, are based on a model law that the National Academy for

State Health Policy (NASHP) introduced in July 2020 — becoming the latest in a host of other legislation templates the organization has developed to help states rein in drug costs.

According to NASHP Executive Director Trish Riley, the new model law came out of a desire to offer a drug-price-reduction strategy to states that minimizes the implementation burden, as many are currently facing budget crises tied to the COVID-19 pandemic. But she says it's also the natural extension of a pair of existing projects.

One is ICER's Unsupported Price Increase (UPI) reports, which the organization developed to "determine whether new clinical evidence or other information has appeared that could support the price increases of those drugs with recent, substantial price increases that have had the largest impact on national drug spending." The organization has produced two such reports so far; the most recent, unveiled on Jan. 12, examined 10 drugs and found that seven had unsupported price increases (see infographic below).

In addition, ICER had formed a partnership with NASHP in which the research organization uses data from states that have implemented NASHP-supported drug price transparency laws to identify high-cost medications that can be reviewed for value *(RDB 7/23/20, p. 1)*. ICER has used that information to identify drugs it wouldn't otherwise review, including the arthritis drug Enbrel (etanercept), which "turned out to be the drug with

Seven of 10 Drugs Saw Price Hikes Without Novel Clinical Evidence, ICER Reports

by Jinghong Chen

Out of 10 drugs with price increases that had a significant impact on national drug spending in 2019, seven of those increases were not supported by new clinical evidence that demonstrates substantial improvement in health, according to the drug price research organization Institute for Clinical and Economic Review. The price increases of these seven drugs alone cost U.S. consumers an additional $1.2 billion a year. The group also evaluated insulin products — whose skyrocketing costs are facing increasing public scrutiny — and found that five of the top 10 insulins had wholesale acquisition cost (WAC) increases from 2018 to 2019, while net price declined for nine of these products.

Assessment for Drugs With Substantial Price Increases in 2019

Drug	2018 to 2019 % Change WAC	2018 to 2019 % Change Net Price	Increase in Spending Due to Net Price Change
Drugs With Price Increases Unsupported by New Clinical Evidence			
Enbrel (Etanercept)	5.4%	8.9%	$403M
Invega Sustenna/Trinza (Paliperidone Palmitate)	6.8%	10.7%	$203M
Xifaxan (Rifaximin)	8.4%	13.3%	$173M
Orencia (Abatacept)	6.0%	7.4%	$145M
Tecfidera (Dimethyl Fumarate)	6.0%	3.7%	$118M
Humira (Adalimumab)	6.2%	2.0%	$66M
Vimpat (Lacosamide)	7.0%	5.6%	$58M
Drugs With Price Increases With New Clinical Evidence			
Entresto (Sacubitril/Valsartan)	9.6%	8.0%	$66M
Entyvio (Vedolizumab)	6.4%	2.3%	$48M
Xtandi (Enzalutamide)	5.9%	2.5%	$37M

Pricing for Top 10 Insulin Products in the US

Product (Manufacturer)	Average WAC (Per Unit) 2018	Average WAC (Per Unit) 2019	Year/Year % Change	Average Net Price 2018	Average Net Price 2019	Year/Year % Change	2019 Sales
Humalog/Mix (Eli Lilly and Company)	$33.64	$34.03	0.0%	$7.82	$7.59	-3.0%	$1,669M
Novolog/Mix (Novo Nordisk A/S)	$33.44	$34.35	2.5%	$6.82	$5.48	-20.0%	$1,330M
Lantus (Sanofi)	$26.56	$28.34	5.2%	$6.39	$4.71	-26.2%	$1,286M
Humulin/Mix (Eli Lilly and Company)	$48.48	$51.59	0.0%	$26.91	$28.21	-1.0%	$880M
Basaglar (Eli Lilly and Company)	$21.76	$21.76	0.0%	$7.39	$8.32	18.2%	$876M
Tresiba (Novo Nordisk A/S)	$52.95	$55.63	7.5%	$17.45	$14.18	-16.8%	$828M
Levemir (Novo Nordisk A/S)	$28.68	$30.79	7.4%	$7.11	$5.55	-21.8%	$763M
Toujeo (Sanofi)	$81.52	$86.30	4.4%	$21.05	$16.79	-19.6%	$324M
Admelog (Sanofi)	$27.48	$21.37	-44.1%	$20.23	$12.26	-52.9%	$263M
Novolin (Novo Nordisk A/S)	$13.77	$13.88	0.0%	$4.43	$3.87	-11.7%	$233M

NOTE: Eli Lilly provided net pricing information based on price per vial rather than price per unit.

