1 CLAIRE M. SYLVIA (SBN 138990) csylvia@pcsf.com EDWARD H. ARENS (SBN 259155) 2 earens@pcsf.com PHILLIPS & COHEN LLP U.S ESTAICT COURT 3 100 The Embarcadero. Suite 300 San Francisco, California 94105 Tel: (415) 836-9000 Fax: (415) 836-9001 JAN 1 9 2016 5 CENTHAL DISTRICT OF CALIFORNIA Attorneys for Qui Tam Plaintiff 6 7 8 UNITED STATES DISTRICT COURT 9 CENTRAL DISTRICT OF CALIFORNIA 10 WESTERN DIVISION 11 UNITED STATES OF AMERICA ex V 16 - 0040 1 RGH(RAOX) 12 rel. STEVEN SCOTT, 13 Plaintiff, COMPLAINT FOR VIOLATION OF THE FALSE CLAIMS ACT (31 14 U.S.C. § 3729, et seq.) V. 15 HUMANA, INC., JURY TRIAL DEMANDED 16 Defendant. 17 FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. 18 § 3730(b)(2) 19 20 21 22 23 24 25 26 27 28 COMPLAINT

(00067353; 4)

1	I.	INTR	ODUCTION1
2	11.	PART	TES5
3	111.	JURIS	SDICTION AND VENUE6
4	IV.	THE BENI	MEDICARE VOLUNTARY PRESCRIPTION DRUG EFIT PROGRAM (PART D)6
5		A.	Medicare Part D Benefits8
6 7			Defined Standard Coverage and Cost Sharing Requirements
8			2. Actuarially Equivalent Standard Coverage9
9			3. Tiered Formularies and Pharmacy Networks10
10			4. Low Income Subsidies and Cost Sharing
11		B.	Testing for Actuarial Equivalence
12	-	C.	Medicare Part D Contracts14
13			1. Bid Requirements
14			2. Contract Requirements
15		D.	CMS Payments to Part D Sponsors19
16			1. Direct Subsidy Payments
17			2. LICS Payments
18			3. Reinsurance Payments21
19			4. Risk Sharing Payments21
20	V.	HUM	ANA'S WALMART PLAN22
21		A.	Benefit Structure23
22		B.	Development of the Bids24
23			1. The PDP Strategy Team24
24			2. The Role of Milliman25
25			3. Actuarial Valuation27
26		C.	Bid Submissions27
27	VI.	THE	DEFENDANT'S FRAUDULENT PRACTICES29
28			
		_	- iii - COMPLAINT
ţ			SOUTH AN MINT

,	A	Humana Knowingly Submite Ride Reced on Information
1 2	A.	Humana Knowingly Submits Bids Based on Information that is Not Accurate, Truthful and Complete as Certified
3		1. Humana's Internal Analysis3
4		2. Humana's False Analysis Provided to CMS
5	B.	Humana Knowingly Misrepresented that the Walmart Plan Was Actuarially Equivalent to the Defined Standard When it Was Not
6 7		Humana's Bids for the 2011 Contract Year Were Knowingly False or Fraudulent
8		2. Humana's Bids for the 2012 Contract Year Were Knowingly False or Fraudulent
0		3. Humana's Bids for the 2013 Contract Year Were Knowingly False or Fraudulent
1 2		4. Humana's Bids for the 2014 Contract Year Were Knowingly False or Fraudulent
3		5. Humana's Bids for the 2015 Contract Year Were Knowingly False or Fraudulent
4		6. Humana's Bids for the 2016 Contract Year Were Knowingly False or Fraudulent
5	C.	Humana's Violations of the False Claims Act59
6		
7		
8		
9		
0		
1 2		
3 4		
5		
6		
7		
8		
٠		- iv -

Qui Tam Plaintiff and Relator Steven Scott ("Relator"), through his attorneys Phillips & Cohen LLP, on behalf of the United States of America ("Government"), for his Complaint against Defendant Humana, Inc. ("Humana"), alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

- 1. This is an action to recover damages and civil penalties on behalf of the United States arising from false and/or fraudulent statements, records, and claims made and caused to be made by Defendant and/or its agents, employees, and co-conspirators in violation of the federal False Claims Act, 31 U.S.C. § 3729, et seq.
- 2. Residents of the United States spend billions of dollars each year on prescription drugs. A large share of the cost of these drugs is paid by the federal government through a variety of health care programs. One of those programs is the Medicare Part D prescription drug program, which provides subsidized access to prescription drug insurance coverage on a voluntary basis to Medicare beneficiaries who enroll and pay a premium. The government contracts with private entities, known as "Part D sponsors," to administer the Part D benefit.
- 3. Humana is a health insurance company and Part D sponsor. Humana insures approximately 12 million people nationwide, including 3.3 million Medicare beneficiaries enrolled in Medicare Part D Prescription Drug Plans ("PDPs"). In 2014, Humana's revenue from PDPs was approximately \$3 billion. This Complaint concerns Humana's ongoing fraudulent scheme against the Medicare Part D program and the beneficiaries that the government intended the program to support.
- 4. Under the applicable statutes and regulations, a Part D sponsor that seeks to offer a PDP must submit a bid to CMS that certifies, among other things, that the value of the benefits provided by a proposed plan is the actuarial equivalent of, or exceeds, the "defined standard" Part D benefit. The defined standard provides, among other things, that beneficiaries on average pay no more than 25 percent of drug costs that exceed the deductible up to an initial coverage limit, with

condition of receiving a Part D contract.

5. As alleged below, since 2011 when Humana first offered its Part D

the Part D sponsor paying the remaining 75 percent. Actuarial equivalence is a

- PDP known as the basic Walmart Plan, Humana has knowingly provided Part D benefits under that plan that have been significantly less valuable than Humana promised in its bids, which it certified as accurate, complete and truthful. Instead of paying 75 percent of the cost of drugs in the initial coverage limit ("ICL") phase, Humana has paid as little as 64.5 percent, with beneficiaries enrolled in the Walmart Plan paying the balance. In the case of low-income beneficiaries whose cost sharing is subsidized by the government, the government pays the excessive cost sharing amounts directly. In each contract year, Humana has provided fewer benefits—and Humana's members have borne higher costs—than Humana presented in its bid for the contract and was required for it to be awarded a Part D contract.
- 6. By misrepresenting the value of its benefits, Humana decreased its costs under the contract relative to the payments it received from the government and beneficiaries and profited handsomely as a result. Based on allowed costs in the ICL phase between 2011 and November 2015, Humana's Part D benefit has been worth approximately \$412 million less than the defined standard it contracted to provide. Humana has realized much of that difference as profit, which has come at the expense of CMS and the enrolled beneficiaries who have paid excessive cost sharing under the Walmart Plan.
- 7. Between 2010 and 2014, for the contract years 2011–2015, Humana submitted a bid each year for each of the 35 CMS geographic regions in which it proposed to offer the Walmart Plan—175 bids in total—and each of those bids represented the Walmart Plan as actuarially equivalent to the defined standard. For the 2016 contract year, Humana has similarly represented the Walmart Plan as actuarially equivalent to the defined standard, bringing the total number of bids that make this representation to 210. CMS has approved the bids that Humana submitted

- 8. Humana knew that the Walmart Plan did not meet CMS requirements at the time it submitted a bid for a contract each year, as demonstrated by the two sets of books Humana maintained. Humana created one analysis that it used to report the actuarial value of the Walmart Plan to CMS, which would justify the award of a contract, and a second analysis that Humana used to set its own internal operating budget and to report its expected financial performance to its shareholders. The latter, accurate analysis, which was consistent with Humana's actual experience, showed that Humana did not expect its Walmart Plan to be actuarially equivalent, as required to obtain a Part D contract. It further showed that Humana falsely certified to CMS that it expected the Walmart Plan to be actuarially equivalent. In no year has Humana budgeted for the Walmart Plan to meet the actuarial equivalence requirement and in no year has the Walmart Plan achieved actuarial equivalence. Yet each year Humana has certified to CMS that the Walmart Plan is actuarially equivalent.
- 9. CMS was unaware of Humana's true expectations for the Walmart Plan, which rendered Humana ineligible for a Part D contract at the time CMS awarded the contracts to Humana. Although the bids submitted to CMS were based upon false information, the false information was not visible to CMS, which relies upon the sponsor's certification of the information and data as accurate and truthful.

- 10. Because Humana fraudulently induced the government to award it the Part D contracts by promising to provide beneficiaries with a plan that was the actuarial equivalent of the defined standard when Humana knew it was not, Humana was not entitled to receive the contracts or any of the payments under them.
- 11. Moreover, because of Humana's fraudulent scheme, LICS members have had significantly higher cost sharing than they would have had under the defined standard. CMS pays the additional costs through higher LICS subsidy payments to Humana. Humana has falsely claimed payment for those excess costs from CMS and has also knowingly retained overpayments for LICS subsidies to which it was not entitled and sought to avoid or conceal an obligation to repay CMS.
- 12. The FCA was originally enacted during the Civil War, substantially amended in 1986, and amended again in 2009 and 2010. Congress enacted the 1986 amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisal or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.
- 13. The FCA provides that any person who presents or causes to be presented false or fraudulent claims for payment or approval to the United States Government; knowingly makes, uses, or causes to be made or used false records and statements to induce the United States to pay or approve false and fraudulent claims; or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the federal government.
- 14. The FCA was further amended by the Fraud Enforcement Recovery Act ("FERA") passed by Congress and signed into law on May 20, 2009 for the

express purpose of strengthening the tools available to combat fraud and to overturn iudicial decisions that had weakened the False Claims Act.

- 15. The FCA allows any person having information about a violation of the FCA to bring an action on behalf of the government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to enable the United States (a) to conduct its own investigation without the defendant's knowledge, and (b) to determine whether to join the action.
- 16. Based on these provisions, *qui tam* plaintiff and relator Steven Scott seeks to recover all available damages, civil penalties, and other relief for the violations alleged in this Complaint.

