Friday, May 22, 2020

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….

In this week's issue:

- Legislative update
- State budget outlook
- Litigation regarding the $.10 provider fee and Express Scripts
- Updated guidance on enrolling as a Medicare Part B provider
- Immunity for pharmacists under the PREP Act
- This year's LPA convention to be "virtual"

Dates to Know

- **May 26th-(4 PM)**—Executive Committee of the Board of Pharmacy will meet via videoconference
- **May 27th-(9 AM)**—Board of Pharmacy will hold a regular meeting via videoconference
- **June 1st (6 PM)**—Legislature adjourns

Members,

This week was an especially eventful one for our LIPA Members and team as we navigated the social distancing requirements at the legislature. We successfully fought back efforts by PCMA (working on behalf of the PBMs they represent) to "nibble around the edges" and undermine the laws enacted just last year for increased oversight of PMBs operating in Louisiana. A contingent of our members attended the House Health & Welfare and Insurance Committee hearings on Tuesday to voice their opposition to HB 608, 609, 297, and 387. Compelling and convincing testimony before the committee was provided by Rob Hollier, Errol Duplantis, Diann Poret, and Randal Johnson on PBM practices such as patient steering and sharing confidential patient data with third parties and opposing even the form that would be used by the Board of Pharmacy for licensing.

The Committee members also received nearly 200 electronic cards in opposition against each bill from our pharmacists who were not able to get away from providing vital services to their patient and make it to Baton Rouge. Your efforts to reach out and educate legislators made a **huge** difference as independent pharmacies had overwhelming support (8-3) from our Insurance Committee members on HB 297, and led to the author to voluntarily defer the bills in Health and Welfare Committee.

Our members, in-person and electronically, were able to communicate to their Representatives the value that our independent pharmacists bring to their communities. We have been able to mitigate disruptive acts that PBM's continue to pursue by continuously working together each year while continuing to provide superior healthcare. The PBM representatives even made a note of this while debating HB 609.

Representative Gabe Firment posed a question to PCMA and the PBMs during testimony, asking: "Apparently data has been misappropriated in the past, is that a valid concern"? The representative from PCMA and the PBMs responded: "This law [Act 124] slammed the door on that. This law that is about to go into effect slams the door hard on any inkling of doing that and goes into effect July 1st. We noticed this when we were doing a review of the law and we needed to be able to make these tweaks to be able to allow us to continue to do the things we are doing right now."

We would like to acknowledge some our legislators who were especially attentive to our pharmacists during the committee meeting including Committee Chairman Chad Brown from Plaquemine and Representatives Sherman Mack from Albany, Danny McCormick from Oil City, Larry Frieman from Abita Springs, Kathy Edmonston from Gonzales, Gabe Firment from Pollock, and Mike Huval from Breaux Bridge They showed interest in learning from the pharmacists in the room about the "front lines" impact of PBM tactics on them and their businesses as healthcare providers. They acknowledged our member pharmacists' role in providing patients with valuable healthcare solutions in their respective districts. The backbone of the healthcare provided in our communities

Continued on next page

comes from our independent community pharmacists, especially within the districts where communities **only** have independent pharmacies available to their patients. We appreciate the attention, support, and questions they provided during the Committee meetings, and we look forward to working with our legislators in the future to enact legislation to further level the playing field for our independent pharmacies.

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Pictured(left to right): Don Caffery, Randal Johnson, Robert Rock, Greg Poret, David Darce, Rob Hollier, Rebecca Reed Cormier, Diann Poret, Maddisyn Wilkinson, Bernard Lebas, Chris LaGrange, Errol Duplantis; Independent pharmacists, students, and LIPA staff that attended the House Insurance Committee meeting in which we successfully prevented PBM's from passing bills to reverse last years' gains. (Social distancing guidelines and masks were worn through the entirety of the process, however, we removed our mask momentarily while holding our breath in order to take this picture.)

We will continue to closely monitor pharmacy-related legislation in other states and explore areas in existing law that can be further strengthened. Much of this depends on the outcome of *Rutledge v PCMA* pending before the U.S. Supreme Court and the ruling on whether ERISA preempts state regulation efforts which is expected to be heard in October 2020.

Good news --for a change-- on the state budget Getting a new budget in place is the top order of business for the final days of the regular legislative session that must end no later than 6 PM on Monday, June 1st. Yesterday, the House Appropriations Committee advanced the Governor's proposed budget for the coming fiscal year with few changes .Thanks to a massive infusion of federal COVID dollars, draconian budget cuts that had initially been feared will **not** be necessary. While the budget includes a $40.6 M cut in LDH's budget for SFY 21, Medicaid is not expected to be significantly adversely impacted .The Appropriations

Committee did add language blocking LDH from implementing a proposed new hospital reimbursement model for Medicaid without approval of the Joint Legislative Committee on the budget because of disagreement related to the knowledge of the details of the approach.

