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Compounding Pharmacies Market Caters To Key Regional Health Care Issues

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With more full-service facilities providing customized medication, the global compounding pharmacies market forecast is expected to remain optimistic over the next few years. Amidst a global backlash against soaring drug prices, numerous hospitals worldwide have been starting their own pharmacies, with significant aid from government authorities.

For example, the Dutch government, has been backing the efforts of specialized compounding pharmacies, which have been striving to curb rapidly growing medicine costs throughout the nation.¹ Developing economies are also on the same path. For instance, the Indian Union Ministry will fund the medical university PGI Chandigarh's own pharmacy, which will offer approximately 40% discounts on MRP of medicines, according to recent reports.²

Today, legacy pharma brands have been the key providers of drugs and medical supplies. As bringing down prescription prices has become a top priority, the Belgian government has been supporting the practice of compounding via rigorous testing and laboratory accreditations. According to the European Association of Hospital Pharmacists (EAHP), there are approximately 163 hospital pharmacies in the nation, strengthening Belgium compounding pharmacies industry outlook.³

These patient-oriented pharmacies are equipped with professional and knowledgeable staff, who have been helping patients with their queries. The number of individuals opting for these custom solutions has grown over the past couple of years because:

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- These pharmacists accept most types of insurances.
- They offer specialized services, including refills, at competitive prices.
- They can ensure a 90-day supply of medications under some plans.
- Orders placed via phone, website, or in-person are delivered on time at the doorstep.

More patients to opt for compounded ophthalmic eye drops in Africa

African countries are prime markets for pharmaceutical companies. South Africa compounded ophthalmic pharmacies industry will grow, owing to the high prevalence of eye conditions among men, women, and children in the region.

Compounded eye drops are considered a great alternative for a certain category of patients who have been on chronic therapies for glaucoma or dry eye because of their cost effectiveness, regulatory compliance, and overall efficiency. For instance, compounded cyclosporine can be a good option for patients who cannot afford other immunomodulators for dry eye.

African countries, including Nigeria and Ghana, have a significant eye disease burden, calling for immediate attention as well as action. The regional governments have been addressing this public health problem by implementing numerous plans and programs.

To cite an instance, the government of South Africa observed the World Glaucoma Week between March 6 and 12, 2022, a joint program between the World Glaucoma Patient Association and the World Glaucoma Association.⁴ The initiative, taking place for over 10 years now, is aimed at spreading awareness regarding the condition and carrying out screening events at local hospitals.

Numerous ophthalmologists across the globe have already been prescribing compounded drops for dry eye and glaucoma because of the ease of regimen management involving multiple drops. Administering a single drop is much more convenient, especially for aging patients, who may miss their dosage due to more complicated instructions. Several compounding pharmacies in South Africa have been providing fast delivery and excellent customer service with online order placement.

High incidence of attention-deficit/hyperactivity disorder (ADHD) in Nordic countries to strengthen demand for pediatric compounds

The European pediatric compounding pharmacy market share is increasing due to the rising awareness regarding the risk of drug allergies among children. Pediatric compounding formulas are available in various child-friendly forms,

including syrups, suspensions, freezer pops, lollipops, and gummy bears, facilitating easier medication administration in children. Bespoke medication makers have been catering to the needs of children who have difficulty with speech, cognitive functions, or swallowing tablets.

Children suffering from sensory processing disorders can have autism, fragile X syndrome, or ADHD. As these children often have reactions to medicines, including vomiting and gagging, compounding pharmacists can alleviate these problems by suiting to their individual tastes and textures.

