

1 SHANE W. TSENG (SBN 200597)  
stseng@lkfirm.com  
2 MICHAEL L. LAVETTER (SBN 224423)  
mlavetter@lkfirm.com  
3 LAMB & KAWAKAMI LLP  
333 S. Grand Avenue, Suite 4200  
4 Los Angeles, CA 90071  
Telephone: (213) 630-5523  
5 Fax: (213) 630-5555

6 Attorneys for Plaintiffs  
7 MARKET PHARMACY, INC., AHCS MENTAL  
HEALTH & WELLNESS, INC., COMMUNITY  
8 PHARMACY GROUP, INC., PRESCRIPTIONS  
PLUS, INC., MIKMARA, INC., and PACIFIC  
9 PHARMACY GROUP, INC.

10 UNITED STATES DISTRICT COURT  
11 CENTRAL DISTRICT OF CALIFORNIA  
12

13 MARKET PHARMACY, INC.; AHCS  
14 MENTAL HEALTH & WELLNESS,  
INC. d/b/a BERRY & SWEENEY  
15 PHARMACY; COMMUNITY  
PHARMACY GROUP, INC. d/b/a  
16 GLESENER PHARMACY;  
PRESCRIPTIONS PLUS, INC. d/b/a  
17 SUPER RITE DRUGS; MIKMARA,  
INC. d/b/a ALLEN PHARMACY; and  
18 PACIFIC PHARMACY GROUP, INC.  
d/b/a VALENCIA PHARMACY,

Case No.  
COMPLAINT

19 Plaintiffs,

20 v.

21 UNITED STATES DEPARTMENT OF  
22 HEALTH AND HUMAN SERVICES;  
ALEX AZAR; CENTERS FOR  
23 MEDICARE AND MEDICAID  
SERVICES, and SEEMA VERMA,

24 Defendants.  
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1 Plaintiffs Market Pharmacy, Inc.; AHCS Mental Health & Wellness, Inc.  
2 d/b/a Berry & Sweeney Pharmacy; Community Pharmacy Group, Inc. d/b/a  
3 Glesener Pharmacy; Prescriptions Plus, Inc. d/b/a Super Rite Drugs; Mikmara, Inc.  
4 d/b/a Allen Pharmacy; and Pacific Pharmacy Group, Inc. d/b/a Valencia Pharmacy  
5 (collectively “Plaintiffs”); by way of Complaint against Defendants, the United  
6 States Department of Health and Human Services (“HHS”), Alex Azar, solely in  
7 his official capacity as Secretary of the United States Department of Health and  
8 Human Services; the Centers for Medicare and Medicaid Services (“CMS”); and  
9 Seema Verma solely in her capacity as Administrator of the Centers for Medicare  
10 and Medicaid Services, allege as follows:

11 **PRELIMINARY STATEMENT**

12 1. California’s state Medicaid program, Medi-Cal, intends to implement  
13 a new reimbursement structure that will significantly reduce the total  
14 reimbursement paid to pharmacies dispensing specialty medications, medications  
15 which often times treat California’s neediest and most vulnerable residents. As  
16 described in detail below, California has chosen to reduce the amount it pays  
17 pharmacies for their ingredient costs to purchase specialty medications, and has  
18 similarly chosen to reimburse pharmacies with an unreasonably low “professional  
19 dispensing fee” when dispensing specialty medications. California intends to  
20 implement this rule despite the fact that pharmacies operating in California that  
21 primarily dispense specialty medications already have razor-thin margins.

22 2. Plaintiffs, a collection of independent pharmacies located in  
23 California that primarily dispense specialty medications (“Specialty Pharmacies”),  
24 have filed this action to enjoin the implementation of these new Medicaid  
25 reimbursement rates. In doing so, Plaintiffs rely on federal law, which requires  
26 state Medicaid programs to establish reimbursement rates that cover pharmacies’  
27 costs to purchase prescription drugs as well as costs associated with dispensing  
28 those drugs to Medicaid patients.





1 serious illnesses. The complexity of the patients' illnesses requires Specialty  
2 Pharmacies to provide services distinct from those provided at non-specialty retail  
3 pharmacies. Specifically, the process of acquiring, storing, handling, and gaining  
4 approval to dispense specialty medications is far more complex than typical  
5 medications obtained at retail pharmacies.