SOURCE: "Unsupported Price Increase Report: 2020 Assessment." Institute for Clinical and Economic Review, January 12, 2021. Visit https://bit.ly/2ZlYh7z.

the single biggest impact in unsupported price increases," in ICER's latest report, Riley says.

When developing its new model law, "what we thought was, ICER is doing this thoughtful, evidence-based review" that includes input from consumers, manufacturers and states, Riley tells AIS Health. So, "why not give the list some teeth?"

In NASHP's model law, those "teeth" come in the form of a fine levied by the state on 80% of the difference between the previous list price and the current list price of a drug identified as having an unjustified price increase. That calculation is also adjusted to account for inflation.

The state will determine which drugs to target by using ICER's annual UPI report and requiring drug manufacturers to reveal: 1) the total sales of the relevant drugs in that state and 2) the list price of those drugs for the current and previous year. "Audits may be conducted by the state tax assessor, and manufacturers who fail to make timely reports are subject to penalties," notes a July 28 post introducing NASHP's model law. The state can also use revenues generated from fines levied on manufacturers to help pay for administering such a law.

Pandemic Constrains Budgets

In addition to the three states that have introduced legislation based on NASHP's model law, Riley says the organization is working with other states to develop similar measures. That said, "this [legislative] session is particularly tough given COVID and budget. It's the first time since we've been tracking governors' 'state of the states' [addresses] that health issues have not been as front and center, other than COVID, because it's just what's driving everybody," she adds.

Meanwhile, one legal and policy expert cautions that such legislation shouldn't be seen as a silver bullet for the problem of unsustainably high drug costs.

"Because drug pricing is such a complex problem with so many different contributing factors, a combination of approaches — at the federal and state levels, acting on different types of drugs whose prices are high for different reasons — will be needed to provide relief to all Americans," says Rachel Sachs, an associate law professor at Washington University in St. Louis and an authority on drug-pricing issues. "Bills like these are an important part of that strategy, but more will be needed."

Not All Experts Are Convinced About UPI

The UPI model has also been met with skepticism by some experts.

"It really doesn't address the core drivers behind price increases...that higher list prices mean greater rebates for payers and so are necessary to keep a drug on formulary," says Lisa Kennedy, Ph.D., chief economist at the life sciences consulting firm Innopiphany LLC.

Philip Ball, Ph.D., head of policy at Innopiphany, adds that "ICER's UPI report has been considered flawed, not least because its analysis only considers a very narrow timeframe of when a product is marketed, lacks real-world evidence, and insufficiently captures true patient outcomes and costs. Caution is needed before implementing wholesale use of these still immature and unproven reports."

A spokesperson for Pharmaceutical Research and Manufacturers of America (PhRMA) also offered a critical view.

"Proposals that rely on flawed, biased reports that discriminate against seniors and those with certain diseases are the wrong approach," the spokesperson says in a statement to AIS Health. "The outcome of these policies would only make it harder for people to get the medicines they need and would threaten the crucial innovation necessary to get us out of a global pandemic. And the organizations pushing these proposals — NASHP and ICER — are part of a network of groups funded by a billionaire political activist that is advocating for misguided policies that would make it more difficult for people to get the health care they need."

As PhRMA alluded, ICER has drawn fire from the disabled community because of concerns surrounding its use of quality-adjusted life years (QALYs). While the post unveiling NASHP's model law acknowledges that controversy, it also points out that ICER doesn't use the QALY metric in its calculation of unsupported price increases. "Pharma has been quite bold in working with various advocacy groups to raise the concern about QALY, often without evidence," Riley says. "It's absolutely unrelated to what this is. This is a price increase, and the evidence has nothing to do with QALY."

Laws Could See Court Challenges

Riley also says she anticipates legal challenges to arise if any states end up finalizing legislation based on NASHP's new model. "Everything will get taken to court, so we know no matter how ironclad it is, it will be challenged. But we developed both these models with careful input from lawyers" to ensure they can withstand those challenges, she adds.

