UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

PHARMACY BUYING ASSOC., INC.	§	
d/b/a/ PBA HEALTH and	§	
TEXAS TRUECARE, et al.,	§	
Plaintiffs,	§	
	§	
v.	§	**CIVIL NO. A-12-CV-0156-SS**
	§	
KATHLEEN SEBELIUS, Secretary,	§	
UNITED STATES DEPARTMENT OF	§	
HEALTH AND HUMAN SERVICES, and	§	
THOMAS SUEHS,	§	
EXECUTIVE COMMISSIONER,	§	
TEXAS HEALTH AND HUMAN	§	
SERVICES COMMISSION,	§	
Defendants.	§	

BRIEF OF AMICI CURIAE IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT,
OR, IN THE ALTERNATIVE, FOR PRELIMINARY INJUNCTION

INTEREST OF AMICI

Amicus Curiae The Texas Association of Mexican American Chamber of Commerce ("TAMACC") is a non-profit entity that promotes growth, development and success of local Hispanic chambers of commerce and serves as the leading advocate of Hispanic businesses throughout Texas. TAMACC supports and promotes affordable access to healthcare for small business and employees as well as continued access to affordable prescription drugs.

Amicus Curiae Greater Houston Business Council – League of United Latin American Citizens # 4245 ("Greater Houston Business Council – LULAC") is a grassroots organization dedicated to serving the business community and advocating for civil rights, increasing educational opportunities, and promoting equal access to healthcare for everyone in the Greater Houston area. The Greater Houston Business Council – LULAC promotes and works to

accomplish the mission of their parent organization, the national League of United Latin American Citizens. The mission of the League is to advance the economic condition, educational attainment, political influence, housing, health and civil rights of the Hispanic population of the United States.

Amici believe that Texas has an obligation to support the very poor and that the general health of Texans is critical to the economic well being of the state.

SUMMARY OF ARGUMENT

Consumers throughout the state of Texas rely on local and independently owned pharmacies to fill their prescriptions and provide needed healthcare services. In particular, those citizens on the government funded Medicaid program require protection and access to quality care. By allowing managed care organizations ("MCO") to allocate the duty of setting reimbursement rates for pharmaceuticals to pharmacy benefit managers ("PBMs"), the Texas government is hurting competition and limiting access to its Medicaid enrollees.

Effective March 1, 2012, Texas law set new rules for Texas's Medicaid Managed Care waiver programs, STAR and STAR+PLUS.[1] The programs have been expanded to include prescription drug benefits at a state-wide level.[2] The purpose of the pharmacy "carve-in" is for Texas to accrue cost savings from the efficiencies of shifting the pharmacy benefit plans to managed care.[3] Enrollment in MCOs is now essentially mandatory for all Medicaid beneficiaries. However, instead of directly setting rates, the MCOs use third party entities, PBMs, to administer the pharmacy benefit component of the managed care system.[4] The PBMs therefore set reimbursement rates for pharmaceuticals for the State's Medicaid program. While

[1] *See* 1 TEX. ADMIN. CODE § 353.901.

[2] *Id.*

[3] *See* TEXAS ADMIN. PROPOSED RULES 36 TEX REG. 8639, 8669 (Dec. 23, 2011).

[4] *Id.* (Negotiations are between managed care *entities* and providers) (emphasis added).

rates differ depending on the PBM, overall these reimbursement rates for pharmaceuticals have been substantially lower than past years.[5]

Although it is laudable for the State to attempt to reduce health care spending through the use of managed care, these reimbursement cuts will have a negative effect driving many independent pharmacies out of business. Second, the forced closings will result in lack of choice and access to basic care for Medicaid recipients and the general population. Finally, the PBM's control over the reduction of these payments is a conflict of interest and raises serious anticompetitive issues.

BACKGROUND: CONSUMERS AND PHARMACIES IN TEXAS

Given the geographic and economic nature of Texas, the changes to the Medicaid reimbursement rates for pharmaceuticals will have a significant negative impact. Texas is a very rural state with a large percentage of low-income citizens. As of 2010, roughly 15 percent of the population, nearly four million Texans, lived in rural areas.[6] In fact, 177 out of 254 counties in Texas are rural, and 64 of those counties are "frontier counties" with less than seven inhabitants per square mile.[7] The average income per-capita in Texas is $38,609, but in rural areas average income falls to $31,262.[8] As of 2010, one-fifth of rural Texans lived below the poverty line.[9] With these numbers, it is unsurprising that a large portion of Texas's population participates in the Medicaid program.