II. PARTIES

- 17. Humana is a health insurance company incorporated in Delaware and headquartered in Louisville, Kentucky. The company is organized into three primary business segments: Retail, which consists of Medicare and commercial health insurance benefits; Group, which consists of similar insurance products marketed to employer groups; and Healthcare Services, which consists of pharmacy, primary care, and other healthcare businesses. The Retail business segment is responsible for Humana's PDPs.
- 18. Relator is a Managing Actuary for Humana, with responsibility for modeling the cost of Humana's Medicare health insurance benefits under different actuarial assumptions. Relator works within Humana's Senior Products Actuarial Rx group and manages a team known as Modeling & Tools. Relator's group supports Humana's entire Part D product portfolio, including three PDP products and multiple other Part D benefit offerings. Relator commenced working for Humana in 2007 as an Actuarial Analyst and has been promoted four times. Relator is a resident of Louisville, Kentucky.

III. JURISDICTION AND VENUE

- 19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.
- 20. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, and because Defendant has minimum contacts with the United States. Moreover, Defendant can be found in, resides, and/or transacts or has transacted business in this District.
- 21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a), and 31 U.S.C. § 3732(a), because Defendant can be found in and/or transacts or has transacted business in this District. At all times relevant to this Complaint, Defendant regularly conducted substantial business, maintained employees, and/or made significant sales in this District. In addition, statutory violations, as alleged in this Complaint, occurred in this District.

IV. THE MEDICARE VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM (PART D)

- 22. Title XVIII of the Social Security Act, commonly known as Medicare, is a federally funded and administered health insurance program, primarily for elderly and disabled persons. Title XIX of the Social Security Act, known as Medicaid, is a federal/state entitlement program that pays for medical assistance for individuals and families with low incomes and resources. The Medicare and Medicaid programs are administered through the Centers for Medicare and Medicaid Services ("CMS"), an operating division of the U.S. Department of Health and Human Services ("HHS").
- 23. Medicare consists of four parts: Hospital Insurance Benefits (Part A), Supplemental Medical Insurance Benefits (Part B), Medicare Advantage (Part C), and the Voluntary Prescription Drug Benefit Program (Part D). Medicare Part A

- 6 -

covers inpatient hospital, home health, skilled nursing facility, and hospice care. Medicare Part B covers physician, outpatient hospital, home health, and other services. Both Part A and Part B operate on a fee-for-service basis, meaning that Medicare pays hospitals, physicians, and other health care providers directly for each service they provide to a Medicare beneficiary.

- 24. Medicare Part C was created in 1997, when Congress established the Medicare+Choice program, now known as Medicare Advantage. Under Medicare Advantage, CMS contracts with private insurance companies to offer traditional Medicare benefits (Part A and Part B benefits) through managed care plans, rather than on a fee-for-service basis. Medicare beneficiaries have the choice of enrolling in a Medicare Advantage plan instead of receiving benefits through traditional Medicare. Under the program's managed care model, Medicare pays the insurer a monthly premium for each enrolled beneficiary, known as a "capitation" payment, and the insurer assumes responsibility for the cost of providing the benefits.
- 25. Congress created Medicare Part D in 2003 through section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare beneficiaries. Part D provides subsidized access to prescription drug insurance coverage on a voluntary basis to individuals entitled to Part A or enrolled in Part B who pay a premium (also known as "beneficiaries" or "members"). Part D also provides premium and cost-sharing subsidies for low-income enrollees. Beneficiaries who qualify for both Medicare and Medicaid automatically receive the Part D benefit. All Part C Medicare Advantage plans, except Private Fee for Service plans, must also offer an option that includes the Part D drug benefit.
- 26. The United States does not pay pharmacies directly for providing covered drugs to Medicare Part D beneficiaries. Rather, the United States pays private companies that contract with CMS. The private companies that contract

with CMS to offer Part D coverage are known as "Part D plan sponsors" or "Part D sponsors," which are typically private insurance companies. Part D sponsors may offer three types of plans: stand-alone PDPs, Medicare Advantage plans that provide qualified prescription drug coverage ("MA-PD"), or Program of All-inclusive Care for the Elderly ("PACE") plans. Similar to Medicare Part C, CMS pays Part D sponsors on a capitated basis to provide services to the Medicare beneficiaries who elect to participate in their plans.

A. Medicare Part D Benefits

27. All Medicare Part D plans must provide enrollees with qualified prescription drug coverage. 42 U.S.C. § 1395w-102; 42 C.F.R. § 423.104. Qualified prescription drug coverage can consist of either standard coverage, which includes both "defined standard" coverage and "actuarially equivalent" standard coverage, or "basic alternative" coverage that provides the same actuarial value. Plans that offer only qualified prescription drug coverage are referred to as "basic" plans. For an additional beneficiary premium, plans may also offer supplemental coverage exceeding the value of basic coverage. Plans that offer supplemental coverage are known as "enhanced alternative" plans. Beneficiaries who enroll in an enhanced alternative plan must pay for the cost of the supplemental coverage; CMS pays Part D sponsors only for qualified prescription drug coverage, no more and no less. The allegations set forth in this Complaint concern basic plans.

1. Defined Standard Coverage and Cost Sharing Requirements

- 28. Defined standard coverage consists of covered Part D drugs, which include most FDA-approved prescription drugs and biologicals, subject to statutory cost-sharing requirements.
- 29. Under Part D, beneficiaries share in the cost of the drugs and the Part D sponsor pays the remainder. Under Part D statutory cost-sharing requirements, a beneficiary must pay an initial annual deductible. In 2015, the amount of the annual deductible was \$320. Once the beneficiary pays the deductible, he or she is

6

7

8

9

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

responsible for 25 percent of drug costs, up to an initial coverage limit ("ICL"). The ICL for 2015 was \$2,960. The Part D sponsor pays the remaining 75 percent of drug costs attributable to the beneficiary. In the case of government-subsidized beneficiaries, the government pays close to 100 percent of the drug costs attributed to the beneficiary. The coverage phase between the deductible and the ICL is referred to as the "ICL phase."

- 30. Once the beneficiary reaches the ICL, the beneficiary becomes responsible for various coinsurance percentages until his or her out-of-pocket expenses exceed an annual threshold. The coverage phase between the ICL and the annual out-of-pocket threshold is commonly known as the "coverage gap" or "donut hole." The 2015 out-of-pocket threshold is \$4,700. The manufacturers of most brand name drugs must provide a 50 percent discount at the point of sale if the beneficiary is in the donut hole, but the full cost of the drug will count as out-ofpocket spending for purposes of reaching the catastrophic coverage phase. In the coverage gap phase, the Part D sponsor pays the part of the costs not covered by the beneficiary, or in the case of government-subsidized beneficiaries, the government pays close to 100 percent of the drug costs attributed to the beneficiary.
- Upon reaching the out-of-pocket threshold, the beneficiary moves into 31. catastrophic coverage, which requires the beneficiary to pay the greater of 5 percent or a small defined copayment amount with the Part D sponsor and the government paying the remaining amount. In the case of government-subsidized beneficiaries, the government pays 100 percent of the drug costs attributed to the beneficiary.
- CMS annually adjusts the deductible, ICL, out-of-pocket threshold, and beneficiary cost-sharing after the out-of-pocket threshold. The benefit parameters are indexed annually to the growth in average per capita Part D costs.

2. **Actuarially Equivalent Standard Coverage**

33. Part D sponsors may offer standard prescription drug coverage under plans that differ from the defined standard, provided that CMS determines that the

- 9 -			
COMPLAINT			

27 28

100067353; 4 }

plan is "actuarially equivalent" to the defined standard. A plan is actuarially equivalent to the defined standard when the actuarial value of the plan's coverage is equal to the actuarial value of defined standard coverage. See 42 C.F.R. § 423.4. Part D sponsors must demonstrate to CMS that their proposed plans are actuarially equivalent to the defined standard in order to receive a Part D contract.

34. CMS requires that the value of the drug benefit be equal to the defined standard in each of the coverage phases. The purpose of this requirement is to prevent Part D sponsors from subsidizing some coverage phases by reducing benefits in other coverage phases. Thus, to meet the actuarial equivalence requirement, average expected member cost sharing during the ICL phase under the sponsor's proposed plan must be 25 percent. Similar requirements exist with respect to the coverage gap and catastrophic coverage phases.

3. Tiered Formularies and Pharmacy Networks

- 35. For actuarially-equivalent standard coverage plans, CMS permits the use of "tiered" formularies and pharmacy networks, in which different covered drugs and pharmacies have different cost-sharing requirements. A tiered formulary provides beneficiaries with lower cost sharing for generic (or preferred) drugs and higher cost sharing for brand-name drugs. A tiered pharmacy network offers lower cost sharing for prescriptions filled at certain retail and mail-order pharmacies, often referred to as "preferred" pharmacies, and higher cost sharing for prescriptions filled at the other, "non-preferred" pharmacies in the sponsor's network. (Except in limited circumstances, beneficiaries generally receive no benefits if they fill prescriptions at out-of-network pharmacies.) For plans with both a tiered formulary and tiered pharmacy network, members benefit the most from using generic drugs and filling those prescriptions at preferred pharmacies.
- 36. The purpose of tiered cost-sharing structures is to incentivize members to use low-cost services, such as generic drugs and preferred pharmacies, instead of high-cost services, such as brand name drugs and non-preferred pharmacies. The

	-	1() -		
CO	М	PΙ	.A	IN	r

 key assumption underlying these structures is that members will be driven to use preferred pharmacies because they will pay less (have a lower cost share) at those pharmacies as compared to others. Thus a tiered pharmacy network will typically change how members use services, steering utilization to the services with the lowest cost sharing.