Read about the model law at https://bit.ly/2ZTdVgx and https://bit.ly/3soJJpT. Contact Riley via Jennifer Laudano at jlaudano@nashp.org and Sachs via rsachs@wustl.edu. ✧

by Leslie Small

Providers Fight 'White Bagging'

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White bagging is the practice increasingly mandated by insurers of requiring practitioners to acquire provider-administered therapies from a payer-preferred specialty pharmacy. Providers traditionally have acquired therapies they administer through a practice known as "buy and bill," by which they will purchase a drug from a wholesaler or distributor, keep it onsite and administer it to patients as needed, submitting a claim to the payer afterward. Through this approach, providers can make a profit by marking up the drug.

White bagging means the provider never takes ownership of the drug, and a patient will pay their copayment or coinsurance to the specialty pharmacy after the physician orders the drug. The specialty pharmacy then delivers the medication directly to the provider. This process can generate savings for a payer. A related procurement process, called brown bagging, is when a patient orders and receives the drug and brings it to the provider to be administered.

UnitedHealth Defends Practices

In response to an inquiry about the claims in the AHA letter, UnitedHealth spokesperson Trasee Carr wrote in an email to AIS Health that "our data shows that, for some outpatient hospitals in our commercial network, the reimbursement rate on certain specialty drugs may be over 400% of the reimbursement rate established by the Centers for Medicare & Medicaid Services (CMS) for the same drug. Our expanded sourcing requirement helps make these specialty drugs more affordable for our customers and members, while maintaining quality of care, drug safety and effectiveness."

However, providers argue that the process has significant downsides for patients. In a letter submitted to public comments for the California Board of Pharmacy meeting, the University of California Health system argued that "white bagging bypasses the safeguards designed into medication systems. It limits the ability of nurses, physicians, and pharmacists to assure the safe acquisition and administration of medications for which they are legally responsible. The receipt, storage, and use of externally supplied prescriptions creates confusion and increases risk of medication errors with multiple drugs for multiple patients from multiple pharmacies, in the same clinic or infusion center." The letter was signed by John Grubbs, chief pharmacy officer of UC Health and the heads of pharmacy at hospitals affiliated with UC Davis, UC Irvine, UCLA, UCSD and UCSF.

Other hospitals that submitted comments arguing against white bagging included Keck Medicine of USC, Stanford University-affiliated Lucile Packard Children's Hospital and Valley Children's Hospital, the Children's Hospital of Orange County and InterHealth Corp.'s PIH Health Whittier Hospital. In its presentation to the board, the CHA wrote that Anthem, CVS Health Corp.'s Aetna, Cigna Corp. and UnitedHealth all have some form of white bagging policy in California.

Physicians Worry About Drug Handling

In the letter to CMS about UnitedHealth's practices, Thomas Nickels, AHA's executive vice president for government relations and public policy, wrote that white bagging prevents clinicians from exercising the usual level of control over drug delivery. White bagging generally entails an insurer authorizing a requested fill from a provider of a physician-administered therapy, then dispensing it from a regional specialty pharmacy, so the process can take days, or even weeks.

"White and brown bagging policies have the potential to directly delay or disrupt the administration of a particular drug to a patient," Nickels wrote. "For example, as the purchasers of pharmaceutical products under these policies, payers, not providers, are responsible for ensuring delivery of the product. However, this practice, especially in brown bagging situations, places significant reliance on the on-time delivery of product. Since these products are ordered on a patient-by-patient basis, as opposed to in bulk by hospitals, the potential for delay in care due to late or mistaken delivery of a product is a realistic outcome."

Rural Providers Face Extra Challenges

These delays can be especially problematic for rural providers. According to a presentation submitted to the California Board of Pharmacy by Thomas Semrad, M.D., of the Tahoe Forest Cancer Center in Truckee, Calif., a rural setting creates additional need for same-day analysis and prescribing for cancer patients. According to the presentation, "due to [the] distance that many patients travel, [the clinic has] multiple structures in place to allow for same day assessment and treatment," including equipment that allows "treatment day labs" to be completed in one hour to facilitate "same day adjustment of treatment plan and dosing."