6 19. As an initial matter, specialty medications are incredibly costly.  
7 Specialty medications are on the cutting edge of medical care and treatment for  
8 diseases that are among the most devastating to the population, including cancer,  
9 hepatitis, behavioral and mental health, and HIV. Many specialty medications,  
10 including behavioral health medications, have acquisition costs in the thousands of  
11 dollars and pharmacies dispensing these medications have very small profit  
12 margins.

13 20. Some specialty medications require special handling when storing and  
14 delivering to patients. Many specialty medications require cold-chain storage and  
15 delivery, as the medication needs to remain at a constant cold temperature to  
16 ensure proper efficacy. This special handling requires capital-intensive storage  
17 facilities at the Specialty Pharmacy, special and costly packaging when delivering  
18 the medication, and close coordination with the patient to ensure the medication is  
19 administered or stored properly once delivered.

20 21. Further, Plaintiffs work closely with prescribers and insurance  
21 companies to aid in the coverage approval process, sometimes referred to as "prior  
22 approval" or Treatment Authorization Requests ("TARS"). Many specialty  
23 medications require more than a valid prescription from a provider, such as prior  
24 approval from the patient's insurance company or from Medi-Cal before the  
25 patient can begin treatment. Plaintiffs work closely with prescribers to ensure  
26 patients requiring specialty medications receive timely prior approval and Medi-  
27 Cal authorization.

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1           22. In addition, patient education, coordination and communication are  
2 key components of Plaintiffs’ operation. Patients must be educated on how to  
3 administer medication, such as self-injectable drugs stored in prefilled syringes.  
4 Plaintiffs must closely coordinate with patients to ensure medication is either  
5 picked up or delivered at a precise time to ensure proper handling of the  
6 medication, as previously mentioned. Plaintiffs must closely communication with  
7 patients and prescribers to ensure that each patient closely adheres to their  
8 treatment regimens, as many specialty medications must be administered in a  
9 specific fashion over a period of time to remain effective in treating a medical  
10 condition. For example, certain types of Hepatitis C can be successfully cured  
11 through proper treatment over a 12-week period. However, if a patient does not  
12 precisely adhere to the treatment regimen over that extended period of time the  
13 treatment may be ineffective.

14           23. Independent Specialty Pharmacies, such as the Plaintiffs, are essential  
15 to the healthcare delivery system in that they provide unique and essential services  
16 that standard mail order and large pharmacies simply cannot. Plaintiffs serve the  
17 lowest functioning and highest risk population within our healthcare ecosystem—  
18 the homeless, indigent, parolees, violent criminals, and those suffering from opioid  
19 epidemic—a majority of which are covered by Medi-Cal. By way of example,  
20 upon information and belief over 70% of California’s mental health patients are  
21 served by independent Specialty Pharmacies. This population of high-risk patients  
22 often do not have transportation to go to Specialty Pharmacies and are in need of  
23 greater assistance to navigate their health care requirements. Plaintiffs, and other  
24 Specialty Pharmacies in California, are the only pharmacies that offer these “high  
25 touch” services on such an involved and attentive basis.  
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1           **B.     BACKGROUND OF MEDICAID**

2           24.     Medicaid is a joint federal and state healthcare benefits program  
3 created under Title XIX of the Social Security Act. Medicaid aims to provide  
4 health care to indigent and needy individuals and families in the United States.

5           25.     The Medicaid program is jointly financed by the federal and state  
6 governments, and is administered by the states.

7           26.     In order to receive matching funds from the federal government, states  
8 must agree to administer their Medicaid program in compliance with the applicable  
9 federal Medicaid laws and regulations. *See* 42 U.S.C. § 1396 *et seq.*

10          27.     Federal law requires that each state specify a single State Agency  
11 established or designated to administer or supervise the administration of the  
12 state’s Medicaid program. 42 C.F.R. § 431.10. The State Agency must make rules  
13 and regulations to administer the state’s Medicaid plan, and is responsible for  
14 determining eligibility for Medicaid benefits in accordance with federal law.

15          28.     Each State Agency must submit for approval a “State Plan” to CMS,  
16 which is a comprehensive written statement describing the nature and scope of the  
17 state’s Medicaid program and gives assurances that the state’s Medicaid program  
18 will be administered in accordance with applicable federal law. 42 C.F.R. §  
19 430.10.