The local sterile compounding pharmacies industry has been catering to the needs of children with food allergies because several commercially available syrups contain sorbitol or corn syrup, which triggers an allergic reaction in some children. According to the Asthma and Allergy Foundation of America, nearly 5.6 million children have food allergies in the United States alone.⁵

With the incidence of ADHD rising amongst the Nordic countries, the industry share for Swedish compounding pharmacies is growing. According to the estimates published by the University of Gothenburg, ADHD is one of the most common conditions in regional adolescent and child psychiatry. Estimates suggest that the condition affects approximately 3%-5% of children attending school in the Nordic region.⁶

Growing availability of anti-cancer compounds in France

Rising incidence of cancer across European countries has been a key reason for the increasing awareness regarding the advantages of personalized medicine. In fact, the European compounding pharmacies industry size was expected to hit a 5.2% CAGR over 2020-2026.⁷

Since ensuring accessibility to high-value medicines to the right patients has been a key challenge for the health care sector, regional hospitals have been offering diversified chemotherapy preparations compounded at hospital pharmacies.

France is a promising market for compounded oncology drugs. In December 2021, Saint Camille Hospital in Bry Sur Marne placed an order for standalone devices for compounding from Pharmacolog SARL.⁸

From January 2022, the hospital pharmacy has been deploying the DrugLog product for enhanced quality control of cytotoxic preparations. The system will help the staff minimize errors associated with compounding. With more hospitals following suit, access to compounded anticancer drugs is increasing in France.

Overall, the past few years have brought significant transformation in the global personalized medicine industry.

Not only can pharmacists now leverage the patient's medical history for formulating effective drugs, but patients can also benefit from single dosage, greater efficacy, and affordability of compounded medications.

With industry participants strengthening their expertise and geographical reach, the global specialty compounding pharmacies market offers an emergent and exciting opportunity to improve compliance among patients suffering from a host of eye, dermatological, and chronic conditions.

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Learning to Stay Ahead of Payer Policy Changes in Biosimilar Coverage Within Oncology Pharmacy Practice

Alana Hippensteele, Managing Editor

There has been a significant gain in clinical confidence in the demonstration process for biosimilars, explained discussion panel moderator Jorge García, PharmD, MS, MHA, MBA, FACHE, during a session at the 2022 ATOPP Summit. However, the challenge remains learning how to overcome and manage the different roadblocks and opportunities that the evolution of biosimilars continues to present to oncology pharmacy practices.

"One of the biggest challenges that we face is really preparing and staying ahead of payer benefit design and changes that come our way throughout the year—sometimes on a quarterly basis," García said.

In light of this rapid pace for the evolution of biosimilars in terms of payer benefit design, García noted that it becomes critical to find a method of staying ahead of policy changes that can ultimately impact operations down the line.

Panel participant Mandy C. Leonard, PharmD, BCPS, the system director of drug use policy and formulary management at Cleveland Clinic, noted that at her institution, due to the everchanging nature of biosimilar payer benefit design, pharmacists at her organization have had to learn how to adapt to these frequent changes by monitoring what's going on at the Cleveland Clinic, not only from an inventory

perspective, but from a formulary management perspective.

"I think we'd all like to say that if we could select one biosimilar to a reference product in our organization, that would be the best for us as far as controlling a lot of aspects of it, but that's not always the case," Leonard said. "So I think some of the challenging things over the past several years after the introduction to some of the biosimilars is how do you manage all of that, and I think one of the biggest lessons that I learned is that I thought we were doing such a fantastic job of streamlining biosimilars within our organization once we had buy in from the medical staff, but then I learned that that may be impacting patient care, because [of issues] on the other side of things with insurance."

Additionally, pharmacists may not always know when there's going to be a payer coverage change. Leonard noted that in light of this, it's important to work with a strong team within the institution who can help to ensure that the pharmacist remains aware of those coverage changes. Whether that team is within billing, marketing, or network strategy department, they can help pharmacists assess ahead of time what they are going to do about coverage changes within the electronic health record (EHR) in order to help providers on their end of things.

Panel participant Kenneth Komorny, PharmD, BCPS, the chief pharmacy officer at the Moffitt Cancer Center, noted that at his institution, they've embraced the managed care department for the purposes of effective collaboration on this front at the Moffitt Cancer Center and meet with them on a quarterly basis to ensure a strong level of communication regarding changes in biosimilar payer coverage.

"We've tried to be proactive, having them comb through the payer policy changes to make sure that we're on top of that. Otherwise, you get surprised," Komorny said. "So they maintain a spreadsheet for us, and we try to capture the majority of them. They have hyperlinks within it; it's a living document, and we're able to click in and find out in real time what the insurance policy is around [a biosimilar]."