4. Low Income Subsidies and Cost Sharing

- 37. CMS subsidizes the cost of Part D premiums and cost sharing for low-income beneficiaries. The low-income cost sharing subsidy ("LICS") is linked to standard prescription drug coverage and varies based on the beneficiary's assets, income, and institutional (or community care) status. Beneficiaries who qualify for a full subsidy will not pay a monthly plan premium if they enroll in an inexpensive Part D plan. Full-subsidy eligible beneficiaries also are not responsible for paying the deductible (which is paid by CMS), bear only minimal cost sharing in the ICL phase and coverage gap, and have no cost sharing once they reach catastrophic coverage.
- 38. In the ICL phase, cost sharing for full-subsidy eligible beneficiaries is fixed at two copay amounts. In 2014, beneficiaries with income below 100 percent of the federal poverty level paid \$1.20 for generic or preferred drugs and \$3.60 for other drugs. Beneficiaries with incomes above 100 percent of the poverty level paid slightly more: \$2.55 for generic or preferred drugs and \$6.35 for other drugs. In both cases, the copay amounts are the same regardless of how the beneficiary chooses to fill the prescription. The LICS member will pay the same cost sharing amount at a preferred pharmacy as they would at a non-preferred pharmacy.
- 39. Because LICS members have minimal cost sharing obligations that do not vary much with the brand of drug and do not vary at all with the pharmacy they choose, they are not as price sensitive as other members and therefore their utilization patterns are different. LICS members are more likely to use brand name drugs because the difference in the copay between generic and brand name drugs is

relatively small. Similarly, LICS members are more likely to fill prescriptions at non-preferred pharmacies, which may be more convenient for them than preferred pharmacies, and the choice has no effect on their copay.

40. LICS members are also subject to special enrollment rules. Unlike other Medicare beneficiaries, CMS may enroll a full-subsidy eligible beneficiary into a PDP automatically if the beneficiary does not elect a PDP on his or her own. The sponsors that receive auto-enrollments from CMS are those that offer basic prescription drug coverage with a premium at or below a benchmark known as the low-income premium subsidy amount. If more than one sponsor in a given region offers a PDP that meets the criteria for auto-enrollments, CMS will allocate beneficiaries on a random basis among the available sponsors. Once it allocates beneficiaries to a sponsor, CMS will enroll them randomly among all of the sponsor's plans that meet the criteria.

B. Testing for Actuarial Equivalence

- 41. To determine whether the value of a sponsor's plan is actuarially equivalent to defined standard coverage, CMS requires the sponsor to perform actuarial equivalence tests. For standard coverage plans, the test compares the "effective coinsurance percentage" of the proposed plan to the effective coinsurance percentage under defined standard coverage, which provides that a member pays 25 percent of the cost and the Plan D sponsor pays the remaining 75 percent. The effective coinsurance percentage is the estimated cost sharing payments of the plan members divided by the sponsor's estimated total cost of drugs.
- 42. CMS requires the sponsor to determine actuarial equivalence using an actuarially representative pattern of utilization. 42 U.S.C. § 1395w-102(c)(1)(C). The sponsor must establish that the value of coverage for its expected member population under the defined standard is equal to the value of coverage for the same members under the proposed plan, accounting for any changes due to a different

- 12 -

level or pattern of utilization of prescriptions. This requires the sponsor to estimate how members will use services based on the proposed plan.

- 43. The use of a tiered cost-sharing structure affects the actuarial value of the Part D benefit in several ways. First, for individual members, changing the level of member cost sharing for different drugs and/or pharmacies means that the value of the member's benefits may be greater or less than the defined standard. In a typical cost-sharing structure, the member cost share for "low-tier" services will be less than 25 percent, while member cost share for "high-tier" services will be more than 25 percent. For the plan to be actuarially equivalent to the defined standard, the cost-sharing structure must be designed so that the weighted-average rate of member cost sharing equals 25 percent of drug costs.
- 44. Second, because tiered cost sharing affects how members use services, the sponsor must account for changes in utilization when determining the average rate of member cost sharing. To do so, the sponsor must make actuarial assumptions about how its members will use services under the proposed plan, or "utilization assumptions."
- 45. In designing benefits, the sponsor typically must calibrate the proposed cost-sharing structure until it meets the actuarial equivalence requirement. Because cost sharing is inversely related to utilization, any modifications that the sponsor makes to cost sharing may affect its utilization assumptions, and vice versa. The sponsor must therefore adjust the proposed plan through multiple rounds of actuarial modeling until the plan achieves equilibrium at an average effective coinsurance percentage of 25 percent.
- 46. Notably, because cost sharing is higher for members who use the more costly options of brand-name drugs and non-preferred pharmacies, the amount that those members spend on prescription drugs has an outsized effect on the effective coinsurance percentage. If the sponsor expects member cost sharing under the proposed plan to be higher than 25 percent due to non-preferred pharmacy spending,

14 15

17

16

18 19

20 21

22 23

24 25

26 27

28

the sponsor must improve benefits, reduce non-preferred utilization, or both in order to reduce the member cost share. Reducing non-preferred utilization has a larger effect than improving benefits, as members will move directly from the highest costsharing tiers to the lowest cost-sharing tiers. Reducing utilization of more costly non-preferred options, however, depends upon the sponsor being able to change member behavior. If members will not switch from higher cost options to lower cost options (such as non-preferred to preferred pharmacies), the only way for the sponsor to make the plan actuarially equivalent is to improve benefits substantially, which imposes greater cost on the sponsor.

C. **Medicare Part D Contracts**

- 47. In order to enroll beneficiaries in a Part D plan and be paid on their behalf, the Part D sponsor must enter into a contract with CMS. 42 C.F.R. § 423.504. Each contract is for a period of 12 months and may be renewed contingent on the Part D sponsor and CMS reaching agreement on the sponsor's bid or bids.
- 48. For a prospective Part D sponsor, the process for entering into a contract has three primary steps: (1) submission of an initial application to determine whether the prospective sponsor meets the eligibility qualifications for a Part D contract; (2) submission of the proposed bids and drug formulary (if any); and (3) execution of a Part D contract. Once a Part D sponsor is deemed eligible for a Part D contract, it does not need to resubmit an application each year in order to renew its Part D contract, but it must submit new bids for each contract year.
- A new prospective sponsor must submit its application for a Part D contract in mid-February. CMS makes its eligibility determination in May, subject to CMS's review and approval of the prospective sponsor's formulary and bids. The sponsor must then submit bids no later than June 1. CMS reviews the bids in June and July by conducting a "desk review" to determine whether the bids meet Part D requirements. Toward the end of the desk review, CMS releases the national base

bids to reflect the base premium amount. These final bids are submitted in August. If CMS approves the formulary and the final bids, it executes the Part D contract with the sponsor on or about September 1. The contract incorporates the sponsor's final bids that form the basis for CMS's payments to the sponsor under the contract.

1. **Bid Requirements**

Potential Part D sponsors must submit a separate bid to CMS for each 50. PDP they intend to offer Medicare beneficiaries in a given geographic region. Because CMS divides the United States into 34 geographic regions (plus other regions for U.S. territories), a potential Part D sponsor who wants to offer a nationwide PDP must submit at least 34 bids annually for each PDP (and more if it wants to include U.S. territories). The sponsor must submit the bids using CMS's Prescription Drug Bid Pricing Tool ("BPT"), which consists of multiple bid worksheets. The sponsor must complete the BPT by entering data into the worksheets in accordance with CMS instructions.

beneficiary premium for the upcoming contract year, and the sponsor may revise its

- Each bid must reflect a uniform benefit package, including the premium and all applicable cost sharing, for all individuals enrolled in the plan. 42 C.F.R. § 423.265(c). The bid must reflect the potential Part D sponsor's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage for a Part D eligible individual with a national average risk profile. Id.
- The specific requirements for each bid include "a description of the coverage to be provided under the plan, including any supplemental coverage and the deductible and other cost sharing." The bid must also include the actuarial value of its components, including "[t]he actuarial value of the qualified prescription drug coverage to be offered under each plan for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1) and the basis for that estimate," and "[t]he assumptions regarding low-income cost-sharing payable under § 423.329(d) used in calculating the bid." 42 C.F.R. § 423.265(d)(2).

5

6

7 8

9

11 12

13

14

15

16

17

18 19

20

21

22 23

24

25

26

27

- 53. The Part D sponsor must prepare the bid in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. 42 C.F.R. § 423.265(c)(3).
- offering the plan comply with all applicable CMS Part D requirements, including those related to the provision of qualified prescription drug coverage and actuarial determinations." 42 C.F.R. § 423.272(b). Specifically, CMS must determine that the plan meets the actuarial equivalence requirement. 42 C.F.R. §§ 423.104(a), (d). In determining whether the plan meets the actuarial equivalence requirement, CMS may approve the bid "only if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements... for benefits provided under that plan, less the sum . . . of the actuarial value of the reinsurance payments." 42 C.F.R. § 423.272(b)(1).
- 55. In addition, CMS must determine that each plan for which the Part D sponsor submits a bid is substantially different from the other plans for which the Part D sponsor submits a bid with respect to beneficiary out-of-pocket costs or formulary structures. 42 C.F.R. §§ 423.265(b)(2), 423.272(b)(3)(i).
- 56. CMS requires plans to submit certain documentation with the bid in order to support the bid estimates. The documentation that CMS requires plans to submit does not include information regarding the assumptions the plan makes about member utilization at preferred and non-preferred pharmacies. Thus, CMS does not have access to those assumptions when it reviews the bid.
- 57. CMS requires the sponsor to submit an actuarial certification following the submission of the bid. The certification is required for each submitted bid pricing tool ("BPT") and must be completed by a qualified actuary who prepared or reviewed the plan's actuarial valuation. 42 C.F.R. § 423.265(c)(3). The actuary must certify both the initial bid in June and the final bid in August.

In the actuarial certification, the actuary must attest that the bid is in compliance with applicable laws, rules, bid instructions, and current CMS guidance.

See, e.g., CMS, Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2016, at 69 (2015). The actuary must further attest that the data and assumptions used in the development of the bid are reasonable for the plan's benefit package. *Id*.