20          29.     If a State Agency intends to make an amendment to its State Plan, it  
21 must submit a “State Plan Amendment.” State Plan Amendments are appropriate  
22 when there is either (1) a change in federal law, regulations, policy interpretations,  
23 or court decisions; or (2) material changes in the state’s law, organization, or  
24 policy, or in the state’s operation of the Medicaid program. 42 C.F.R. § 430.12(c).

25          30.     CMS is then tasked with reviewing the State Plan Amendment to  
26 ensure that the state’s Medicaid program will remain in compliance with all  
27 applicable law. CMS’s Regional Administrator will then notify the State Agency  
28

1 whether the State Plan Amendment was approved or disapproved. 42 C.F.R. §  
2 423.16.

3 31. One such applicable federal law that CMS is tasked with ensuring any  
4 State Plan Amendment abides by is 42 U.S.C. § 1396a(a)(30)(A) (“Section 30A”),  
5 which requires each State Plan:

6 *to assure that payments are consistent with efficiency,*  
7 *economy, and quality of care and are sufficient to enlist*  
8 *enough providers so that care and services are available*  
9 *under the plan at least to the extent that such care and*  
*services are available to the general public in the geographic*  
*area.*

10 (emphasis added).

11 32. When a State Agency is proposing changes to the State’s ingredient  
12 cost reimbursement or professional dispensing fee reimbursement, federal law  
13 requires that the total reimbursement to the pharmacy provider is in accordance  
14 with [Section 30A]. 42 C.F.R. § 447.518(d).

15 33. Further, federal law requires that “States must provide adequate data  
16 such as a State or national survey of retail pharmacy providers or other reliable  
17 data other than a survey to support any proposed changes to either or both of the  
18 components of the reimbursement methodology. States must submit to CMS the  
19 proposed change in reimbursement and the supporting data through a State plan  
20 amendment through the formal review process.” 42 C.F.R. § 447.518(d).

21 **C. OUTPATIENT PRESCRIPTION DRUG**  
22 **REIMBURSEMENT IN MEDICAID**

23 34. Until recently, State Agencies were required to reimburse pharmacies  
24 for the dispensing of drugs based on two figures: (1) reimbursement for the drug  
25 ingredient cost and (2) reimbursement for the cost of dispensing.

26 35. Federal regulations required that reimbursement for drug ingredient  
27 costs was to be no more than the State Agency’s best estimate of the acquisition  
28 cost for a drug.

1           36. A drug’s estimated acquisition cost, or “EAC” is defined as the state’s  
2 best estimate of the prices generally and currently paid by providers for a drug  
3 marketed or sold by manufacturers or labelers in the package size of the drug most  
4 frequently purchased by providers.

5           37. In order to obtain EAC for dispensed drugs, many State Agencies  
6 utilized published drug pricing benchmarks, such as the Average Wholesale Price  
7 (“AWP”), Wholesale Acquisition Cost (“WAC”), or Average Sales Price (“ASP”).

8           38. For instance, California’s State Plan has determined that the EAC for  
9 drugs dispensed to California Medicaid beneficiaries is roughly AWP -17%.

10           39. The second part of the reimbursement formula—the cost of  
11 dispensing, or “dispensing fee”—is typically a nominal fee. For instance,  
12 California’s current dispensing fee is \$7.00.

13           40. The reimbursement rates currently utilized by California’s State Plan,  
14 consisting of the ingredient cost plus a dispensing fee, lead to razor-thin margins  
15 for Specialty Pharmacies dispensing specialty medications, with such Specialty  
16 Pharmacies breaking even or making just a marginal profit each time they dispense  
17 a specialty drug to a Medicaid beneficiary.

18           **D. CMS ADOPTS NEW PRICING REGULATIONS FOR**  
19           **THE DISPENSING OF DRUGS IN MEDICAID**

20           41. In February 2016, CMS promulgated a new regulation that drastically  
21 changed the reimbursement structure for pharmacies participating in the Medicaid  
22 program (the “CMS Rule”). 81 Fed. Reg. 5170 (Feb. 1, 2016).

23           42. The CMS Rule required states to base ingredient cost reimbursement  
24 on actual acquisition cost of the drug, or “AAC,” as opposed to EAC. 42 C.F.R. §§  
25 447.502, 447.512(b).