With the living document noting payer policy changes in real time, Komorny noted that pharmacists at the Moffitt Cancer Center can make a one-page guide for pharmacy staff to ensure everyone stays informed regarding which drugs are available. Additionally, the pharmacists note the major payers in the system as well as the different products, and whether they are they covered or not covered by the insurance company, and whether they are formulary or non-formulary.

"It works as a guide for the pharmacy staff to know which

drugs we have available and which ones we don't. But again, it's really reaching out to your managed care department and your payer strategies department and working with them to create this [spreadsheet]. We don't have the expertise to be able to comb through these insurance policies—they are very, very long," Komorny said. "So we kind of lean on them to do that part, and then we boil it down from the pharmacy perspective."

Komorny noted that even with this living document noting payer policy changes that impact the pharmacist's practice, it also remains important to run benefits investigations for every patient and every date of service because policies can change from quarter to quarter.

"In fact, that's what we see in practice," Komorny said. "We also have patients change jobs in Florida, we have temporary Medicaid, where patients may have insurance in one month but not in the other. So it's a lot of work to stay ahead of the policies and then run that benefits investigation every time."

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Build Connections With Legislators When Advocating for PBM Reform

Aislinn Antrim, Associate Editor

With heightened scrutiny from regulators and even an investigation by the Federal Trade Commission (FTC), pharmacy industry advocates are seeing renewed energy for pharmacy benefit manager (PBM) reform, according to a session at McKesson ideaShare 2022.

The PBM industry has played a large role in the health care supply chain since the mid-1980s, said speaker Matt DiLoreto, senior vice president of state government affairs and alliance development at Healthcare Distribution Alliance. It is important for pharmacists and advocates to recognize that PBMs have extraordinarily strong lobbying and public affairs power, which has allowed them to largely evade attention until recently.

Since 2017, DiLoreto said the National Conference of State Legislatures indicates that approximately 1000 PBM

reform bills have been introduced at the state level, tackling everything from gag clauses to patient steering.

"It's a kaleidoscope of targets that you're trying to hit," DiLoreto said. "It is very difficult to legislate your way out of contractual agreements between 2 entities."

Legislation prohibiting gag clauses has been the most common provision since 2017, followed by bills about limiting patient cost sharing, requirements for licensing or registration, and reimbursement requirements.

Because of the challenge of addressing many different issues, DiLoreto said the response from pharmacy advocacy groups has changed. Originally, the industry tried to make terminology as specific as possible, but this allowed PBMs to simply change their language and avoid ramifications. Now, advocacy groups are trying to make their approach as broad as possible.

PBMs have also adapted, moving from a strategy of opaqueness to evasion. Instead of threatening lawsuits or telling legislators that changes could increase the costs for states, PBMs are now pointing toward wholesalers and other entities. The goal of this strategy, DiLoreto said, is to slow down the conversation and any potential legislation efforts, eventually minimizing or entirely avoiding impacts on PBMs.

With all of these changes in mind, DiLoreto said it is important to be proactive rather than reactive. The PBM industry has been remarkably proactive thus far, anticipating legislative changes and lobbying against them early.

“It’s a much different game when you are reacting to what’s already been put in place, so I think being proactive is key,” DiLoreto said.

Pharmacists and pharmacy owners have vital roles to play in these efforts, DiLoreto said. Pharmacists can offer themselves as a resource to legislators, explaining the facts and relating it to patients and the broader community. Presenter Matt Williams, vice president of state government affairs at McKesson, said pharmacists should speak to legislators as if they were a patient. Although it can be frustrating, explaining things with care and concern is more likely to be effective.

“If you come in with care and concern, I think you have a better chance of hearing that care and concern back,” Williams said.

Partnering with pharmacy organizations at both the state and national level is another way to stay informed and involved, particularly as the federal government ramps up activity regarding PBM investigations and reform efforts. In addition, DiLoreto concluded that involvement cannot simply be focused on legislators, because other entities play important roles. He pointed out that the FDA authorized pharmacists to prescribe Paxlovid without going through Congress.