2. Contract Requirements

- 59. If CMS approves one or more of the prospective sponsor's bids, it may offer the sponsor a Part D contract. Under the contract, the sponsor agrees to operate the PDP as described in its submissions to CMS and in accordance with Part D statutes, regulations, solicitations, and all other applicable federal statutes, regulations, and policies. *See* Exhibit 1, Contract with Approved Entity Pursuant to Sections 1860D-1 Through 160D-43 of the Social Security Act for the Operation of a Voluntary Medicare Prescription Drug Plan, art. I, ¶ A (2015). *See also* 42 C.F.R. § 423.505.
- 60. The contract requires the sponsor to provide basic prescription drug coverage as defined in the Part D regulations. Ex. 1, art. II, ¶ B.1. In providing coverage, the sponsor must "provide Part D benefits as described in PDP sponsor's bid(s) approved each year by CMS." *Id.* The contract incorporates the sponsor's bid or bids in Attachment A, which is replaced each year to reflect the sponsor's approved bid or bids for the succeeding contract year. *Id.*
- 61. The sponsor is contractually required to provide certifications to CMS in accordance with 42 C.F.R. § 423.505(k). Ex. 1, art. II, ¶ P. Under that provision, entitled "[c]ertification of data that determine payments," CMS requires as a condition of payment that sponsors certify the accuracy, completeness and truthfulness of data relating to payment, including bid submission data:

As a condition for receiving a monthly payment . . . the Part D Plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must

- 17 -

request payment under the contract on a document that certifies (based on best knowledge, information and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

42 C.F.R. § 423.505(k)(1). The sponsor must also certify that the information in its bid submission is accurate, complete, and truthful:

 The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265.

42 C.F.R. § 423.505(k)(4).

62. In addition, the sponsor is required to certify that the claims data it submits are accurate, complete, and truthful, and acknowledge that the data are used for the purpose of obtaining Federal reimbursement. 42 C.F.R. § 423.505(k)(3).

63. The sponsor must further certify "that the information provided for purposes of reporting and returning of overpayments" is accurate, complete, and truthful. 42 C.F.R. § 423.505(k)(6).

64. The contract also requires the sponsor to submit information to CMS that is necessary for CMS to administer and evaluate the Part D program, including the benefits covered under the Part D plan. Ex. 1, art. III, ¶ B.

65. The contract requires the sponsor to comply with the False Claims Act and all other federal laws and regulations designed to prevent fraud, waste, and abuse. Ex. 1, art. V.

66. When the sponsor signs the contract, it must also sign a Prescription Drug Plan Attestation of Benefit Plan. See, e.g., CMS, Prescription Drug Plan

Attestation of Benefit Plan (2015), incorporated herein as Exhibit 2. In that attestation, the sponsor must state that "the benefits identified in the [Plan Benefit

Packages] are those that the [sponsor] will make available to eligible beneficiaries" and that "we have reviewed the bid pricing tools (BPTs) with the certifying actuary

and have determined them to be consistent with the [Plan Benefit Packages] attested to here." *Id.* The sponsor must also certify that "these benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations and program guidance." *Id.*

D. CMS Payments to Part D Sponsors

67. CMS pays Part D sponsors through four payment mechanisms: (1) direct subsidies; (2) LICS subsidies; (3) reinsurance subsidies for catastrophic coverage; and (4) risk sharing payments. 42 C.F.R. §§ 423.315, 423.329.

1. Direct Subsidy Payments

- 68. The direct subsidy is a capitated payment, made on a per-member-per-month basis, which is equal to the product of the sponsor's standardized bid and each member's "risk adjustment score," minus the monthly beneficiary premium.

 See 42 C.F.R. §§ 423.315(b), 423.329(b). The "risk adjustment score" adjusts the direct subsidy amount for the member based on the member's individual health status.
- 69. CMS determines the amount of the direct subsidy based on the bid that the sponsor submits to CMS and the enrollment records that the sponsor additionally submits to CMS to establish the beneficiaries for which the sponsor claims Part D payment. CMS pays the direct subsidy prospectively, as a monthly payment for each beneficiary enrolled in the PDP as of the first day of the payment month. CMS adjusts the amount of the monthly payment to reflect changes in the member's risk adjustment score. CMS determines the final amount of the direct subsidy, reflecting the member's final risk adjustment score, after the end of the contract year.

2. LICS Payments

70. CMS pays the full value of the LICS to the Part D sponsor on behalf of low-income subsidy eligible beneficiaries enrolled in the sponsor's Part D plan for the coverage year ("LICS members").

- 71. CMS makes interim LICS payments to the sponsor on a monthly basis during the contract year. CMS's payments are equal to the low-income estimate calculated from the sponsor's bid and the number of LICS members enrolled in the PDP that month. After the end of the contract year, CMS adjusts (or "reconciles") the amount of its interim LICS payments to reflect the costs the sponsor actually incurred during the contract year. 42 C.F.R. § 423.329(d)(ii). If CMS's interim payments did not fully cover the sponsor's LICS costs during the contract year, CMS will make up the difference with an additional payment to the sponsor. If CMS's interim payments exceeded the sponsor's LICS costs, CMS will recoup the overpayment from the sponsor.
- 72. CMS determines the necessary payment adjustment based on Prescription Drug Event ("PDE") records from the sponsor. Each time a pharmacy fills a prescription for an enrolled beneficiary, the sponsor must notify CMS of the drug transaction on a PDE record. The PDE is an electronic record that includes multiple fields about a specific drug transaction, including the amount that the patient paid, the amount that the plan paid, and the LICS amount (if any) that the plan paid. Through PDE reports, the sponsor claims payment from CMS for the total amount of its LICS costs during the payment year. CMS adjusts its LICS payments to the sponsor based on the LICS costs set forth in those PDE records.
- 73. CMS will overpay the plan for LICS subsidies if plan benefits are worth less than the actuarial equivalent of the defined standard. The portion of the LICS payment that exceeds the subsidy that CMS would have paid under an actuarially equivalent plan represents a loss to the United States because it inflates overall Part D spending. Under Part D, different PDPs may offer different cost sharing requirements for the pharmacies that LICS members choose to visit. If a PDP is not actuarially equivalent and sets high cost sharing requirements for the pharmacies that LICS members use, CMS will pay more than it would have paid had the LICS members used the same pharmacies under a different PDP with lower

cost sharing requirements for those pharmacies. Thus, even though LICS members may go to the same pharmacies no matter what PDP they join, a plan that is not actuarially equivalent will increase CMS's program costs by claiming higher LICS payments than an actuarially equivalent plan. Moreover, even if the LICS payments to an ineligible Part D sponsor did not increase CMS's overall costs, CMS would not have paid the LICS subsidies to the ineligible sponsor.

3. Reinsurance Payments

74. CMS pays the sponsor a reinsurance subsidy to cover the Part D share of drug costs above an enrollee's catastrophic threshold. CMS pays the subsidy in the form of a monthly estimated amount based on the information in the sponsor's bid. After the contract year, CMS adjusts its estimated payments based on the actual reinsurance costs set forth in the sponsor's PDE reports. 42 C.F.R. § 423.329(c)(ii).

4. Risk Sharing Payments

- 75. CMS shares part of the insurance risk of the Part D program with plans by limiting the plans' losses or profits if plan spending turns out to be much different from the spending estimated in the plans' bids. Based on the sponsor's total spending during the year, CMS will make a risk sharing payment to the sponsor if the sponsor's spending was much higher than the bid, or receive a risk sharing payment from the sponsor if the sponsor's spending was much lower than the bid.
- 76. Under CMS's payment system, the sponsor has full risk if its actual spending falls between 95 percent and 105 percent of the bid. Within that range, CMS will not pay the sponsor for costs above the bid amount or receive payment for cost savings below the bid amount.
- 77. If the sponsor's actual costs exceed 105 percent of the bid, CMS pays the sponsor a percentage of the excess costs (*i.e.*, plan losses). For plan spending that is between 105 and 110 percent of the bid amount, CMS pays 50 percent of the excess costs. For plan spending above 110 percent of the bid, CMS pays 80 percent

of the excess costs. Conversely, if the sponsor's actual costs are below 95 percent of the bid, the sponsor must pay CMS a percentage of its gains (profits). For actual costs between 90 and 95 percent of the bid amount, the sponsor must pay CMS 50 percent of its profit (the amount between 90 and 95 percent of the bid amount). For actual costs below 90 percent of the bid, the sponsor must pay CMS 80 percent of its profit (the amount between the actual cost and 90 percent of the bid amount).

- 78. CMS determines the amount of risk sharing payments based on the PDE reports that the sponsor submits.
- 79. If a plan submits a bid that overstates its estimated costs, CMS will overpay the plan because the plan will keep some or all of the difference between the overstated bid and its actual costs as additional profit. The profits are in addition to the profit margin that the plan already included in its bid. Moreover, by overstating costs the plan protects itself from loss (the risk that its costs will exceed the bid), thus leaving CMS with most or all of the insurance risk and the plan with little or none.

V. HUMANA'S WALMART PLAN

- 80. Since 2010, Humana has contracted with CMS to operate a national PDP that Humana has marketed as the "Humana Walmart-Preferred Rx Plan" and "Humana Preferred Rx Plan" (collectively, the "Walmart Plan"). The Walmart Plan is a "basic" plan that offers standard coverage. Since its inception, Humana has offered the Walmart Plan in all fifty states as well as Puerto Rico. Humana changed the name of the plan from "Humana Walmart-Preferred Rx Plan" to "Humana Preferred Rx Plan" in 2014 after introducing a new co-branded PDP with Walmart known as the "Walmart Enhanced Plan." From 2014 to the present, Humana has offered the Walmart Plan for "basic" coverage and the Walmart Enhanced Plan for "enhanced alternative" coverage.
- 81. From its inception, the Walmart Plan has been one of the largest PDPs in the country. The Walmart Plan's average monthly membership was nearly

- 22 -

{00067353; 4 }

13 14 15

16 17

18 19

20 21

22

23 24

25

26

27 28

968,000 in 2011, 1.5 million in 2012, 1.8 million in 2013, and 1.7 million in 2014. Between 2011 and 2014, Humana has received approximately \$3.2 billion in direct subsidies from CMS for the Walmart Plan. Between 2011 and 2014, CMS paid Humana over \$4.357 billion in LICS subsidies under the Walmart Plan, of which over \$469 million were payments made after adjusting for Humana's actual costs.