26           43. The CMS Rule also required each State Agency to establish a new  
27 “professional dispensing fee” sufficient to cover a list of pharmacy costs associated  
28 with dispensing drugs, including:

- 1 a. reasonable costs associated with a pharmacist's time in
- 2 checking the computer for information about an individual's
- 3 coverage,
- 4 b. performing drug utilization review and preferred drug list
- 5 review activities,
- 6 c. measurement or mixing of the covered outpatient drug,
- 7 d. filling the container,
- 8 e. beneficiary counseling,
- 9 f. physically providing the completed prescription to the Medicaid
- 10 beneficiary,
- 11 g. delivery,
- 12 h. special packaging, and
- 13 i. overhead associated with maintaining the facility and
- 14 equipment necessary to operate the pharmacy.

15 44. CMS required that each state submit a State Plan Amendment in order  
16 to implement the aforementioned reimbursement changes by April 1, 2017.

17 45. CMS allowed the states to implement an AAC model of  
18 reimbursement based on a number of pricing methodologies. CMS indicated that  
19 states may develop an AAC model of reimbursement based on data received from  
20 a state survey of retail pharmacy providers' pricing. States may also develop an  
21 AAC model of reimbursement based on published compendia prices, such as  
22 WAC.

23 46. However, in an effort to establish uniform AAC reimbursement, CMS  
24 created the National Average Drug Acquisition Cost ("NADAC") pricing  
25 benchmark. The NADAC pricing benchmark was designed to represent a national  
26 pricing methodology based upon an average of voluntarily-submitted retail  
27 pharmacy acquisition costs for a number of drugs.

28

1 47. To develop NADAC, CMS contracted with Myers and Stauffer, LC, a  
2 public accounting firm, to conduct surveys of pharmacy ingredient prices. The  
3 surveys collect acquisition costs and invoice purchase prices for outpatient drugs  
4 purchased by predominately chain retail pharmacies and independent retail  
5 pharmacies.

6 48. Specifically, on a monthly basis Myers and Stauffer LC collects  
7 acquisition data from a random sample of pharmacies selected from all 50 states  
8 and the District of Columbia. The pharmacy entities surveyed are independent and  
9 chain retail community pharmacies.

10 49. Critically, many Specialty Pharmacies are *excluded* from the surveys.  
11 Myers and Stauffer identifies Specialty Pharmacies based on their classification in  
12 the National Council for Prescription Drug Programs (“NCPDP”) database, as  
13 well as whether the pharmacy is URAC certified in specialty pharmacy. If a  
14 Specialty Pharmacy is classified as such in the NCPDP database or is URAC  
15 certified, that pharmacy’s data will not be considered by Myers & Stauffer when  
16 developing a NADAC price for a specialty medication.

17 50. The survey filled out by pharmacies participating in the NADAC  
18 survey includes the following information: (1) the type of medication, (2) the unit  
19 price paid by the pharmacy, (3) the invoice date, and (4) the quantity purchased.  
20 Myers and Staffer, LC collect the documentation and then create the NADAC  
21 pricing.

22 51. CMS has instructed Myers and Staffer, LC to require at least five cost  
23 observations for each drug in order to determine a NADAC ingredient cost  
24 reimbursement.

25 52. Despite NADAC excluding the participation of Specialty Pharmacies  
26 from its surveys, NADAC nevertheless establishes reimbursement rates for  
27 specialty medications based on data collected from retail non-specialty  
28 pharmacies. The data received from retail non-specialty pharmacies regarding the

1 costs of acquiring and dispensing specialty medications is oftentimes  
2 misrepresentative of such costs for Specialty Pharmacies, resulting in many  
3 Specialty Pharmacies being reimbursed at unreasonably low rates when  
4 dispensing specialty medications to Medicaid patients.

5 53. If NADAC pricing is applied, based on a matrix that reflects the  
6 acquisition cost of non-specialty pharmacies or chain drug stores (many of which  
7 have lower acquisition costs due to more favorable contracts with wholesalers) or  
8 the acquisition cost of hospitals who typically purchase medications in a greater  
9 scale, it will become nearly impossible for independent Specialty Pharmacies,  
10 such as Plaintiffs, to continue to stay solvent, let alone provide the “high touch”  
11 services that improve patient outcomes.

12 **E. CALIFORNIA CONDUCTS STUDY AND**  
13 **ULTIMATELY ADOPTS NADAC PRICING**  
14 **TO COMPLY WITH AAC REQUIREMENT**

15 54. In order to issue its State Plan Amendment to CMS in accordance  
16 with the CMS Rule, California’s Department of Health Care Services (“DHCS”)  
17 engaged Mercer Government Human Services Consulting (“Mercer”) to conduct a  
18 study on outpatient pharmacy provider costs associated with purchasing and  
19 dispensing outpatient prescription drugs to California Medicaid members.