Ultimately, emphasizing the accessible nature of pharmacies and why this is essential for patients can help legislators and others understand why changes are necessary.

“Independent pharmacy is hands down still the most accessible, face-to-face, Norman Rockwell view of health care in this country,” DiLoreto concluded.

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PBMs, Lack of Transparency Spur New Models for Specialty Pharmacy Benefit Management

Aislinn Antrim, Associate Editor

Because of widespread frustrations with pharmacy benefit managers (PBMs) and a lack of transparency, many employers are finding creative new models for specialty pharmacy benefit management, according to a session at the Asembia 2022 Specialty Pharmacy Summit titled “Quality, Equity, and Affordability: Employers, Change, and New Models for Specialty Pharmacy Benefit Management.”

Prescription medications are vital to optimal patient outcomes, but they are also becoming increasingly expensive, according to moderator John O’Brien, PharmD, MPH, president and CEO of the National Pharmaceutical Council. Novel therapies are emerging for a myriad of conditions, but the high costs and new administration models are outpacing the preexisting benefit management systems.

“These therapies aren’t inexpensive, and employers and other claims sponsors are increasingly being forced to pay

for these treatments in a drug benefit that was designed for blood pressure and cholesterol medicines from the ‘90s,” O’Brien said.

Panelist Elizabeth Mitchell, president and CEO of Purchaser Business Group on Health, agreed and said that she has seen a growing level of frustration among the corporations and entities that she represents. Mitchell explained that she represents large employers that bear the risks of insurance claims, and as drug prices have skyrocketed over the past 2 years, she said these payers have become increasingly unhappy.

“They want to pay for quality, outcomes, value, and now equity,” Mitchell said. “That is their strategic aim.”

One novel new benefit management model has come from this frustration. When the organizations found that partners such as PBMs or health plans were unhelpful, they decided

to contract directly in order to bypass the red tape and lack of transparency in the existing system.

Transparency was a major theme for all of the panelists. Because of a lack of clarity from PBMs, Mitchell said that not only are customers unable to get access to the care that they deserve, but key data are also inaccessible. Many PBM contracts even have clauses that prohibit the disclosure of some data, she added.

EmsanaRx is the PBM founded to bypass the challenges that Mitchell's clients were finding in the preexisting system. Founder and CEO of EmsanaRx, Greg Baker, RPh, agreed that transparency is a major obstacle in the health care system and benefit management system overall. He also added that these problems lead to pharmacy deserts and the lack of equity that is currently being seen across the health care system.

Community pharmacies, in particular, have seen a steadily decreasing margin because of PBM costs and the lack of data transparency, Baker said. He added that the primary

controllable expense is payroll, so many pharmacies have turned to cutting their employees and even closing their doors entirely.

“Those stores don't close in affluent neighborhoods,” Baker said. “They close in the lower-income neighborhoods, neighborhoods of marginalized people and populations. And so, we're really creating these pharmacy deserts in the process.”

Baker concluded that these issues are not simply a financial problem. Ultimately, a lack of communication across all health care stakeholders is at the root of many of these issues. In order to reduce drug spend and overall health care costs, Baker said there is a need for improved communication.

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New Program Model Allows Pharmacies to be a Primary Care Option for Rural Communities

Alana Hippensteele, Managing Editor

Pharmacy Times interviewed Joe Duarte, co-founder and president of ContinuumMD, on pharmacies that are providing virtual and in-person primary care options for rural communities.

Alana Hippensteele: Hi, I'm Alana Hippensteele with *Pharmacy Times*. Joining me is Joe Duarte, co-founder and president of ContinuumMD, who is here to discuss how pharmacies are starting to provide primary care options for rural communities.

Joe, how did you get started in this field, and what was your background before getting involved in pharmacy?

Joe Duarte: Prior to being in the health space, I was a professional fighter, I was a former world champion. One of the things is that I've been passionate about is, growing up without insurance, I wanted to help create accessibility to it—make it accessible, and affordable for people—and figuring out what those challenges are and be able to use the technological tools that we have created to make that happen by partnering with pharmacies and local providers while using our national doctor network, as well.