82. CMS has assigned contract numbers S2874, S5552, and S5884 to the Walmart Plan. CMS divides the contracts into 35 geographic regions (comprising the 50 states plus Puerto Rico) and has assigned Humana a separate plan ID for each region in which it has been approved to operate. Humana submits a separate annual bid for each geographic region. To date, Humana has submitted 210 annual bids for the Walmart Plan.

Benefit Structure A.

- 83. The Walmart Plan purports to provide actuarially equivalent standard coverage. The Walmart Plan uses the defined standard for three of the four Part D coverage phases: the deductible, the coverage gap, and catastrophic coverage. It is only in the ICL phase (between the deductible and the ICL) that the Walmart Plan departs from the defined standard through the use of a different cost-sharing structure. Accordingly, it is only in the ICL phase that Humana must establish that the value of the benefits offered under the Walmart Plan is actuarially equivalent to defined standard coverage.
- 84. For the ICL phase, the Walmart Plan, like other Part D plans, uses a tiered pharmacy and tiered formulary benefit structure. Humana classifies pharmacies into four groups: a preferred mail order pharmacy, a preferred retail pharmacy, non-preferred mail order pharmacies, and non-preferred retail pharmacies. Preferred pharmacies are those with which Humana has negotiated price discounts under the PDP, while non-preferred pharmacies are all other network pharmacies at which a beneficiary may fill a prescription. Under the Humana benefit structure, members who fill their prescriptions at a preferred pharmacy have

pna

a lower cost share percentage than those who fill their prescriptions at non-preferred pharmacies.

- Pharmacy, which is a wholly-owned subsidiary of Humana. Prior to June 2015, Humana Pharmacy was known as RightSource. The preferred retail pharmacy is Walmart's network of retail pharmacies, including Walmart, Sam's Club, and Neighborhood Market. All other mail order and retail pharmacies in the network, including Walgreens, CVS, and Rite Aid, are "non-preferred." Humana encourages members to use RightSource and Walmart by reducing its members' cost sharing obligation at those pharmacies while increasing the cost sharing obligation at non-preferred pharmacies.
- 86. Under the tiered formulary, Humana divides covered drugs into five tiers. Tiers 1 and 2 constitute generic drugs, which are typically less expensive, while tiers 3 through 5 comprise brand name drugs. Under Humana's benefit structure, members pay more (have a higher cost share percentage) for brand name drugs than for generics.
- 87. Humana uses the combination of the tiered formulary and pharmacy type to determine the value of the Part D benefit (and thus cost sharing) for individual members. For example, a member who fills a prescription at Walmart with a tier 1 generic drug will have copays as low as \$1 per prescription in the ICL phase. A member who fills a prescription for a brand name drug at a non-preferred pharmacy, by contrast, will incur a high copay or coinsurance. Thus, the Walmart Plan's benefit structure incentivizes members to fill prescriptions at preferred pharmacies, and to choose generic drugs over brand name drugs.

B. Development of the Bids

1. The PDP Strategy Team

88. Humana's PDP Strategy Team oversees the actuarial valuation and bid preparation of Humana's Part D plans, including the Walmart Plan. The PDP

Strategy Team includes managers from the following Humana divisions: Senior Products, Senior Products Finance, Senior Products Actuarial Rx ("Actuarial Rx"), Product Design, and Sales & Marketing.

- 89. Actuarial Rx is responsible for many of the assumptions in Humana's bids. The division comprises four teams: PDP Pricing & Assumptions, MA-PD Pricing, Medicare Group Rx Pricing, and Modeling & Tools. The head of Actuarial Rx is Actuarial Director David Pottschmidt. The head of PDP Pricing & Assumptions is Actuarial Director Matt Hayes.
- 90. Actuarial Rx uses information from the other divisions within the PDP Strategy Team to form its bid assumptions. In particular, Actuarial Rx uses information from Senior Products and Sales & Marketing to estimate how Humana's planned business activities will affect member behavior, including the amount that the members will spend at different pharmacy types.
- 91. Within Senior Products, the Humana employee directly responsible for providing information to Actuarial Rx about the effect of business activities on member utilization is Strategic Consultant Carl Koontz. From approximately 2011 to 2014, Mr. Koontz reported to Vice President of Senior Products Administration Susan Diamond, who in turn reported to Alan Wheatley, Humana's President of Medicare, Medicaid, and Long-Term Care. In or around 2015, Humana promoted Ms. Diamond to Vice President of Corporate Finance and replaced her within Senior Products Administration with Raymond Daub, who currently manages Mr. Koontz. Ms. Diamond, Mr. Daub, and Mr. Koontz were and/or are the representatives from Senior Products on the PDP Strategy Team.

2. The Role of Milliman

92. Humana develops its bids in conjunction with Milliman, an external actuarial firm operating under contract with Humana. Milliman's services include populating the BPT using its proprietary bid model, assisting Humana in the development of certain bid assumptions, documenting bid assumptions, and

- 25 -

justifying bid assumptions to CMS during desk audits. Milliman serves as the Part D Certifying Actuary for Humana's Part D bids.

4 5

3

93. The Part D Certifying Actuary for the Walmart Plan is Milliman Principal and Consulting Actuary Douglas Proebsting. Mr. Proebsting reports to Mr. Pottschmidt and communicates regularly with Mr. Hayes.

8

6

The process of preparing Humana's bids typically begins in January, when Humana and Milliman begin to prepare assumptions for the upcoming contract year. Humana and Milliman use claims experience from prior years (if available) as well as the claims experience accumulating in the current year to make projections about Humana's future costs.

10 11

12

Milliman works with Humana's actuaries between January and June to refine the assumptions in the bids and to prepare the bids and supporting documentation for submission to CMS. Once the bids are submitted, Milliman typically works on a reduced schedule during the desk review, and rarely performs services once CMS approves the bids. Thus, the firm's engagement generally covers only the months between January and June of each year.

provide Milliman with information about its operations beyond the minimum

amount needed to prepare the Part D bids. In the case of many assumptions,

assumptions internally and provides Milliman with only the final numbers and brief

including the assumption about member utilization, Humana develops the

descriptions of the justifications. Milliman often incorporates Humana's

assumptions into the bids, even though it may lack the information needed to

Consistent with the limited scope of the engagement, Humana does not

13 14

15

16 17

18 19

20

21

22 23

24

25

26

27

28

determine whether the assumptions are reasonable. When Milliman certifies the bid projections for Humana's Walmart Plan, it lists the data and assumptions that Humana had provided Milliman in final form to incorporate into the bids. Milliman's certifications state that it relies on Humana for data and assumptions related to member utilization of preferred and non-preferred pharmacies. - 26 -

97.

3. Actuarial Valuation

percentages for all pharmacy types is 25 percent. Humana calculates the effective coinsurance percentage by forecasting the allowed amount at each pharmacy type.

98. To forecast the allowed amount for each pharmacy type, Humana must make utilization assumptions for the different pharmacy types. For preferred pharmacies, Humana makes assumptions about the "preferred mail dispensing rate".

defined standard if the weighted average of the effective member coinsurance

The Walmart Plan's benefit structure is actuarially equivalent to the

pharmacies, Humana makes assumptions about the "preferred mail dispensing rate" and the "preferred retail rate"—the rates at which members use RightSource and Walmart, respectively. Humana additionally makes assumptions about the relative spending at non-preferred mail order and retail pharmacies. In making its assumptions, Humana relies on member utilization from prior years (if any) as well as assumptions about future drug costs and member behavior, including the expected impact on member behavior of any business activities to increase utilization at preferred pharmacies and the expected impact on member behavior of

C. Bid Submissions

any proposed changes to the benefit structure.

99. Since 2010, Humana has submitted 35 bids to CMS each year for the Walmart Plan by preparing and filing BPTs. Through the BPTs, Humana must list the effective coinsurance percentages for the proposed plan and test whether those percentages are actuarially equivalent to the defined standard. The BPT requires Humana to list and test the percentages separately for each coverage phase. Once approved, the bids have been incorporated into Humana's Part D contracts with CMS.

100. In each PDP bid submitted to date, Humana has represented that the Walmart Plan's Part D benefits are actuarially equivalent to the defined standard even though, as set forth below, Humana knows that is not true. Humana's 2011 and 2012 bids, for example, reported effective member coinsurance percentages of

- 27 -

24.2 percent and 25 percent, respectively. Humana's 2016 bids reported an effective coinsurance percentage for the ICL phase of 25.5 percent. (25.5 percent is the maximum cost sharing percentage that meets the actuarial equivalence requirement.) Through these statements, Humana represented to CMS that the value of the benefits in its bids were actuarially equivalent to (or better than) the defined standard. At the same time that it reported those expected coinsurance percentages to CMS, Humana was internally using its actual valuation of the plan benefit, which showed that Humana believed the plan was worth much less than Humana represented to CMS.

- 101. Humana supports the effective coinsurance percentage in its bids by reporting its projected cost-sharing and allowed amounts in the BPT. The BPT requires Humana to break out the projections into eight subcategories for different combinations of drugs (generic, preferred brand, non-preferred brand, and specialty) and points of service (retail and mail order).
- 102. The BPT does not require Humana to report its estimates for member utilization at preferred pharmacies versus non-preferred pharmacies, nor does it require Humana to report how it expects member utilization of those pharmacies to differ between LICS and non-LICS members. Although not reported in the BPT, estimated member utilization of preferred pharmacies and the estimated rates at which LICS and non-LICS members use preferred pharmacies have a significant effect on the cost-sharing and allowed amounts that Humana reports in the bids.
- 103. Humana prepares its utilization assumptions between January and June of each year as part of the bid preparation process. Humana develops the assumptions internally and provides them to Milliman in final form. Milliman then inputs the assumptions into its bid model in order to populate the BPT.
- 104. Because member utilization at preferred and non-preferred pharmacies affects member cost sharing and allowable costs, the assumptions that Humana provides to Milliman affect the BPT projections for the cost sharing and allowed

1 amounts in the ICL phase and the effective coinsurance percentage for the ICL 2

3

phase.