20 55. To conduct the study, Mercer issued two different surveys to  
21 California pharmacies: (1) a survey which collected data necessary to calculate the  
22 average cost of dispensing a prescription (the “Dispensing Fee Survey”), and (2) a  
23 survey aimed at identifying pharmacy purchase prices for brand and generic drugs  
(the “Ingredient Cost Survey”).

24 56. With regard to the Dispensing Fee Survey, Mercer issued surveys to  
25 5,644 pharmacies and only received usable information from 2,562 pharmacies.  
26 Notably, Mercer only received data from three (3) Specialty Pharmacies, and  
27 opted not to include the data for purposes of determining the appropriate  
28 Dispensing Fee due to the “small number of responses.” Indeed, Mercer’s final

1 report indicates that “costs of dispensing for...specialty pharmacies could not be  
2 estimated because of the low number of responses for these pharmacy types.”

3 57. Mercer did, however, obtain data from non-specialty retail pharmacies  
4 regarding the costs associated with dispensing specialty drugs in its Dispensing  
5 Fee Survey. However, acquisition costs and dispensing costs associated with  
6 dispensing specialty medications are far different between non-specialty retail  
7 pharmacies and Specialty Pharmacies. This is due to a number of realities,  
8 including buying power, the level of patient care and “high touch” services  
9 provided by Specialty Pharmacies, and overall differing dispensing portfolios.

10 58. Notably, Mercer’s final report states that:

11 A number of additional variables were included in the survey to  
12 explore specialty prescription costs. Unfortunately, these  
13 appeared to introduce irreconcilable incongruities between  
14 specialty revenue and prescription sales and may be a cause of  
15 many of the **93 pharmacies that reported higher costs of  
dispensing than total sales**. In any case, introduction of these  
variables into the regression did not produce intuitive results.

16 (emphasis added).

17 59. Despite acknowledging that reports by pharmacies that dispensing  
18 specialty medications results in “higher costs of dispensing than total sales,”  
19 Mercer’s final report recommended three proposed Dispensing Fees applicable to  
20 retail pharmacies and Specialty Pharmacies alike, including the two tier  
21 Dispensing Fee that would ultimately be adopted by DHCS, as further described  
22 below.

23 60. With regard to the second survey issued by Mercer—the Ingredient  
24 Cost Survey, Mercer surveyed 600 pharmacies and had 372 pharmacies  
25 participate.

26 61. After reviewing the data, Mercer proposed three proposed methods of  
27 obtaining the appropriate ingredient cost, including the adoption of NADAC  
28 pricing for brand and generic products, which was ultimately be adopted by  
DHCS.

1           62. Critically, in its final report Mercer indicated that “the main challenge  
2 with [the adoption of NADAC pricing] is the lack of NADAC rates for many  
3 specialty drugs and supplies.”

4           63. Upon receipt of Mercer’s final report dated January 4, 2017, DHCS  
5 submitted its State Plan Amendment to CMS on May 30, 2017, which proposed to  
6 change California’s Medicaid reimbursement structure in order to comply with the  
7 Medicaid Rule.

8           64. DHCS’s State Plan Amendment set California’s Medicaid Ingredient  
9 Cost as the lesser of:

- 10           a. The NADAC of the drug, or when no NADAC is available, the  
11 Wholesale Acquisition Cost (WAC) + 0%, or  
12           b. The Federal Upper Limit, or  
13           c. The Maximum Allowable Ingredient Cost.

14           65. The DHCS State Plan Amendment adopted Mercer’s recommendation  
15 and utilized a two tier approach for the Professional Dispensing Fee:

- 16           a. Less than 90,000 claims submitted by the pharmacy = \$13.20,  
17 or  
18           b. 90,000 or more claims = \$10.05.

19           66. California’s DHCS adopted the aforementioned Ingredient Cost and  
20 Professional Dispensing Fee structure despite Mercer’s final report indicating that  
21 it did not receive sufficient data to determine an appropriate dispensing fee for  
22 Specialty Pharmacies and that many specialty medications do not have NADAC  
23 pricing.

24           67. By way of correspondence dated August 25, 2017, CMS approved  
25 DHCS’s State Plan Amendment.

