Friday, April 2, 2021

Louisiana Independent Pharmacies Association

What's New and What to Watch

LIPA Newsletter:
Bringing you the latest news and information concerning independent pharmacies and the profession at-large….

Members,

Upcoming Louisiana Legislative Session

We're now 10 days away from the state of the 2021 Regular Legislative Session. It convenes at Noon on Monday, April 12th and must adjourn no later than 6:00 p.m. on Thursday, June 10th. The 2021 Session is a "Fiscal Session" that limits legislators to 5 "non-fiscal" bills that must be filed by 5:00 p.m. today. Any bill that is not a local bill or does not relate to the state budget, taxes, or fees are considered "non-fiscal."

The committees responsible for the state budget, House Appropriations and Senate Finance, have scheduled several hearings next week in preparation for the beginning of the legislative session. Regular committees will begin meeting on Tuesday, April 13th.

As of today Noon today, 526 House bills and 188 Senate bills have been filed. Several of these bills, including one that will allow the Department of Insurance to license Pharmacy Services Administrative Organizations (PSAOs), address PBM and other pharmacy regulations. Once we reach the 5:00 p.m. deadline, we'll review each bill filed and identify the bills that may impact LIPA or our members. We will share a full update on that list and the status of those bills in the Newsletter next week.

Moderna Extends Window to Use Vial of COVID Vaccine from 6 Hours to 12 Hours

Politico reported today to the FDA has approved several changes requested by Moderna. We know those of you who are struggling to use all of the vaccine in a vial will be happy to learn that the window for doing so has increased from six hours to 12 hours! Also, the FDA is also allowing Moderna's vaccine to be kept at room temperature **for 24 hours**, up from 12 hours, according to the company. The headline of the story was that Moderna has received the "green light" to boost the number of doses per vial from 10 to 15 (which exacerbates the amount of vaccine for which immunizers may not be able to find any takers within the new twelve- hour window). Moderna indicated they will begin shipping the new 15-dose vials "in the coming weeks."

Save the Date! DEA Red Flag CPE Training on Sunday April 18th

LIPA is offering a CPE activity on Sunday, April 18th from 3 PM to 4 PM that will focus on controlled substance "red flags" and suggestions for a pharmacy's policies and practices for dispensing controlled substances to comply with the DEA's "corresponding responsibility" expectations. This is a topic that many of you have requested we address through a CPE Activity as goalposts are continually moved.

We are pleased that Karl Koch, a Baton Rouge attorney who has represented multiple Louisiana independent pharmacies in interactions with the DEA—and has insight into their current thinking—will serve as our faculty for this Activity. Look for an e-mail from LIPA early next week with a link to register for the training. Please freely share the link for opioid-related training with other pharmacists and pharmacy technicians who work at your pharmacy—either part-time or full-time. There is no registration fee for LIPA member pharmacy employees. We will include a link in the April 9th and April 16th LIPA newsletters as well.

Independent Pharmacies to be Added to Federal Retail Pharmacy Partnership in Louisiana

It was announced on Monday that the number of pharmacies getting COVID vaccine through the Federal Retail Pharmacy Partnership will increase from 17,000 to more than 40,000 over the coming weeks. A number of our LIPA member pharmacies have signed up as providers in one of the federal partner networks through either CPESN-USA, Good Neighbor/Elevate PSAO (Amerisource Bergen), Health Mart Pharmacies, LeaderNet and The Medicine Shoppe PSAOs (Cardinal), Managed Health Care Associates or GeriMed and will be able to get vaccine through the federal partnership (as well as through the state).

While vaccine received through the federal partnership is **not** received and tracked in LINKS inventory, vaccines administered must be entered in LINKS within the timeframe included in the CDC Provider Agreement terms and conditions, which is 24 hours from administering the dose.

Prognosticating COVID Vaccine Changes at the State Level

We can see that a COVID vaccine "glut" is fast approaching, which will result in multiple changes in the state's procedures and policies. Our understanding is that the state was able to fulfill almost all—if not all—vaccine requests for the weeks of April 5 and 12. As vaccine becomes widely available with scarcity no longer an issue, we can expect to see-- within the next several weeks --a shift to providers ordering vaccine directly through LINKS rather than the current online Vaccine Request Form ordering system with Regional Medical Directors making recommendations. Vaccine providers will order the vaccine they need, when they need it through LINKS—whether it is first or second doses.