5

105. In each contract year, Humana's bids have incorporated the assumption that RightSource and Walmart would have high utilization rates and non-preferred pharmacies would have low utilization rates, which is information that Humana knows is not accurate, complete and truthful. These assumptions are broken down by LICS status and pharmacy type:

	8
	9
1	0
1	1
1	2
1	3
1	4
1	5

LICS Members Non-LICS Members RightSource Walmart Total RightSource Walmart Total Preferred Preferred 2011 Bid | 5% 71% 76% 5% 90% 95% 2012 Bid | 12% 66% 78% 28% 65% 93% 2013 Bid | 30% 30% 60% 30% 60% 90% 2014 Bid 8% 29% 37% 22% 58% 81% 2015 Bid | 8% 23% 31% 24% 53% 77% 2016 Bid | 12% 19% 31% 27% 52% 79%

17 18 19

20

21

22

16

106. CMS relies on the information in Humana's bids in determining whether to enter into a PDP contract with Humana. Had CMS known that the information in Humana's bids was not accurate, complete and truthful and that the plan was not actuarially equivalent to the defined standard, CMS would not have awarded Humana a Part D contract, paid Humana substantial capitation payments for providing beneficiaries with plans that required an average 25% cost share, or paid Humana substantial subsidies for the premiums and cost sharing for lowincome beneficiaries.

23 24

VI. THE DEFENDANT'S FRAUDULENT PRACTICES

25 26

107. From the beginning of the Walmart Plan, Humana's bids for a Part D contract have been knowingly false or fraudulent because they have been based upon information that was not accurate, complete and truthful, as demonstrated by

4

5 6 7

10

12 13

11

25

26

27

28

Humana's simultaneous use of different and accurate assumptions for its own internal budget projections for reporting to its management and shareholders.

108. For each year that Humana submitted bids based on the Walmart Plan, the assumptions about member utilization at RightSource and Walmart that Humana used to support those bids were much higher than Humana actually believed or that were borne out by experience. Instead of submitting bids that reflected either its actual estimate of projected utilization rates or its experience with actual utilization rates, Humana created assumptions specifically for use on the bids submitted to CMS that assumed large increases in RightSource and Walmart utilization that Humana knew at the time it submitted the bids would not happen. Humana incorporated the false assumptions into each of the 35 bids it submitted each year for the Walmart Plan.

109. As set forth below, Humana manages actuarial assumptions throughout the year for use in the bids and in setting its internal operating budget. For nearly all assumptions, the amount that Humana uses in the bids is the same as the amount Humana uses to set its budget. In the case of preferred utilization under the Walmart Plan, however, Humana maintains two sets of books. Internally, Humana prepares its budget on the assumption that utilization at RightSource and Walmart will remain low, as it historically has, resulting in Humana paying a smaller share of covered drug costs in the ICL phase than it would under the defined standard, which would require that Humana pay 75 percent. Humana budgets for beneficiaries and CMS to fund the difference through member cost sharing that exceeds the 25 percent they would pay under the defined standard, with Humana earning greater profits by not covering the costs it contracts to cover. For purposes of the bids, however, Humana assumes that utilization at RightSource and Walmart will rise significantly, resulting in Humana paying 75 percent of the covered drug costs in the ICL phase and thereby complying with its contractual requirement that the Plan be actuarially equivalent to the defined standard. Humana's effective coinsurance

percentage in the bids that Humana reports to CMS has been significantly higher each year than the effective coinsurance percentage Humana uses to set its own budget.

- 110. Milliman warned Humana repeatedly that the assumptions that Humana had created for the bids were "aggressive" and inconsistent with Humana's actual experience. Humana knew that the bid assumptions contradicted Humana's internal estimates, but did not revise its bids or reveal to Milliman that they did not reflect Humana's internal actuarial valuations of the Walmart Plan.
- 111. By using false information in each year it presented a bid, Humana represented to CMS that the Walmart Plan was actuarially equivalent to the defined standard, when Humana knew that this was not true. Not only would Humana not have received the Part D contract had it provided accurate, complete and truthful information about the Walmart Plan, by providing beneficiaries with fewer benefits than required Humana has shifted nearly \$412 million in costs onto beneficiaries, and in the case of LICS members, onto CMS, resulting in an equal amount of unlawful profits for Humana.
 - A. Humana Knowingly Submits Bids Based on Information that is Not Accurate, Truthful and Complete as Certified
- 112. The falsity of Humana's PDP bids is demonstrated by Humana's simultaneous employment of two actuarial models: the model that Humana uses internally to estimate its financial results for its senior management and shareholders, which represents Humana's most accurate assessment of what it expects will occur, and the model that Humana uses to prepare its bids for CMS, which presents a different valuation that Humana has altered to misrepresent that the Walmart Plan meets Part D requirements that it does not meet.

1. Humana's Internal Analysis

113. The actuarial model Humana uses to set its annual budget forecasts Humana's future claims expense based on past experience and Humana's assumptions about future events. Humana refines the model over time by

comparing model results to actual results and making changes in the assumptions or techniques used. Humana runs the model throughout the year, making adjustments as needed. The results from the model represent Humana's best estimate of actuarial value for its Part D plans. Humana refers to the model as the "Regular" or "Budget" Model.

- 114. The assumptions used in the Regular Model are the responsibility of Actuarial Rx, the same division that is responsible for preparing Humana's Part D bids. The group within Actuarial Rx that sets the assumptions used in the Regular Model is PDP Pricing & Assumptions, led by Matt Hayes, the same group that sets the assumptions for Part D bids. Thus the actuaries who set the assumptions in the Regular Model are the same actuaries who prepare the bids for CMS.
- 115. Humana begins to prepare its budget shortly after CMS releases information in the early fall about competitor premiums, which informs Humana about the competitiveness of its plan and thus its potential membership in the coming year.
- 116. Because Humana's information about the Walmart Plan at the time it submits its final bids in August remains substantially (if not entirely) the same at the time it prepares the budget projections, the assumptions used in the bids should be similar to the assumptions used in the budget projections. For similar reasons, the actuarial assumptions in the bids should be the same as the actuarial assumptions in the Regular Model (from which Humana sets its budget projections) because the bids submitted to CMS must reflect Humana's best estimate of the actuarial value of its Part D Plans.
- 117. In nearly all respects, Humana uses the same assumptions in the Regular Model that it uses in its bids. The primary exception is the assumptions about member utilization of preferred pharmacies under the Walmart Plan, including related assumptions about the number of LICS members in the plan.

2. Humana's False Analysis Provided to CMS

- pharmacies, *i.e.*, Walmart and RightSource, Humana does not use the assumptions in the Regular Model, but rather creates different utilization assumptions specifically for purposes of the bids. Humana does not reconcile the bid assumptions to the assumptions in the Regular Model, nor does it use the bid assumptions for any purpose other than the bids.
- 119. Humana has used two sets of books with respect to preferred utilization since the beginning of the Walmart Plan in 2011. In October 2013, Actuarial Rx documented this practice in an internal procedure, No. xxx-SPA-11Rx-Preferred Utilization ("Utilization Procedure"), which it prepared in response to a directive from Humana's Chief Actuary, Roy Goldman, to formally document its policies and procedures. The purpose of the Utilization Procedure was to "provide guidance in the development of preferred utilization assumptions for bids and budget," and it set forth "the activities performed by [Actuarial Rx] to develop the preferred utilization assumptions." Managing Actuary Lazar Ivetic prepared the Utilization Procedure and Matthew Hayes was listed as its original approver.
- 120. For the Regular Model, the Utilization Procedure followed Humana's general practice of making actuarial assumptions based on actual results. According to the Procedure, Humana "gathers the previous year's information and current year's actuals on preferred pharmacy utilization on a days [sic] basis" by region, month, and low-income status, and then analyzes the pattern or trend "to see if the current year's pattern will be ok to use for the projected period in our budgeting process. If the pattern is not flat, a projection to future years will be needed."
- 121. For the bids, however, the Utilization Procedure mandated a different procedure under which Humana would create assumptions about preferred utilization that were different—and more aggressive—than those it used in the Regular Model:

For Bids, a separate projection is prepared by the Senior Products Finance, and is used as an assumption for the bids as this includes any programs that will be implemented during the projected period to increase preferred pharmacy utilization. Documentation of each of these programs is needed from Senior Products Finance.

Due to risk share and bid mechanics it is better to err on the side of aggressive in the bids.

Humana Procedure No. xxx-SPA-11Rx-Preferred Utilization (Oct. 21, 2013) (emphases added). Thus, as documented in the Utilization Procedure, Humana prepares its assumptions about member utilization of preferred pharmacies in the Regular Model based on actual results, but prepares its assumptions about member utilization of preferred pharmacies in the bids based on a "separate projection" that Actuarial Rx receives from Senior Products Finance and that intentionally "err[s] on the side of aggressive." The Utilization Procedure does not require Humana to reconcile the different amounts or otherwise determine that it is valid to use a different and more favorable estimate in the bids. Instead, the Procedure states that Humana should change the estimate for the bids in order to gain a more favorable bidding and risk share position with CMS.

- 122. Once Actuarial Rx receives the "separate projection" from Senior Products Finance, it provides it to Milliman to incorporate into the bids and also enters it into a second internal actuarial model, known as "Milliman" or "Match Milliman," which Actuarial Rx creates and runs exclusively in the months when it prepares the bids. The purpose of Match Milliman is to emulate Milliman's proprietary bid model, allowing Humana to replicate and confirm Milliman's work. During the bid season, Humana refines Match Milliman so that it replicates the final estimates in Humana's bids. Consistent with this purpose, Humana prepares Match Milliman using the assumptions that it provides to Milliman for use in the bids.
- 123. Because Humana must use true, accurate, and complete estimates in its bids, the assumptions Humana uses in the bids should be the same as those it follows internally, and accordingly the assumptions in Match Milliman should be

that the Regular Model is consistent with Match Milliman and for updating the Regular Model at the time it submits each bid so that Humana uses the same assumptions internally and in the Part D bids. If Humana were preparing its bids truthfully, the Regular Model and Match Milliman would converge by the time Humana submits the bids, so that either model would produce the same actuarial estimates as the bids.