In anticipation of a special session News this afternoon is that we can anticipate a Special Session of the legislature which could begin immediately following Monday night, June 1st, at 6:01 PM, following adjournment of the regular legislative session. As we recently discussed , a majority of each house of the legislature or the governor can call the house into a special session. The legislature calling themselves in is an unusual occurrence. The special session would be required to end no later than June 30 at 6 PM. Our information is that the petition for the special session has already gained enough signatures in both the Senate and the House. Only items included in the official call can be considered, which we expect to include major budget bills, including the capital outlay plan. Other matters for legislation that are included in the petition are Medicaid funding, hospital reimbursement, tax credits, Medicaid coverage for home health services, expansion of broadband coverage, and a number of other matters arising from the pandemic that will help with economic recovery. Each topic will need to be specified and included in the "call" as only such areas can be subject to legislation during a special session.

***LIPA vs Express Scripts, Inc* filed yesterday in Lake Charles** in response to Express Scripts' (ESI's) May 12, 2020 communication to our Louisiana pharmacies stating that Medicare preempted the ten-cent provider fee, the LIPA Board directed and authorized the filing of a federal lawsuit that is attached.

LIPA, as your association is asking the federal district court to rule whether or not Medicare preempts (forbids the enforcement of) the ten-cent provider fee in Louisiana law .You might remember several years ago that the Louisiana Department of Insurance (LDI) and the Louisiana Department of Health (LDH) initially took contrary views about the preemption issue .In that situation, LIPA filed a declaratory judgment action, asking the court to determine who was correct .Ultimately, LDI and LDH entered into a consent agreement in which they agreed that the $0.10 provider fee was due on **all** prescriptions, regardless of payor source.

ESI refuses to acknowledge that and continues to not reimburse our members the $0.10 provider fee on Medicare prescriptions .The federal lawsuit that LIPA filed this week asks the court to determine whether or not federal law prevents the enforcement of those statutes. Our position is simple – either the $0.10 is required on **all** prescriptions, and PBMs must reimburse that amount, or it is not due and our member pharmacies should not remit that amount to the LDH. The case is assigned to Judge James Cain in the Lake Charles Division of the Western District of Louisiana. We expect that ESI, after it is served, will challenge LIPA's ability to file the lawsuit on its members' behalf. We will keep you apprised of the progress of the lawsuit.

We are hearing of calls being made to pharmacies. Please notify the LIPA Team if you are receiving calls or other contact from Express Scripts advising your pharmacy that ESI has not accurately paid parish taxes.

Class action lawsuit filed against Optum Rx by independent pharmacies While our primary attention is on ESI and their continuing violation of the $0.10 provider fee reimbursement, we are also watching the recent class action lawsuit filed in federal court in Pennsylvania--by 50+ independent pharmacies against OptumRx for failure to comply with state pharmacy claims reimbursement law. The lawsuit alleges OptumRx 1) acted unlawfully by ignoring state legal requirements, paying local pharmacies substantially less than it paid large chain retail pharmacies like CVS or Walgreens (and far below what it paid its own mail order pharmacy for the same prescriptions) and 2) that the PBM often knowingly reimbursed local pharmacies below wholesale cost to stock necessary generic prescription drugs.

CMS' "curveball" on what pharmacies need to do to bill Medicare for point-of-care testing It has been practically whiplash-inducing to keep up with CMS guidance on what pharmacies need to do to bill Medicare for COVID-19 and other point-of-care testing. CMS now says that pharmacies will need to be enrolled in Medicare Part B as an **Independent Clinical Laboratory.**

While there is a new process by which pharmacies who are already enrolled in Medicare Part B with Service Type Pharmacy or Mass Immunizer (**and** who have their CLIA Certificate of Waiver) can **temporarily** enroll by phone as an Independent Clinical Laboratory, we strongly recommend that you **not** do so. **Temporary enrollment will terminate 30 days after the public health emergency ends and the Section 1135 waiver is lifted.** Right now, enrollment in Medicare Part B as a Pharmacy and/or Independent Clinical Laboratory is both **fast** (7 days or less) and **free** (the usual $596 fee is being waived) and is **good for five years**. To enroll as both, you will need to submit two separate applications.

Remember that Medicare has two divisions: **DME** (that also includes prescription drugs) and **Clinica**l (that includes immunizations and point of care testing). It is a great time to enroll as both a Medicare Part B **Pharmacy** and **Independent Clinical Laboratory** Service Type, even if you are undecided about point-of-care testing.