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[5] *See* Jim Fuquay, *Medicaid change to cut Pharmacy Payments in Texas*, Star-Telegram, Jan. 28, 2012, *available at* http://www.star-telegram.com/2012/01/28/3694175/medicaid-change-to-cut-pharmacy.html.

[6] U.S. CENSUS BUREAU, GROWTH IN URBAN POPULATION OUTPACES REST OF NATION (2010), http://www.census.gov/newsroom/releases/archives/2010_census/cb12-50.html.

[7] TEXAS RURAL HEALTH ASS'N, RURAL HEALTH AND WORKFORCE DEVELOPMENT (2011), http://www.senate.state.tx.us/75r/senate/commit/c610/h2010/0223-BeckyConditt.pdf.

[8] Health and Hum. Services Info. for Rural Am.: Rural Assistance Ctr., http://www.raconline.org/states/texas.php (last visited July 6, 2012).

[9] *Id.*

The Medicaid program covers the most vulnerable Texans. As a dual federal and state program, all 50 states participate in the Medicaid program providing essential health insurance coverage for low income Americans. In May 2012, over 3.3 million people enrolled in the Texas Medicaid program.[10] However, the number of uninsured in Texas dwarfs the Medicaid enrollment, leading the nation in uninsured individuals at over six million people, roughly a quarter of the state's population.[11] While the uninsured do not have access to Medicaid services, many of the rural uninsured rely on clinics and local pharmacies for their basic health care needs. The purpose of Medicaid is to "furnish rehabilitation and other services to help such families and individuals retain capability for independence or self-care,"[12] while also ensuring "adequate access and quality of care" in the context of providers which includes pharmacies.[13] The Medicaid statute and implementing regulations require that medical services provided by the state are "consistent with efficiency, economy, and quality of care and are sufficient to enlist *enough providers* so that care and services are available under the plan."[14] The reductions in Medicaid reimbursements for pharmaceuticals have already caused a large number of pharmacies to close, and will continue to do so, therefore causing Texas to fall short of meeting the necessary federal Medicaid requirements.

ARGUMENT

I. Reduction of Medicaid payments for pharmaceuticals will cripple independent pharmacies throughout the state of Texas.

The arbitrary cuts to Medicaid reimbursement rates established by PBMs will result in

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[10] TEXAS HEALTH AND HUM. SERVICES COMM'N, POINT IN TIME COUNT- MEDICAID ENROLLMENT BY COUNTY- MAY 2012 (2012), http://www.hhsc.state.tx.us/research/MedicaidEnrollment/PIT/201205.html.

[11] TEXAS MED. ASS'N, THE UNINSURED IN TEXAS (2012), http://www.texmed.org/template.aspx?id=5517.

[12] 42 U.S.C. § 1396.

[13] *Arkansas Medical Society v. Reynolds*, 6 F.3d 519,530 (8th Cir.).

[14] 42 U.S.C. § 1396a(a)(30(A)(2006) (emphasis added); *see also Clark v. Kizer*, 758 F. Supp. 572 (E.D. Cal. 1990) (relevant part aff'd on appeal).

independent pharmacies going out of business in Texas. Local pharmacies cannot compete at these reduced reimbursement rates. The average "cost to dispense" for pharmacies in Texas is roughly $11.27 in total gross margin.[15] This number includes both the dispensing fee and margin on ingredient expenditure. Independent pharmacies largely rely on the pharmaceutical reimbursement and dispensing fees to stay in business. If pharmacies do not achieve this margin and are forced to dispense below cost, they will not remain profitable and will be forced to cut services or face bankruptcy.

In fact, local pharmacies are already feeling the economic strain. Through the use of PBMs, pharmacists have seen their dispensing fees drop from $6.35 to $1.35, or roughly 80 percent.[16] The Texas Health and Human Services Commission ("THHSC") believes that the move to managed care will save money while returning reimbursement rates to the same levels as Medicare and private insurance. THHSC spokeswoman Stephanie Goodman specifically stated, "We really need to get those rates back in line with what Medicare, what private insurers, what other folks pay."[17] However, the PBMs are paying a lower reimbursement rate than was intended by the administrative law. As such, THHSC is considering "targeting reimbursement levels to [meet] local needs" while the state legislature also is planning on making changes to the law during the next legislative session.[18]

The impact of this fee schedule has already caused a substantial number of pharmacies to close. As of June 14, 2012, 26 independent pharmacies have shut down due to the changes in

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[15] Kenneth A. Lawson & Michael T. Johnsrud, *Estimates of the Cost of Dispensing a Prescription in Texas Pharmacies*, Ctr. for Pharmacoeconomic Studies (2008).