124. For the Walmart Plan, however, the Regular Model and Match Milliman have not converged because, as set forth in the Utilization Procedure, Humana's assumptions about member utilization at RightSource and Walmart are different for each model. At the time Humana submits the bids, it updates the Regular Model so that it conforms to Match Milliman and the bid on nearly every assumption—the major exceptions being utilization at Walmart and RightSource and the percentage of LICS members in the Walmart Plan. For those key assumptions, Humana does not update the Regular Model to reflect the assumptions in the bid and Match Milliman. Instead, Humana intentionally uses different assumptions in the Regular Model and intentionally disregards the different actuarial estimates that result.

125. Actuarial Rx monitors the differences between the Regular Model and Match Milliman. One monitoring tool is the "bid-budget-actual variance" report, which tracks the differences between Humana's bids, budgets, and actual results. The reports that Actuarial Rx has prepared for Humana's internal use reveal significant differences in member utilization under the Walmart Plan between the estimates in Humana's bids and the estimates in its budgets. As a matter of actuarial practice, such consistently large differences would require Humana to reevaluate the actuarial soundness of its bids. Humana has failed to do so.

126. Instead of reevaluating the actuarial soundness of its bids, Humana changed its internal reporting. Beginning in 2012, Humana excluded its bid

estimates from the bid-budget-actual variance. From that point on, Actuarial Rx reported only the "budget-actual variance," which showed only the minor differences between Humana's budget estimates and its claims experience. Humana no longer reported the large differences between the budget estimates or actual experience and its bid estimates.

127. Because Humana's bids to CMS have not reflected Humana's actual estimates for the Walmart Plan, which Humana has recorded in a separate set of books that it uses to operate its business, Humana has knowingly submitted bids each year that were not truthful, accurate, or complete. To obtain approval of the bids and Part D contracts, Humana falsely certified to CMS that the bids were truthful, accurate, and complete.

B. Humana Knowingly Misrepresented that the Walmart Plan Was Actuarially Equivalent to the Defined Standard When it Was Not

128. Since the beginning of the Walmart Plan, Humana's internal analyses, prepared for its senior management and shareholders, have concluded that the Walmart Plan was not actuarially equivalent to the defined standard, contrary to Humana's representation to CMS. Humana's internal analyses showed that the Walmart Plan's overall effective coinsurance percentage in the ICL phase is higher than the fixed standard of 25 separates.

than the defined standard of 25 percent:

Contract Year	Actuarial Equivalence Requirement (Bid)	Humana's Internal Projected Effective Coinsurance Percentage (Budget)
2011	25%	32.2%
2012	25%	35.3%
2013	25%	33.2%
2014	25%	29.6%
2015	25%	28.0%

129. These internal estimates have been borne out by actual claims

experience:

Contract	Humana's Internal Projected Effective	Humana's Actual Effective
Year	Coinsurance Percentage (Budget)	Coinsurance Percentage
2011	32.2%	35.3%

- 36 -

COMPLAINT

2012	35.3%	35.5%
2013	33.2%	32.4%
2014	29.6%	27.9%
2015	28.0%	28.1%

The striking difference between Humana's bid and actual effective coinsurance percentages is primarily due to its assumptions regarding utilization at RightSource and Walmart. In the Regular Model, Humana has accurately forecasted low utilization at RightSource and Walmart, especially among LICS members. In contrast, when preparing its bids, Humana has assumed large increases in utilization at RightSource and Walmart, including among LICS members.

Walmart Plan has been worth less than the defined standard overall, the Walmart Plan has been worth less than the defined standard every year in each of the 35 geographic regions for which Humana submits a bid. Between 2010 and 2014, for the 2011–2015 contract years, Humana submitted 175 bids to CMS representing that the Walmart Plan was actuarially equivalent to the defined standard in each region. For every single one of those bids, Humana's actual results have shown that the Walmart Plan was worth less than the defined standard. Moreover, Humana has budgeted for the Walmart Plan to be worth less than the defined standard in 2016 in each of the 35 geographic regions. Thus, the Walmart Plan's benefits have been worth less (or are expected to be worth less) than the defined standard for each of the 210 bids that Humana has submitted to CMS.

pharmacies are unrealistic because of its understanding of beneficiary behavior.

LICS members are less price sensitive than other members because they do not bear the cost of their choice of pharmacies. Accordingly, a LICS member would have no reason to switch from a neighborhood pharmacy, such as CVS or Walgreens, to a Walmart retail store which may not be anywhere near where they live. Nor would they have an incentive to switch to a mail order pharmacy, which would have no

- 37 -

(00067353; 4)

1

4 5

7 8 10

6

11 12 13

14

15 16 17

18

19 20 21

22

23 24

25

26

27 28 cost savings for them. While a non-LICS member might have some reason to switch to save a little money, member behavior is still very stubborn, as people tend to stick to their patterns.

- 132. Humana has papered its false bid assumptions internally by designing "business initiatives" that will purportedly increase utilization at RightSource and Walmart. Carl Koontz, a Strategic Consultant for Senior Products Finance, is responsible for creating the business initiatives, which he provides to Actuarial Rx to review and incorporate into Humana's bids. Based on substantial experience and industry knowledge, Humana has known that the initiatives would not actually increase utilization. Accordingly, Humana does not include the initiatives in its assumptions in the Regular Model or its budget projections, even though they are the only purported basis for the "separate projections" about preferred utilization that Humana incorporates into its bids to CMS.
- 133. Had CMS known that the benefits in the Walmart Plan were worth significantly less than qualified prescription drug coverage, i.e., the defined standard, it would not have approved or renewed Humana's Part D contract. Humana knew that the actuarial value of the Walmart Plan was less than the defined standard and that CMS would not approve its bids if they admitted that fact, because a PDP must provide benefits equal to or greater than the defined standard in order to be eligible for a Part D contract. 42 U.S.C. § 1395w-102; 42 C.F.R. § 423.104. CMS has consistently advised that inability to provide actuarially equivalent or better benefits renders a plan ineligible for a Part D contract. For example, in an Actuarial User Group Call on April 26, 2012, a prospective Part D sponsor asked CMS: "If a bid is not able to obtain actuarial equivalence and remain within the copayment thresholds, is there flexibility in the limits to reach equivalence?" CMS responded: "No."

1. Humana's Bids for the 2011 Contract Year Were Knowingly False or Fraudulent

Humana first introduced the Walmart Plan for the 2011 contract year. Humana began preparing the initial bids in the spring of 2010. At the time, Humana anticipated that the Walmart Plan would offer enhanced coverage rather than standard coverage and designed the plan to attract non-LICS beneficiaries through a low supplemental premium and low copayments at RightSource and Walmart. Because of those features, and because CMS does not auto-assign LICS members to enhanced plans, Humana assumed the Walmart Plan would have few LICS members and high usage of preferred pharmacies. In designing and testing plan benefits, Milliman wrote Humana on May 16, 2010 that "[w]e are assuming only 10% of members will be low income by CMS's definition. We think 10% is somewhat conservative since this plan will not be eligible to accept auto-assigned members, and since we expect the supplemental premium . . . to deter LI seniors from enrolling."

Humana that "[i]t is possible that the Walmart product may need to be significantly modified to pass CMS's requirements." During desk review, Humana determined that CMS was likely to reject its bids because the proposed out-of-pocket cost for the Walmart Plan was unacceptably similar to that of another Humana PDP, and Part D regulations require that different PDP plans proposed by the same sponsor cannot be substantially similar to each other. Rather than withdraw the bids, in a hastily called "fire drill," Humana quickly recast the Walmart Plan as a standard plan instead of an enhanced plan. The switch eliminated the supplemental premium and meant that Humana would provide only standard coverage.

136. As a result of the change in coverage, Humana now expected that the Walmart Plan would be eligible to receive auto-assigned LICS beneficiaries from CMS. Accordingly, Humana updated its assumption for the percentage of LICS

members in the Walmart Plan from 10 percent in the original enhanced coverage bids to 22–23 percent in the new standard coverage bids. A consequence of this increase was that the Walmart Plan would no longer be actuarially equivalent under the original plan benefits because LICS members utilize preferred benefits less than non-LICS members. As Milliman had recently informed Humana with respect to generic drugs, "[s]ince low income members receive cost sharing subsidies, they have little incentive to switch to lower cost generic alternatives." Humana knew that this same principle applied to the pharmacies that LICS members used.

137. In order for the revised bids to reach actuarial equivalence under the revised preferred utilization assumptions, Humana would have had to increase benefits by lowering member cost share. However, increasing benefits would have resulted in lower profit margins necessitating premium increases to maintain the previous margin levels. Increasing the premium, though, would have reduced the number of beneficiaries who might enroll in the plan and made the co-branded plan less appealing to Walmart. While Humana made some benefit and premium changes between the initial and revised bids, it decided to reach actuarial equivalence in the bids primarily through a different strategy—making a massive change in the preferred utilization assumption for LICS members.

138. Between the original and final bids, Humana increased the assumption for the percentage of utilization at Walmart by LICS members from 50 percent of retail utilization in the original bid to 75 percent of retail utilization in the final bid. This increase was completely inconsistent with the change in the projected LICS population. The LICS members that Humana had estimated in the original bids were relatively likely to use Walmart because they would have chosen the Walmart Plan voluntarily, not through CMS auto-assignment. In the final bids, however, Humana expected CMS to auto-assign a large portion of its LICS members. The LICS members that CMS assigned would be less likely to fill prescriptions at Walmart because they would not have chosen the Walmart Plan themselves and

might not even live near a Walmart store. Thus, adding such members to the original projected LICS population for the updated bids should have resulted in a lower overall assumption for LICS member utilization at Walmart. Instead, Humana assumed a major increase. Based on its experience, Humana had reason to know this was utterly implausible.