Alana Hippensteele: When did going to a pharmacy as a primary care option start to occur for patients in rural communities?

Joe Duarte: I think, if you look back in terms of the history of it, Minute Clinic started in 2000—I believe it was 2000—in 2000, like 22 years ago, and that might be the oldest working model. Now, they have over 1100 locations in 33 states, and I think that it kind of shows that that type of care is viable, it's needed, and it's efficient. So, you see this with CVS's clinics as well. You're starting to see this more in terms of those big pharmacies offering these services; however, they're far less personable. This is where I really kind of leaned towards looking at the independent pharmacies, the community pharmacies, as a strategic partner to create these health care hubs and align myself with.

Alana Hippensteele: When the pharmacy connects patients with a licensed medical provider in a telemedicine setting, are the providers nurse practitioners, pharmacists, physicians or another type of health care professional? And this is a part of that model that you were talking about for

Minute Clinic, and then ContinuumMD.

Joe Duarte: So, based on the services that are needed, that will determine the type of provider that will be appointed to that. That's all built into our software. It maps to providers that are licensed for that particular use case. We use everything from MDs, DOs, NPs, RNs, PAs. There are various providers that we use to be based on the need of the patient.

Alana Hippensteele: Is it possible for patients across the country to use pharmacies as a primary care option, or are there only certain states where this is currently possible?

Joe Duarte: Beautiful thing about technology is it's made this possible in every state. With our platform that we have, all states are viable for providing primary health care. It directly connects. The health care hub is connected to primary care providers, and they can offer our services right out of the pharmacy. It's beautiful in the sense of it ties into local providers, as well as a backup national doctor network that we have, to make sure that those scripts are turned around in a timely manner, patients are not lapsing in their medications, and making sure that they get the care they need, when they need it and where they need it. We realize that time is—nowadays, it's really difficult for a person to take time out to go to a doctor, to sit in a waiting room, to be seen by the doctor for 5 to 10 minutes just to renew a script or get a new one. This pathway really allows that pharmacy to be the heart of community health care.

Alana Hippensteele: Would this telemedicine service facilitated by the pharmacy only be possible for certain disease states? I would imagine the same level of patient care might be trickier with specialty pharmacy, for example, which would be dealing with areas like oncology and HIV. Is that an area where the pharmacy might not be able to be the primary site coordinating care for patients?

Joe Duarte: Yes, certain disease states are best suited, obviously, for in-person visit. However, many common conditions are treated via telemedicine. One of the things that you'll notice is, with the advancement and innovation of technology, we're able to not only treat more disease states but manage them as well. Remote patient monitoring has really become a holistic approach and a way for providers to stay ahead of the problems that are causing patients to avoid emergency room visits and urgent care visits and things of that nature.

And also, I think 1 of the things that we're seeing is that when you make something accessible, patients are able to improve their adherence rates. We're seeing this in every place that we work in. I'm a perfect, perfect example. I'm a

perfect example. I moved to Texas last August. My primary care appointment was canceled 2 weeks ago, and the next available appointment is July 19. Fortunately for me, having a company like this, I put myself on the schedule, and I get my script renewed that I need, and it makes it easier and closes that gap. That's essentially what we're doing. We want to offer to pharmacies in every state so that they can give their patients the best care.

Alana Hippensteele: What do you see as the future of the pharmacy's role in rural communities with perhaps limited access to health care services?