Semrad explained that these onsite, rapid adjustments are necessary because "on [the] day of treatment, a dose may need to be increased (resulting in delay if insufficient dose provided) or decreased (resulting in waste), due to changes in weight, organ function, toxicity, or as a result of clinical

judgment." Semrad added that, due to Truckee's location in the Sierra Nevada mountains, "delivery is not reliable in winter months due to weather."

Jayson Slotnik, an attorney and partner at Health Policy Strategies LLC, tells AIS Health via email that "there is merit" to the notion that white bagging is dangerous to patients, and that it's "a claim that has been made for years." But he points out that a health plan would be foolish to "permit a specialty pharmacy to do risky behavior from a liability point of view."

Slotnik adds that there is likely little that regulators can do to prevent white bagging. "For commercial, this would likely be considered a benefit design issue and therefore governed by ERISA such that, for these types of plans, there is little CMS or the states can do," Slotnik explains. "Under Medicare, CMS practically encouraged this policy a few years ago in its call letter and I do not think will walk it back. CMS looks at this as a way to control drugs' costs and provide greater choices for patients."

One California regulator has already declined to intervene in white bagging. Sarah Ream, general counsel of the state's Department of Managed HealthCare, wrote in a slide deck presented to the Board of Pharmacy meeting that "the DMHC does not have authority to prohibit 'white bagging,' so long as the practice does not harm enrollees or impact enrollees' ability to receive medically necessary care."

"The only group outside of manufacturers to push back are physicians," Slotnik says. Slotnik points to the example of oncologists in Tennessee, who early in 2020 publicly opposed payer white bagging efforts from plans including BlueCross BlueShield of Tennessee.

As the recent actions of the CHA and CMA demonstrate, California physicians have clearly taken the same tack. Elan Rubinstein, Pharm.D., founder and principal of EB Rubenstein Associates, a pharmacy consulting firm, says he expects the state's larger hospital systems will be able to exercise their influence. "I doubt that individual hospital providers have sufficient clout to resist United's new policy. But I'd bet that the University of California health system does," Rubinstein says.

"Similarly," Rubinstein adds, "I suspect that health systems which dominate their geographic regions have significant negotiating power vis-a-vis contracting health plans, including United, and could institute policies similar to UC's re[garding] white bagging."

Find the AHA letter at https://bit.ly/375XGkq, a recording of the California hearing at http://bit.ly/2ZMHNez, presentations from the hearing at http://bit.ly/3uupeKj and comment letters at https://bit.ly/3spwm93. Contact Rubinstein at elan.b.rubinstein@gmail.com and Slotnik at jayson@healthpolicystrategiesllc.com. ✧

by Peter Johnson

News Briefs

✦ ***AlohaCare chose Anthem, Inc. PBM IngenioRx for a three-year contract to serve Medicaid and dual-eligible Medicare/Medicaid beneficiaries in Hawaii, Anthem said on Feb. 24.*** IngenioRx will serve AlohaCare's QUEST Integration members, who will be able to opt for services including pill packets for multiple-medication regimens and home delivery. The goal is to "improve the pharmacy experience and drive better health outcomes, while further lowering costs," per a news release from the company. For more information, contact Lori McLaughlin at lori.mclaughlin2@anthem.com.

✦ ***In January, prescription volumes continued their downward trend but showed some slight improvement over recent months, according to a recent research note from Citi analyst Ralph Giacobbe, citing IQVIA Health data.*** Adjusted total prescriptions, which includes both new scripts and refills, were down 4.5% year over year, compared with -6.1% year over year in December and -5.3% in November. Adjusted new prescriptions, which represents the first time a patient has been prescribed a particular drug, was down 6.7% in January, "which indicates slight improvement from trends in December and November that were both down 7.2%," Giacobbe wrote. Visit www.iqvia.com to learn more.

✦ ***Sen. Marsha Blackburn (R-Tenn.) and Sen. Mike Braun (R-Ind.) recently re-introduced legislation that would have the Government Accountability Office investigate the role of rebates and fees in the PBM business model.*** The bill, S. 1532, would examine data from the 10 largest PBMs regarding the amount of rebate passed on to patients, payers and the PBM for each drug in their formularies, as well as subjects such as prior authorization and step therapy. Read more at https://bit.ly/37J1MPV.