[16] *Goodman: When it comes to Managed care, HHSC's top priority is the client*, RIO GRANDE GUARDIAN, Mar. 20, 2012.

[17] *Id.*

[18] Daniel Weiss, *State Medicaid Changes Squeeze Independent Pharmacies*, PHARMACY TIMES, Mar. 20, 2012, http://www.pharmacytimes.com/news/State-Medicaid-Changes-Squeeze-Independent-Pharmacies.

reimbursement rates.[19] Ten of these pharmacies were located in the impoverished Rio Grande Valley where Medicaid patients represent 80 percent of a health provider's patients.[20] In all, a study commissioned by independent pharmacy groups has predicted that nearly 1,300 independent pharmacies throughout Texas will close as a result of the rate decreases.[21] Before implementing the rule, THHSC estimated that 996 independent pharmacies would be "affected and may experience an adverse economic impact," but made no mention of forced closures.[22] The actual results and reports conflict with the THHSC's initial assessment and represent a dire situation for independent pharmacies.

Independent pharmacies face an impossible choice: Either take the substantially lower rates and attempt to survive on limited revenue, or stop providing services for individuals on Medicaid. For pharmacies like those in the Rio Grande Valley, there is no choice. Medicaid recipients make up a vast majority of their patients, and dropping Medicaid patients will only lead to store closings. The purpose of switching to managed care was to create cost-savings while minimizing the negative impact on local pharmacies.[23] The rule did not intend to force pharmacy closures; however, this unintended consequence is exactly what has occurred, and what is likely to continue absent THHSC's reevaluation of its administrative rule.

II. Reduced reimbursement rates will lead to the destruction of network adequacy, harming the most vulnerable Texans.

The reduction in pharmaceutical rates will harm Medicaid enrollees and lead to decreased access of pharmaceuticals and services. As stated in the section above, due to these

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[19] Becca Aaronson, *For Some Druggists, Medicaid Changes Mean Pain*, N.Y. Times, June 14, 2012, A31A, *available at* http://www.nytimes.com/2012/06/15/us/texas-medicaid-overhaul-means-pain-for-some-pharmacists.html?pagewanted=all.

[20] Amber Dixon, Lawmakers Consider Managed Care changes in the Valley, Valleycentral.com, Mar. 15, 2012, *available at* http://www.valleycentral.com/news/story.aspx?id=731025#.T2dFGnmDHGi.

[21] *Supra* note 15.

[22] *Supra* note 3 (As written in the proposed rule for Texas).

[23] *Id.*

reimbursement rates, many independent pharmacies will go out of business. A substantial number of these independent pharmacies operate in rural areas and are the sole provider of pharmaceuticals for their communities. Without their services, Medicaid recipients, as well as other Texans, will have to find new places to obtain basic health care and fill prescriptions.

With the limited income of Medicaid recipients, these individuals often do not have access to public or private transportation to travel to other pharmacies. Foreseeing this potential problem, THHSC wrote in the final rule that the MCOs must "ensure that a member has access to at least one network pharmacy within 15 miles from his or her residence," and "a member has access to at least one network pharmacy with 24-hour coverage within 75 miles of his or her residence."[24] This standard is arbitrary and does not conform to the realities of most Medicaid recipients, who often cannot afford transportation or lack access to public transportation. Furthermore, given the number of pharmacies leaving the market, especially in rural areas, the State will struggle to meet the aforementioned standards. Already, there are 29 counties in rural Texas that have no pharmacies that accept Medicaid patients.[25] That number is subject to increase as more pharmacies either drop their Medicaid coverage or are forced to close.

Not only will there be a lack of general access, but many patients will suffer from losing their local pharmacies. Independent pharmacies do more than simply fill prescriptions. They are vital members of the community and can be a source of critical medical services for patients, including providing medication therapy management, basic disease-state care and immunizations. Local pharmacies know their patients and often adapt their care to meet patients' specific needs. Many local pharmacies compound drugs for their patients who suffer

[24] 1 TEX. ADMIN. CODE § 353.915.