We also expect to see changes in Louisiana's "use vaccine in seven days" guidance as COVID vaccine is "normalized," as well as recognition that **not all doses of vaccine in a vial can realistically be administered within six hours of puncturing the vial and that's OK and to be expected.** LIPA has asked the Immunization Program to clarify which is more important from the state's perspective: getting a dose of COVID vaccine to one person or avoiding vaccine loss.

Pharmacists Training to Become Certified Immunizer Offered During April

The Louisiana Pharmacists Association is offering the ACPE-accredited training required in order for pharmacists to qualify to order and administer vaccines—either by the Louisiana Board of Pharmacy or the PREP Act—later this month. The course—which will be taught by ULM College of Pharmacy faculty members—consists of 12 hours of self-study and 8 hours of live (via webinar) study. The eight hours of live study will be held on Tuesday, April 27th and Wednesday, 28th from 1PM to 5 PM each day. More information can be found here. **The deadline to register is April 19th.**

An ACPE-accredited vaccine training for pharmacy technicians is also available, but without a "live" component so your pharmacy technicians can register for and take the training at any time. At this point, the public health emergency is expected to end no earlier than December 2021–and is likely to extend beyond that date. The PREP Act gives authority (that supersedes any state regulations which are more restrictive) for pharmacy technicians to administer vaccines and the act is in effect for the duration of declaration of emergency. The required CPR training necessary for pharmacy technicians to qualify can be an online CPR training course and does not have to be "live."

Reducing Vaccine Hesitancy—How Fast is Too Fast?

A news story in Sunday's **The Advocate** titled "In rural Louisiana officials look for answers to improve lagging vaccination rates" highlighted the challenges we will face in the months ahead in achieving COVID vaccine take-up at a rate sufficient to achieve "herd immunity." The estimates are 70% are higher in every community—not just the state average. People who was highly motivated to get the COVID vaccine have been able to get it in most areas of Louisiana.

Pharmacists are highly trusted health professionals, and you can expect that patients who aren't sure about getting the vaccine will have questions for you. One of the most frequent concerns expressed is the **speed** with which the vaccine was developed and assumption that shortcuts must have been taken. After-all, these vaccines were developed in less than a year when all other vaccines have taken much longer! The answer is money/resources (price was no object), existing technology, public support (the vaccines trials which can take years to get participants filled up rapidly) and government backing to cut through the usual government "red tape." Making something highest priority pays dividends. Here's one summary in Healthline that helps to explain the speed with which the vaccines were developed.

This week, the results of two polls looking at vaccine attitudes in Louisiana were released: one by LSU's Public Policy Research Lab and the other by the Louisiana Public Health Institute. In comments on the LSU poll—which found that more 40% of Republican surveyed stated they do not intend to get the vaccine, Congressman Steve Scalise is quoted as saying this about the speed with which the vaccines were developed, *"Some people might be under the false impression that it was rushed," Scalise said. "There was no rushing or cutting corners. We probably tested this vaccine, multiple vaccines, on more people than we've seen before. Tens of thousands of Americans signed up to be tested just for the vaccine."*

Independent Pharmacy Onsite Vaccines (IPOV)

The LIPA Board recently passed a resolution authorizing LIPA to enter into a social services contract with the state and LDH to secure the ability for LIPA and its member pharmacies to administer vaccine to nursing home staff and residents. The contract between LIPA and LDH has been signed and is effective April 1, 2021 through January 31, 2022. LIPA is partnering with the state in the Independent Pharmacy Onsite Vaccines (IPOV) initiate to facilitate ongoing vaccines of residents and employees of nursing homes and other congregate settings by Louisiana independent pharmacies.

We know some of you are already in communication with nursing homes with whom you are partnering and already have visits scheduled to administer vaccines onsite. LIPA is developing resources you can use such as Consent Forms and protocols for onsite vaccine events. The state (Dr. Kanter) has indicated they have no vaccine preference for administration at nursing homes. It can be Moderna, Pfizer or Janssen (J&J). LDH is hoping to see further improvement in the immunization rates for both residents and employees at nursing homes and other congregate settings.