LIPA staff watched and we highly recommend the updated 14-minute video on Medicare enrollment and testing from our federal partner. They have clarified directly with CMS that the correct Service type to indicate on the CMS 855 Medicare enrollment application is Independent Clinical Laboratory (and **not** Independent Diagnostic Testing Facility that is directly below it on the form). The video contains helpful information about the functionality that your billing system needs when you have two Medicare PTAN (Provider Transaction Access Numbers).

HHS Advisory opinion: federal law pre-empts any state limitations on COVID-19 testing HHS' General Counsel issued an advisory opinion on May 19th regarding any state licensing laws that restrict the ability of pharmacists to order and administer COVID-19 diagnostic tests where HHS has expressly authorized pharmacists, under the PREP Act, to do so. The conclusion was that the PREP Act, in conjunction with the Secretary's March 10, 2020 declaration, preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the Food and Drug Administration (FDA) has authorized. We are sharing this Advisory Opinion with the Board of Pharmacy as well as LDH.

Immunity for pharmacists under the PREP Act With all of the focus at both the federal and state levels on protecting businesses from COVID-19- related liability, we want to point out that the April 8" guidance from HHS on licensed pharmacists and COVID testing expressly **grants immunity** to pharmacists who perform COVID-19 testing. ***Pharmacists qualify as "covered persons" under the PREP Act and may receive immunity with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized COVID-19 tests.***

Updates on the Medicaid front Another week has passed and we are yet to see any payments made by HHS to targeted Medicaid providers from Cares Act Provider Relief funding. States have sent data files with Medicaid payment information for calendar years 2018 and 2019 (for all Medicaid provider types) to CMS. CMS is validating the data and forwarding the files to HRSA who will actually allocate the funding although no details on how this will be done have been released. It is understandable that LDH wants to see whether Louisiana pharmacies are included in these payments and at what level, before pursuing other options such as a temporary increase in the professional dispensing fee that could be retroactive to March 1st.
LIPA has requested information in the possession of LDH that would show whether a Medicaid enrolled pharmacy—including those out of state—are remitting the 10-cent provider fee as required by law. With the push for mail-order this is now even more important since the provider fee is used as state match for the Medicaid pharmacy program. The penalty for failure to pay the fee is revocation of the pharmacy's Louisiana license.

This year's LPA's annual convention will be a "virtual" event. LPA has announced that after carefully weighing the emerging facts as well as their duties to LPA, their members, meeting attendees, sponsors and exhibitors, and the local communities they serve, LPA made the difficult, but necessary, decision to cancel their live Annual Convention and Trade Show which was to be held in Alexandria, LA in July. They indicated they are "embracing the opportunity" to REIMAGINE a virtual event that still provides members with an opportunity to meet annual CPE requirements, conduct annual business, celebrate members, and to of course continue to foster the relationship their members have with LIPA as a supporting. partner. **LIPA will serve as host of the Annual Virtual Event on Saturday, July 25, 2020** so mark your calendars for that date!

PHARMACY FACTS

Program Updates from Louisiana Medicaid

May 18, 2020 *Revised 5/18/2020*

Brand Over Generic List

The Louisiana Department of Health (LDH) scheduled a Pharmaceutical & Therapeutics (P&T) meeting in April 2020. Due to the COVID-19 crisis, the P&T meeting was cancelled. The LDH pharmacy staff reviewed the potential financial and clinical impact provided by Magellan to determine which recommendations are in the best interest of the medical assistance program for brand over generic list. There are times when brand products are preferred over generics because it is beneficial for the state in collecting of rebates.

NOTE: Preferred brands removed from list are on page two for inventory adjustment purposes.

Brand Over Generic List for Spring 2020 Effective July 1, 2020		
	Preferred	**Require Prior Authorization / Non-Preferred**
1	REVATIO® SUSPENSION (ORAL)*	SILDENAFIL SUSPENSION
2	FOCALIN XR® (ORAL)	
3	COPAXONE® 20 MG/ML (SUBCUTANE.)	
4	NATROBA® (TOPICAL)	
5	TRANSDERM-SCOP® (TRANSDERM)*	SCOPOLAMINE TRANSDERMAL
6	TOBRADEX® SUSPENSION (OPHTHALMIC)	
7	PROCENTRA® (ORAL)	
8	CATAPRES-TTS® (TRANSDERM)	
9	ALPHAGAN P® 0.15% (OPHTHALMIC)	
10	HUMALOG® VIAL/PEN (SUBCUTANE.)*	AUTHORIZED GENERIC OF INSULIN LISPRO VIAL/PEN AND ADMELOG® VIAL/SOLOSTAR® PEN
11	NOVOLOG® MIX VIAL/ PEN (SUBCUTANE.)*	AUTHORIZED GENERIC OF INSULIN ASPART/INSULIN ASPART PROTAMINE VIAL/PEN
12	NOVOLOG® PEN/VIAL/CARTRIDGE (SUBCUTANE.)*	AUTHORIZED GENERIC OF INSULIN ASPART PEN/VIAL/CARTRIDGE
13	SUBOXONE® FILM (SUBLINGUAL)	