[25] Becca Aaronson, Interactive: Mapping Medicaid Patients' Pharmacy Access, The Texas Tribune, April 10, 2012, *available at* http://www.texastribune.org/library/data/texas-medicaid-pharmacy-access-enrollment/.

from rare conditions. Some pharmacies go as far as to provide delivery services for their Medicaid patients who do not have access to personal or public transportation. And some local pharmacies have been willing to provide durable medical equipment, which many "chain pharmacies" will not deal with due to high costs and complicated billing procedures. If independent pharmacies close or refuse to serve Medicaid patients, these services will cease to be available.

The mandatory provision of 42 U.S.C. §1396a(a)(30)(A) requires that there be "enough providers" available to meet the demands of care. Absent many independent pharmacies, Medicaid recipients and other Texans will lack provider access. Given the lack of pharmacy access in a number of regions throughout Texas, the changes to reimbursement already appear to violate network adequacy. Furthermore, under the Affordable Care Act,[26] if Texas decides to increase Medicaid enrollment, the state would see a 63.5 percent increase in Medicaid participants.[27] Thousands of new Medicaid recipients would struggle to obtain access to pharmacies as those independent pharmacies still in operation attempt to cope with an increased Medicaid population and unsustainable Medicaid reimbursement rates.

III. PBM's control over the reduction of rates raises significant anticompetitive concerns.

The reductions in reimbursement rates not only harm consumers and pharmacies but also raise anticompetitive issues. By moving to managed care, Texas effectively allows MCOs to enlist PBMs to set pharmaceutical reimbursement rates. On the surface, there is a basic conflict of interest as many of these PBMs are part of larger corporations that also operate chain pharmacies. It is not unfathomable to state that, due to unsustainable rates, independent

[26] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat 119 (2010).
[27] John Holahan & Irene Headen, *Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL*, Kaiser Foundation (May 2010).

pharmacies will leave the market and chain pharmacies will remain and benefit from increased customers. Under predatory pricing practices,[28] PBMs could "price out" the smaller local pharmacies in order to benefit the subsidiary chain pharmacies. In return, the chain pharmacies would lose profits during the scheme, only to recoup those losses once competitors have left the market.

In the proposed rule, the Texas legislature noted ample evidence to suggest that the effect of proposed cuts would have a drastically larger impact on independent pharmacies as compared to chain pharmacies. The report found that Medicaid reimbursement rates through managed care for independent pharmacies would be six percent less under the new system whereas rates for chain pharmacies would only be .3 percent less.[29] Many chain pharmacies already have lower distribution rates and can afford the lower rates due to their national prominence. However, a six percent decrease in potential revenue for local pharmacies has a devastating impact on their ability to operate a profitable business. As noted, these reimbursement rates have already priced out 26 independent pharmacies.[30]

There is also evidence that chain pharmacies are actively trying to consolidate market power. A CVS supervisor sent an internal memorandum out to CVS pharmacies in Dallas, Texas specifically stating that the change in reimbursement rates presents "a huge opportunity for us to grow our company and the scripts and patients we service."[31] Since CVS Caremark, a PBM that is regulating rates for pharmacies through the Texas plan, is part of the same corporation as CVS retail chain pharmacies, this statement by a supervisor raises serious competitive concerns. In addition, the entire reimbursement system is secretive. Before signing

[28] *See* 15 U.S.C. § 2.

[29] *Supra* note 3, at 8669.

[30] *Supra* note 18.

[31] *Id.*

agreements with PBMs, independent pharmacies are not told the methodology or standards utilized that establish the dispensing fees. By THHSC allowing PBMs to set rates, Texas is perpetuating the operation of an anticompetitive market for Medicaid reimbursement to independent pharmacies.

CONCLUSION

Allowing MCO through PBMs to set reimbursement rates for independent pharmacies will have a drastic negative impact on local pharmacies, consumers, and competition within the market. For the forgoing reasons, *Amici Curiae* respectfully support Plaintiffs' Motion for Summary Judgment, or, in the Alternative, for Preliminary Injunction.

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Amber S. Miller
ZS BRADY & CO.
3409 19th Street
Lubbock, Texas 79410
Tel: (806)771-1850
Email: amber@zsbrady.com

David A. Balto
LAW OFFICES OF DAVID BALTO
1350 I Street, NW
Suite 850
Washington, DC 20008
Tel: (202)789-5424
Email: david.balto@dcantitrustlaw.com

Counsel for Amici Curiae