If you have feedback, questions or suggestions email vaccines@lipa.org or call Ruth Kennedy who is LIPA's designated IPOV Project Manager at 225-241-1437.

Pfizer Vaccine for 12 to 15 Year Old's

Pfizer announced this week that it will be seeking approval from the FDA to lower the minimum age for Pfizer vaccine from 16 to 12 as their clinical trials have shown that the vaccine is safe and effective for adolescents ages 12 –15 and provides "a robust immune response." While children and adolescents have had less adverse effects from COVID, inoculating them is considered a critical step in conquering the virus. According to this Reuters story, "*young people have been less likely to suffer severe disease and more likely to have asymptomatic infection, allowing them to unwittingly transmit COVID-19 to others."* They are actually the most apt to spread the virus. Pfizer's CEO Albert Bourla hopes that the vaccine will be approved to administer to ages 12 and up before school begins in the fall.

As things go forward, one thing we need to be thinking about is availability of Pfizer vaccine through additional distributors (*e.g.,* LWD) for quantities of less than 1170 doses. LWD is now enrolled in LINKS as a COVID vaccine redistribution site and can order and receive vaccine. The fact that the Pfizer vaccine can be maintained in a regular freezer for 14 days-- and then an additional 5 days in the refrigerator-- makes it a much more viable option than when the 120-hour window to "use it or lose it" was applicable once the vaccine was removed from ultra-cold storage.

A Different Kind of Red Flag for Pharmacies—New Medicare "Star Ratings" Challenges

LIPA subscribes to and reviews multiple e-mail industry newsletters with an eye on any **changes that could impact our pharmacies**. **HMA Weekly Roundup** from Health Management Associates, a firm that provides healthcare consulting services primarily to public payers (Medicare, Medicaid, CHIP) is one that we pay close attention to. The latest edition caught our eye as the lead story is titled "HMA Analyses of Medicare Advantage Star Rating Challenges." The MA Star Rating system is behind a lot of the DIR fees that have continued to grow over the last several years. HMA believes that "three major items have the potential to disrupt the Medicare Stars performance landscape" and one of those is "Increased importance of pharmacy related measures". As HMA explains it,

CMS makes changes from time to time in the measures that make up the Star Rating program. For example, the Plan All-Cause Readmissions (PCR) measure was removed from rating calculations for two years and it will come back in the 2022 measurement year for the 2024 Star Rating. In the future, CMS will temporarily remove two Health Outcomes Survey (HOS) measures due to measurement changes. This is important to note because as measures shift, the weighting of the remaining measures will change, which can have a significant impact on whether plans can improve or maintain their Star Rating. As a result of the most recent measure shifts, pharmacy measures will now have a higher impact on plans' summary scores. Additionally, HMA is seeing pharmacy influenced measures become even more important in the Part C domain such as statin use.

HMA advises *"If the Medicare Advantage plan outsources pharmacy services to a PBM, now is the time to discuss quality improvement goals and be more intentional about the pharmacy-related measures. Plans that have consistently demonstrated high performance generally have a data-driven approach to strategically address and resolve barriers to care that lead to poor measure performance, including social determinants of health (SDOH) and access to providers and pharmacies, in order to realize year over year CAHPS performance improvement."*

It remains to be seen what the end result will be for our pharmacies. Will DIR fees become even more onerous? On the flip side, might access to community pharmacies—and additional services they can provide (and for which the MA plan reimbursed the pharmacy—be the key to improving increasingly important patient satisfaction rates? It is something we all need to be closely watching.

Cigna/ExpressScripts Offers $500 "Carrot" to Switch to Another Drug

A story recently posted on the American Journal of Managed Care (AJMC) website titled "Cigna Dangles $500 to Persuade Patients to Switch Psoriasis Drug" highlights the practice of "non-medical switching" which according to a physician and medical school professor, Mark G. Lobwohl "is a very hot topic right now." Dr. Lobwohl who is on the medical advisory board of the National Psoriasis Foundation (NPF) stated "a standard thing in medicine is, if you are doing very well on a treatment, why would you stop it?" In a statement to *AJMC®*, Cigna, which owns ExpressScripts, said patients were "offered several alternative medications that are equally effective and more affordable."