*Yellow highlight denotes a new addition to the brand over generic list

Questions? Feel free to contact us!
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PHARMACY FACTS

Program Updates from Louisiana Medicaid

Brand Over Generic Products Removed for Spring 2020 Effective July 1, 2020		
	Preferred	**Require Prior Authorization / Non-Preferred**
1	OSELTAMIVIR CAPSULE (ORAL)	TAMIFLU® CAPSULE (ORAL)
2	CAPECITABINE	XELODA® (ORAL)
3		RENAGEL® (ORAL) AND SELVELAMER HCL TABLET
4	IMATINIB MESYLATE	GLEEVEC® (ORAL)
5		DERMA-SMOOTHE-FS® (TOPICAL) AND FLUOCINOLONE ACETONIDE 0.01% OIL
6	ALBUTEROL HFA	PROVENTIL HFA®
7	AMBRISENTAN TAB	LETAIRIS®
8	SOLIFENACIN TAB	VESICARE®

Questions? Feel free to contact us!
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IN THE NEWS

Businesses Urge Court To Keep Oklahoma PBM Law On Ice

Law360

The State Chamber of Oklahoma and Hobby Lobby Stores Inc. have urged a federal judge to maintain the status quo and keep Oklahoma from enforcing a state law regulating pharmacy benefit managers until the U.S. Supreme Court provides more clarity on ERISA preemption.

The business organization and Hobby Lobby asked the court Friday to submit an amicus brief in the Pharmaceutical Care Management Association's suit claiming that H.B. 2632, the Patient's Right to Pharmacy Choice Act, was preempted by the Employee Retirement Income Security Act and Medicare Part D.

In the brief, the amici argued that the Oklahoma Insurance Department shouldn't be allowed to begin enforcing the law, as the agency said it intended to, before the Supreme Court reached a decision in Rutledge v. PCMA, a **case involving** an ERISA preemption challenge to an Arkansas law regulating PBMs.

"ERISA plans and those who manage them should not be required to alter the structure, administration, or finances of the plans until Rutledge is decided," the amici said. "A contrary ruling could cause irreparable injuries to the plans and those who manage them."

According to the amici, Oklahoma is trying to directly regulate significant aspects of ERISA plans, including dispute resolution, network providers, and the relationship between pharmacies and benefit plans. And the state law also aims to regulate plan structure, administration and finances, the amici said.

The amici told the court that having a bunch of state laws that regulated PBMs differently would throw "ERISA plans and their managers into a regulatory morass." Already 40 states have enacted laws regulating PBM reimbursement practices, but Oklahoma is the only state moving forward with enforcement before Rutledge was decided, the amici said.

"Soon, this court, Oklahoma, and everyone else will learn from Rutledge whether ERISA preempts state laws like the Oklahoma PRPCA," the amici said. "There is no point in permitting Oklahoma to begin enforcing the PRPCA because it could very well be preempted by ERISA."

The PCMA and Oklahoma Insurance Department had agreed in January to stay the case while the Supreme Court mulled Rutledge, but the agency **asked the court** in April to lift the stay, arguing that the COVID-19 pandemic changed the situation.

Further, the agency announced its intention to withdraw from a November stipulation, in which it agreed not to enforce the law before the resolution of the case while the PCMA in return agreed not to seek a preliminary injunction against the law.

The agency said that it would wait at least 21 days before enforcing the law once the stay was lifted unless the PCMA moved for a preliminary injunction, in which case the agency would wait until the court ruled on that request before starting enforcement.

U.S. District Judge Bernard M. Jones **lifted the stay** at the end of April, and the PCMA filed its request for a preliminary injunction in May.

The organization said that enforcement of the law would cause irreparable harm that outweighed "any interest the defendants might have in enforcing a statute preempted by federal law." Additionally, enforcement would hurt the public by diverting PBMs' resources away from responding to the pandemic, the PCMA said.

A spokesperson for the PCMA told Law360 in a statement Monday that "the law would increase health care costs and threaten access to prescription drugs for Oklahoma's businesses, employees, and Medicare beneficiaries."