26           68. Notably, the changes to California’s Medicaid reimbursement  
27 structure, once implemented through the State Plan Amendment, will be  
28 **retroactively** applied back to April 1, 2017. While DHCS has yet to implement its

1 State Plan Amendment modifying the Medicaid reimbursement, once the State  
2 Plan Amendment becomes effective, the new Ingredient Cost and Professional  
3 Dispensing Fee reimbursement structure will be retroactively applied to every  
4 Medicaid claim submitted by participating pharmacies from April 1, 2017 to the  
5 effective date. Said another way, DHCS is going to “claw back” the difference in  
6 reimbursement to participating pharmacies once the State Plan Amendment is  
7 enacted.

8 69. Upon information and belief, California’s State Plan Amendment will  
9 be enacted in late 2018.

10 **F. THE IMPACT CALIFORNIA’S STATE PLAN**  
11 **AMENDMENT WILL HAVE ON PLAINTIFFS**

12 70. The impact California’s State Plan Amendment will have on Plaintiffs  
13 is nothing short of devastating.

14 71. Indeed, the failure of California’s DHCS as well as the NADAC  
15 pricing benchmark to incorporate acquisition costs and dispensing costs of  
16 *Specialty Pharmacies*, despite setting reimbursement rates of *specialty*  
17 *medications*, will result in dramatically decreased reimbursement rates, as the data  
18 relied upon to set the NADAC pricing benchmark for these specialty medications  
19 is only provided by non-specialty retail pharmacies, which have better margins  
20 due to the offering of more generic, less patient-centric services and increased  
21 buying power and leverage.

22 72. In addition, NADAC pricing is based on national averages of  
23 acquisition cost for pharmacies, and does not account for California’s higher cost  
24 of business, such as higher rent prices, higher wages, higher Worker’s

25 73. Once California implements its State Plan Amendment, Plaintiffs,  
26 along with countless other Specialty Pharmacies located in California, will see a  
27 dramatic decrease in their reimbursement rates, such that Plaintiffs will now be  
28 reimbursed below their actual cost of dispensing the medication. In other words,

1 Plaintiffs will not make any profit in connection with dispensing a host of  
2 specialty medications to California Medicaid beneficiaries, but rather lose money  
3 each time they dispense said medications.

4 74. For instance, about 64% of Market Pharmacy's business is dedicated  
5 to serving California Medicaid patients.

6 75. Currently (prior to the implementation of California's State Plan  
7 Amendment), Market Pharmacy is reimbursed AWP -17% plus a dispensing fee  
8 of \$7.00 for each prescription dispensed.

9 76. However, once California's State Plan Amendment is implemented,  
10 Market Pharmacy will be reimbursed in accordance with the NADAC rate of each  
11 dispensed medication, plus a \$10.00 professional dispensing fee.

12 77. This change will result in Market Pharmacy's reimbursement rates  
13 being insufficient to cover Market Pharmacy's medication acquisition cost and  
14 overhead.

15 78. By way of example, Market Pharmacy anticipates losing  
16 approximately \$600,000 per year if the pharmacy maintains dispensing specialty  
17 drugs to California Medicaid patients.

18 79. Even worse, due to the retroactive application of California's State  
19 Plan Amendment, Market Pharmacy will have approximately \$800,000 –  
20 \$1,000,000 clawed back in connection with claims submitted from April 1, 2017  
21 to the date of implementation.

22 80. This negative impact is consistent among all of the Plaintiffs.

23 81. Simply put, the reimbursement rates set forth in California's State  
24 Plan Amendment fail to reimburse Plaintiffs their "actual acquisition cost" but  
25 rather reimburse Plaintiffs far below their cost of dispensing specialty  
26 medications.

27 82. As a result of California's State Plan Amendment, Plaintiffs, along  
28 with many other Specialty Pharmacies located in California, will stop filling

1 prescriptions for Medi-Cal beneficiaries due to being reimbursed below the cost of  
2 dispensing the medication. This will result in California Medicaid patients losing  
3 access access to their life-saving medications and to the critical and unique  
4 services that independent Specialty Pharmacies like the Plaintiffs provide.

5 **FIRST CAUSE OF ACTION**

6 **VIOLATION OF ADMINISTRATIVE PROCEDURE ACT**

7 **5 U.S.C. §§ 701-706**

8 83. Plaintiffs hereby incorporate by reference the prior paragraphs of this  
9 Complaint as though fully set forth herein.