Joe Duarte: A key asset to closing that gap is obviously working collaboratively for improving patient care. There's a lot of gaps when it comes to script renewals. Maybe patients are in between doctors, maybe they misjudged and are out of a medication that they need. But all of these things come back to making things very accessible, especially in rural communities where you might have 88 providers for 10,000 people, a population of 10,000 or more. Accessibility is always a challenge. And I think as providers, they want to serve the community the best, they want to improve as much of the health care as they possibly can, but they are bottlenecked because of the process that a brick-and-mortar facility operates in. The nice part about the Continuum Healthcare Hub is that you kind of have a hybrid model where a patient can go into the facility to see the physician, and on that refills, refill it through the platform. That's a beautiful thing, because it alleviates visits at a doctor's office to allow more patients, increase that doctor's ability to see more patients or a new patient, and that current patient is able to just get the refills, or any new scripts done via telemedicine. It's a beautiful thing in a sense where a doctor can both be a telehealth provider if he's a local physician, but also at the same time see patients in his office and alleviate some gaps. There's a lot of opportunity that I see just in the community that I'm in and then talking with the pharmacies that I've been speaking with in the different networks.

Alana Hippensteele: Any closing thoughts?

Joe Duarte: I grew up on an island and it's difficult for people to not only take time off and get the care they need, but I think one of the things that we don't think about a lot of times is how this impacts everything from the type of quality of life that we're getting. I think that's my closing thoughts: how can we improve quality of life and get people what they need when they need it. Like I said, our goal is to restore the independent pharmacies, the community pharmacies as the cornerstone of community health care. That's the goal, our mission of our company.

Study Finds Fiber Supplements Convey Similar Benefits to Gut Health

Erin Hunter, Assistant Editor

In nearly all areas of health care, patients in Appalachia face heightened challenges and health disparities, according to a report from the Appalachian Regional Commission (ARC).

Although there are a variety of gut health-promoting fiber supplements on the market, a recent study found that regardless of the type of fiber supplement, anyone can benefit from them, though people who eat a low-fiber diet will especially benefit, according to researchers from Duke University.

“The people who responded the best had been eating the least fiber to start with,” study lead Lawrence David, associate professor of molecular genetics and microbiology at Duke University, said in a press release.

Fermentable fiber (undigestible dietary carbohydrates that some gut bacteria can digest) is an essential nutrient for a healthy body. When bugs in the gut microbiome are fed a diet high in fermentable fiber, they produced short-chain fatty acids, which protect against gut-related diseases, colorectal cancers, and obesity.

Specifically, gut microbes produce more of the short-chain fatty acid butyrate, which can improve the gut’s defenses against pathogens, lower inflammation, and create a healthier intestinal gut lining. Fiber supplements can increase short-chain fatty acid production, including acids such as butyrate.

“We’ve evolved to depend on nutrients that our microbiomes produce for us,” Zack Holmes, a co-author of two new papers on fiber, said in a press release. “But with recent shifts in diet away from fiber-rich foods, we’ve stopped feeding our microbes what they need.”

American adults only consume 20%-40% of their recommended daily fiber intake. A low-fiber diet could be the cause behind issues such as obesity, cardiovascular disease, digestive disorders, and colon cancer, according to the study authors.

David and his team noticed that many fiber supplements

appeared to be interchangeable. Since every individual is different, the researchers wanted to learn whether personalizing supplements could produce better short-chain fatty acid production.

The investigators tested 3 popular fermentable fiber supplements on 28 participants—inulin, dextrin (Benefiber), and galactooligosaccharides (Bimuno). Participants randomly took 1 of the supplements for a week, then took a week off the supplement so their microbiome could return to baseline, and then took a new type of supplement for another week. This process was repeated for each of the 3 supplements.

Researchers found that the type of supplement did not matter for participants who already ate lots of fiber at the time of the study. They also displayed the least amount of change in their microbiome because they already had optimal gut microbe diversity.

Participants on an initially low-fiber diet also did not notice a difference between the supplement type and efficacy. However, these participants experience a higher production of healthful butyrate compared to the participants on an initially high-fiber diet, according to the study authors.

David’s lab, supported by the US Office of Naval Research, did a second study that explored fiber doses. According to this study, gut microbes positively changed their gene expression for digesting food in just 1 day, showing that any fiber, and more of it, is good.

The study authors said that it’s not necessary to supplement with fiber, as foods rich in fiber are a healthy addition to any diet.

“Folks who were already eating a lot of fiber, which comes from plants like beans, leafy greens, and citrus, already had very healthy microbiomes,” Holmes said in the press release.

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