With the rise of specialty drugs, usually biologics, non-medical switching has become more of an issue. Specialty drugs make up a little more than 2% of US prescriptions, but account for half of drug spending, and that share is expected to rise. Dermatology and rheumatology are 2 of the specialties most often affected. "They pick on dermatology for sure, because they figure no one's going to die," said Lebwohl.

On the Lighter Side: Vaccine Reveal Party

Finally, we had to smile at this cartoon posted on **The New Yorker**'s Instagram page this week.

In the NEWS:

It is time to address the bully in Florida's prescription drug program

Sun-Sentinel 03/31/2021

Florida is home to over 1,400 unique independent pharmacies, many that provide exceptional care and lead to lifelong relationships between patients and their pharmacy. As the relationship between providers, insurance companies and drug manufacturers has become more complex, the pharmacy benefit manager role was created to help manage claims. As pharmacy claims increased and became more complicated, the power of pharmacy benefit managers (PBMs) increased.

PBMs, however, have little accountability, which allows them to engage in anti-competitive practices. They have developed formulary lists driven by rebates from manufacturers; encouraged vertical integration of the pharmacy market, thereby reducing competition and dictating costs; and reduced access to care by squeezing independent pharmacies out of business. These numerous, anti-competitive practices are pushing pharmacies that have served communities for generations to the curb.

To combat these practices and ensure access to care, I have filed House Bill 1155 in the Florida Legislature, which prohibits the use of transaction fees in Florida's Medicaid Managed Care program. Over the past year, the Florida Agency for Health Care Administration tasked a third-party to analyze how Florida appropriates money in our Pharmacy Medicaid Managed Care program. It found that in Florida, the state pays its pharmacy providers (those who dispense the drugs) $58 million and our PBMs (the middleman) $113 million. Of the $113 million, nearly $6 million came from "transaction fees," which PBMs can charge for any reason they deem necessary. These fees range from communication fees between the pharmacist and the PBM, to the submission of a claim, denial of a claim, retroactive claw-backs and more.

Guest opinion: Fix prescription drug access, take on prescription drug middlemen

News-Press 03/31/2021

Nothing to see here. During a state meeting in Tallahassee, when the Agency for Health Care Administration (AHCA) met with state senators, that seemed to be their message. AHCA is the agency that oversees Florida's multi-billion Medicaid Program. Yet there is ample evidence that the big Pharmacy Benefit Managers (PBMs) that run the Medicaid Pharmacy Program are making profits of millions of dollars. These companies are not Florida-based and are a drain on taxpayer funds.

Every single state leader and resident should be rattled. Here is why.

Access to prescription drugs for vulnerable and underserved communities is shrinking. According to the National Community Pharmacist Association (NCPA) in just four years 700 independent pharmacies shut their doors across the United States. These closures effectively block access to affordable prescription drugs in poor and inner-city locations because independent pharmacies often serve higher numbers of Medicare and Medicaid patients. One of the major reasons there is a severe access issue and affordable prescription drugs is because of PBMs. These prescription drug middlemen have incredibly broad power – power that is wielded in secret. They pick which drugs are covered by your insurance company, often more expensive drugs that are more profitable for them; decide which pharmacies you can go to; and even determine how much a pharmacy gets reimbursed. And because big PBMs own and operate their own pharmacies, the power they exert in the pharmacy marketplace directly impacts the bottom lines of the companies they own, as well as their competitors. When you begin to unpack exactly how PBMs work today, the reality of their unregulated power comes into focus.

$38M health education center lauded by Louisiana leaders as place 'to train future heroes'

NOLA.com 03/31/2021

At a groundbreaking Wednesday for the Ochsner Center for Nursing and Allied Health at Delgado Community College, a new building and program slated to open in 2023, Gov. John Bel Edwards urged attendees to recall last spring, when the state had the steepest growth rate of COVID-19 cases being measured anywhere.

It was health care heroes at hospitals and clinics, he said, who rose to the challenge.

But though the state has beat back three waves of the virus, Edwards cited tremendous work in improving health outcomes for all residents, as the state remains at or near the bottom of United Health Foundation's "America's Health Rankings."

One of the ways up, he said, is through public and private partnerships like Ochsner and Delgado's, which together are creating the $38.6 million center.