10 84. Under the federal Administrative Procedure Act (“APA”), 5 U.S.C. §§  
11 701-706, courts must overturn agency action that is arbitrary, capricious, an abuse  
12 of discretion, or not otherwise in accordance with the law.

13 85. CMS’s approval of California’s State Plan Amendment on August 25,  
14 2017 constitutes “agency action” as defined at 5 U.S.C. § 551(13).

15 86. CMS’s approval of California’s State Plan Amendment is invalid  
16 under the APA because it is arbitrary, capricious, an abuse of discretion, and  
17 otherwise inconsistent with governing law.

18 87. More specifically, California DHCS, and thus CMS, failed to conduct  
19 an analysis of whether the State Plan Amendment’s reimbursement rates for  
20 Specialty Pharmacies dispensing specialty medications were sufficient to assure  
21 that Medi-Cal beneficiaries would have the same access to care as the general  
22 public in the same geographic area. In fact, the Mercer Report, of which both  
23 California DHCS and CMS relied upon to approve the new reimbursement rates,  
24 indicated that “costs of dispensing for . . . specialty pharmacies could not be  
25 estimated because of the low number of responses for these pharmacy types.”

26 88. Thus, it is a factual impossibility for CMS to have properly considered  
27 whether the reimbursement rates implemented by California’s State Plan  
28 Amendment would be sufficient to ensure that Medi-Cal beneficiaries would have

1 the same access to specialty medications as the general public as required by  
2 Section 30A.

3 89. Further, the NADAC pricing benchmark's reliance upon data  
4 submitted by non-specialty retail pharmacies to establish appropriate  
5 reimbursement rates for specialty medications widely dispensed by Specialty  
6 Pharmacies is entirely improper and leads to unreasonably low reimbursement  
7 rates which are oftentimes lower than Plaintiffs' cost of dispensing the  
8 medications.

9 90. As a result, CMS's approval of California's State Plan Amendment is  
10 invalid under the APA because it is arbitrary, capricious, an abuse of discretion,  
11 and a flagrant violation of governing law, i.e. Section 30A.

12 **SECOND CAUSE OF ACTION**  
13 **(DECLARATORY RELIEF)**

14 91. Plaintiffs hereby incorporate by reference the prior paragraphs of this  
15 Complaint as though fully set forth herein.

16 92. An actual and justiciable controversy exists between Plaintiffs and the  
17 Defendants regarding whether California's State Plan Amendment complied with  
18 the requirements of Section 30A of the Federal Medicaid Act. Plaintiffs contend  
19 that CMS's approval of California's State Plan Amendment was arbitrary,  
20 capricious, an abuse of discretion, and not in accordance with applicable law.

21 93. Accordingly, pursuant to 28 U.S.C. § 2201, Plaintiffs request this  
22 Court to declare that the reimbursement rates set forth by California's State Plan  
23 Amendment and approved by the Defendants are invalid and unlawful pursuant to  
24 Section 30A.

25 94. No administrative appeal process or other administrative remedy is  
26 available to Plaintiffs to challenge the reimbursement rates set forth in  
27 California's State Plan Amendment.  
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**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. For an Order declaring that Defendants’ approval of California’s State Plan Amendment was arbitrary, capricious, an abuse of discretion, and not in accordance with applicable law.
- B. For an Order setting aside Defendants’ approval of California’s State Plan Amendment.
- C. For a Declaration that Defendants’ approval of California’s State Plan Amendment was contrary to law and violated Section 30A of the Medicaid Act;
- D. For the costs of suit, including reasonable attorneys’ fees incurred by Plaintiffs;
- E. Such other relief as deemed just and proper by this Court.

Dated: September 28, 2018

Respectfully submitted,

LAMB & KAWAKAMI LLP  
SHANE W. TSENG  
MICHAEL L. LAVETTER

— and —

FRIER & LEVITT, LLC  
JONATHAN E. LEVITT  
(pro hac vice application to be filed)  
TODD MIZESKI  
(pro hac vice application to be filed)  
ROBERT R. GRANZEN  
(pro hac vice application to be filed)

By: /s/ Shane W. Tseng  
Shane W. Tseng  
Attorneys for Plaintiffs  
MARKET PHARMACY, INC.,  
AHCS MENTAL HEALTH &  
WELLNESS, INC.,  
COMMUNITY PHARMACY  
GROUP, INC., PRESCRIPTION  
PLUS, INC., MIKMARA, INC.,  
AND PACIFIC PHARMACY  
GROUP, INC.