Oklahoma Insurance Commissioner Glen Mulready said in a statement Monday that it was "no surprise" that the amici filed the brief.

"We will wait to hear what the courts say in the coming months," Mulready said.

Medicaid Providers Are Last in Line for Federal COVID Funding

Truthout

Casa de Salud, a nonprofit clinic in Albuquerque, New Mexico, provides primary medical care, opioid addiction services and non-Western therapies, including acupuncture and reiki, to a largely low-income population.

And, like so many other health care providers that serve as a safety net, its revenue — and its future — are threatened by the COVID-19 epidemic.

“I’ve been working for the past six weeks to figure out how to keep the doors open,” said the clinic’s executive director, Dr. Anjali Taneja. “We’ve seen probably an 80% drop in patient care, which has completely impacted our bottom line.”

In March, Congress authorized $100 billion for health care providers, both to compensate them for the extra costs associated with caring for patients with COVID-19 and for the revenue that’s not coming in from regular care. They have been required to stop providing most nonemergency services, and many patients are afraid to visit health care facilities.

But more than half that money has been allocated by the Department of Health and Human Services, and the majority of it so far has gone to hospitals, doctors and other facilities that serve Medicare patients. Officials said at the time that was an efficient way to get the money beginning to move to many providers. That, however, leaves out a large swath of the health system infrastructure that serves the low-income Medicaid population and children. Casa de Salud, for example, accepts Medicaid but not Medicare.

State Medicaid directors say that without immediate funding, many of the health facilities that serve Medicaid patients could close permanently. More than a month ago, bipartisan Medicaid chiefs wrote the federal government asking for immediate authority to make “retainer” payments — not

IN THE NEWS

related to specific care for patients — to keep their health providers in business.

"If we wait, core components of the Medicaid delivery system could fail during, or soon after, this pandemic," wrote the National Association of Medicaid Directors.

So far, the Trump administration has not responded, although in early April it said it was "working rapidly on additional targeted distributions" for other providers, including those who predominately serve Medicaid patients.

In an email, the Centers for Medicare & Medicaid Services said officials there will "continue to work with states as they seek to ensure continued access to care for Medicaid beneficiaries through and beyond the public health emergency."

CMS noted that states have several ways of boosting payments for Medicaid providers, but did not directly answer the question about the retainer payments that states are seeking the authority to make. Nor did it say when the funds would start to flow to Medicaid providers who do not also get funding from Medicare.

The delay is frustrating Medicaid advocates.

"This needs to be addressed urgently," said Joan Alker, executive director of Georgetown University's Center for Children and Families in Washington, D.C. "We are concerned about the infrastructure and how quickly it could evaporate."

In the administration's explanation of how it is distributing the relief funds, Medicaid providers are included in a catchall category at the very bottom of the list, under the heading "additional allocations."

"To not see anything substantive coming from the federal level just adds insult to injury," said Todd Goodwin.

He runs the John F. Murphy Homes in Auburn, Maine, which provides residential and day services to hundreds of children and adults with developmental and intellectual disabilities. He said his organization — which has already furloughed almost 300 workers and spent more than $200,000 on COVID-related expenses including purchases of essential equipment such as masks and protective equipment that will not be reimbursable — has not been eligible for any of the various aid programs passed by Congress. It gets most of its funding from Medicaid and public school systems.

The organization has tapped a line of credit to stay afloat. "But if we're not here providing these services, there's no Plan B," he said.

Even providers who largely serve privately insured patients are facing financial distress. Dr. Sandy Chung is CEO of Trusted Doctors, which has about 50 physicians in 13 offices in the Northern Virginia suburbs around Washington, D.C. She said about 15% of its funding comes from Medicaid, but the drop off in private and Medicaid patients has left the group "really struggling."

"We've had to furlough staff, had to curtail hours, and we may have to close some locations," she said.

Of special concern are children because Medicaid covers nearly 40% of them across the county. Chung, who also heads the Virginia chapter of the American Academy of Pediatrics, said that vaccination rates are off 30% for infants and 75% for adolescents, putting them and others at risk for preventable illnesses.

The biggest rub, she added, is that with the economy in free fall, more people will qualify for Medicaid coverage in the coming weeks and months.

"But if you don't have providers around anymore, then you will have a significant mismatch," she said.

Back in Albuquerque, Taneja is working to find whatever sources of funding she can to keep the clinic open. She secured a federal loan to help cover her payroll for a couple of months, but worries what will happen after that. "It would kill me if we've survived 15 years in this health care system, just to not make it through COVID," she said.