- 139. Based in large part on the fabricated increase, Humana assumed in the final bids that Walmart Plan members would use preferred pharmacies—RightSource and Walmart—for 95 percent and 76 percent of total utilization for non-LICS and LICS members, respectively. On the basis of that assumption, Humana represented to CMS that the bids were actuarially equivalent.
- 140. At approximately the same time that Humana was increasing the utilization assumption in the bids, Humana updated the Regular Model to reflect the new plan benefits. Humana's updates did not include the increased preferred utilization assumption, however. Instead, for that assumption, Humana used a different percentage in the Regular Model than the percentage it had used in the bids. For its internal estimates, Humana assumed that utilization at preferred pharmacies RightSource and Walmart would be significantly lower than the bid assumptions. On October 4, 2010, for example, Humana's internal estimates assumed that Walmart would account for 85 percent of retail spending by non-LICS members, but only 15 percent of retail spending by LICS members. Based on those internal assumptions, Humana estimated that the Walmart Plan's effective coinsurance percentage in the ICL phase would be 30.7 percent.
- 141. Humana adjusted its internal assumptions despite not having enrolled a single beneficiary in the new plan. Without new information about membership or costs, there was no basis for Humana to change the assumptions it had used in the bids if the latter was in fact based on accurate, complete, and truthful information.
- 142. Humana prepared its annual budget on the basis of the assumptions in the Regular Model. For the 2011 contract year, Humana budgeted for the Walmart

7

10

8

11 12 13

14 15

17 18

16

19 20

21

22 23

25

24

26 27

28

1 Plan's effective coinsurance percentage in the ICL phase to be 32.2 percent. Thus, Humana expected to provide significantly fewer benefits than it represented in its bids as a condition of obtaining the contract, with members paying a higher percentage of drug costs. The additional costs that the members incurred would translate to higher profits for Humana, and in the case of LICS members, higher costs for CMS.

2. Humana's Bids for the 2012 Contract Year Were Knowingly False or Fraudulent

- 143. Humana continued the fraudulent scheme the following year. At the time it prepared its bids for the 2012 contract year, the Walmart Plan was operational and Humana was receiving claims data from the new membership. The emerging data showed that the Walmart Plan's effective coinsurance percentage was running at approximately 35 percent, an amount even higher than Humana's budget projection (32.2 percent). The higher rate of member cost sharing was due primarily to members using preferred pharmacies in the manner that Humana had projected internally.
- 144. Due in large part to high member cost sharing, the Walmart Plan was quickly becoming a major financial success for Humana, having attracted large numbers of members and earning high margins. As Humana prepared the bid, it knew that it would have to increase benefits significantly for the Walmart Plan to be actuarially equivalent to the defined standard in 2012 and that the increased benefits would significantly reduce Humana's profits.
- 145. On March 28, 2011, Milliman wrote to Humana regarding the first two months of claims data from the new plan. Among the results that Milliman reported was the fact that "[u]se at Walmart stores is lower than we assumed, particularly for low income members." In particular, Milliman found that Walmart use compared to other retail pharmacies (i.e., not including mail-order pharmacies, which Humana's

utilization percentages usually include) averaged 67 percent for non-LICS members and only 13 percent for LICS members.

146. Less than a month later, on April 15, 2011, Milliman wrote Humana regarding pricing scenarios for the 2012 bid. According to Milliman, the scenarios "are intended to summarize the impact of critical bid assumptions on pricing and benefit results." As with the prior letter, Milliman informed Humana that utilization at Walmart relative to other retail pharmacies was significantly lower than Humana had assumed in its prior bid: "Through February, the average retail Walmart use was about 67% for non LI members and 12% for LI members." Milliman also informed Humana that the percentage of LICS members in the Walmart Plan was significantly higher than Humana had estimated in the prior bids and was increasing monthly: "The 2011 bids assumed a LI membership percentage of 22%. The actual 2011 LI member mix is about 33% through March and has been increasing monthly."

LI membership percentage on the Walmart plan benefits and premiums." Milliman explained that "[a]s the projected Walmart use varies, the benefits need to be adjusted to reach an actuarially equivalent bid since the average cost sharing depends on the level of preferred network use." Based on that fact, Milliman concluded that "[a]t the low end of projected Walmart use (the current 67% non LI and 12% LI), the non-preferred benefits need to be significantly richer than the current 2011 benefits because the non-preferred benefits are weighted more heavily in the bid." According to Milliman, "the level of Walmart use has a larger impact on benefits than on premiums because the benefits always need to be adjusted back to Defined Standard equivalent levels. . . . Even a modest decrease in the projected Walmart use has a significant impact on the actuarially equivalent benefit plan." Milliman then warned:

- 43 -

1 Although we believe it is reasonable to expect the current level of Walmart use to increase, it is important that the 2012 bids reflect attainable goals. Humana will need to justify the 2012 bid assumptions during CMS desk review and audit. The difference between assumed Walmart use and actual Walmart use has a significant impact on member cost sharing in the ICL. The Walmart use assumption is particularly important so that CMS can expect that the benefits meet equivalence testing guidelines in 2012. 2 3 4 5 If we assume a high level [of] Walmart use for 2012 and the actual experience does not improve despite Humana's / Walmart's best 6 efforts, it would be very difficult to justify this assumption to CMS in 2012 or 2013 and beyond, particularly because CMS pays the majority of cost sharing for LI members through the LI cost subsidy. 7 We recommend that Humana and Walmart work together closely to establish NLI and in particular LI Walmart use initiatives and be 8 prepared to fully document these programs to us and to CMS during desk review of the 2012 bids. It is critical that both parties understand the importance of increasing LI preferred network in order to preserve the future viability of the Walmart PDP plan as it exists today. 10 11 April 15, 2011 Letter from Milliman to Humana (emphasis added). Despite 12 Milliman's warnings, Humana assumed a substantial increase in utilization at 13 Walmart for the 2012 bid. In a May 13, 2011 letter, Milliman informed Humana 14 that for its "largely final" results: 15 We updated the projected Walmart use as a percentage of total retail to 90% for non LI members and 75% for LI members. As we discussed, Humana will need to support these assumptions to CMS. We reviewed the information that Humana prepared summarizing the estimated impact of each initiative aimed at increasing Walmart use for LI 16 17 members. We believe these targets are aggressive given current 18 Walmart use levels but are possible with effective programs. 19 Milliman also informed Humana that it had "updated the actuarially equivalent 20 benefits associated with the Walmart use assumptions from above," thus confirming 21 that Humana's "aggressive" assumption directly affected the level of plan benefits. 22 148. On May 19, 2011, shortly before submitting the 2012 Walmart Plan 23 bid, Humana held a "2012 PDP Market Call" meeting between Actuarial Rx and 24 Senior Products Finance. In a PowerPoint prepared for the meeting, Humana 25 identified "High Non-Walmart cost-share" as an area for "Walmart Risk 26 Mitigation." The presentation summarized the situation: 27 Non-preferred benefits are much leaner than the standard benefit. Higher than expected non-preferred use in 2011. 28 - 44 -

COMPLAINT

LIS: 86% non-preferred / 12% Walmart / 2% Mail.

NonLIS: 25% non-preferred / 53% Walmart / 22% Mail.

2011 savings from non-preferred = \$7 pmpm or \$84 million.

Adjustments must be made to bring back to actuarially equivalent.

The \$7 "pmpm" (per-member-per-month) "savings" represented the difference between the defined standard and the benefits that Humana had provided in 2011. By providing \$7 less than the defined standard per-member-per-month, the total value of the benefits that Humana provided in 2011 was \$84 million less than what Humana had contracted to provide. For Humana, the \$84 million in "savings" was additional profit.

- 149. The PowerPoint identified two options to make the Walmart Plan actuarially equivalent to the defined standard as required by law. The first was to "Improve non-preferred benefits and increase premium," which would have made the Walmart Plan less competitive in the marketplace and significantly less profitable for Humana. The second option was to "drive more use to Walmart," a preferred pharmacy.
- 150. Unlike improving benefits, there was little financial risk to Humana in making a favorable assumption about increased use of preferred pharmacies. If Humana improved benefits, it would eliminate the excess profits (\$84 million), increasing the financial risk of the plan. If Humana assumed higher usage at Walmart, however, the excess profit margin would remain in the bids and protect Humana from loss. If Humana realized the assumption, the Walmart Plan would be actuarially equivalent to the defined standard. If Humana did not realize the assumption, it would benefit from having provided lower value benefits (avoiding tens of millions of dollars in costs) and receiving excess LICS payments from CMS.
- 151. Humana decided to maintain its existing benefit structure and to assume that member utilization at preferred pharmacies would increase dramatically between 2011 and 2012 even though it had no basis for that assumption and did not

believe it would occur. At the meeting, Humana's executives "committed"
themselves to "driving 90% NonLI and 75% LI retail use to Walmart in 2012."
These proposed increases represented an incredible 23% and 63% increase,
respectively, over Walmart retail utilization in 2011. The assumed increase for
LICS usage was particularly unwarranted because Humana knew that it is hard to
change the behavior of LICS members who are not price sensitive.

- 152. In the 2012 bid, Humana ultimately assumed even more aggressive increases in utilization of preferred pharmacies, assuming use by LICS and non-LICS members would be 78 percent and 93 percent of total utilization, respectively. On the basis of the assumed increases, Humana represented in the BPT and certified to CMS that the Walmart Plan was actuarially equivalent to defined standard coverage. CMS approved Humana's 2012 bids on the basis of the actuarial equivalence representation.
- actuarial equivalence were not the assumptions that Humana included in the bids to claim actuarial equivalence were not the assumptions that Humana used internally to set its budget. Actuarial Rx did not incorporate the assumed utilization increases into the Regular Model that it used to project its budget. Instead, Actuarial Rx prepared budget projections estimating that the Walmart Plan's effective coinsurance percentage in 2012 would be approximately 35 percent, which was close to Humana's actual claims experience at the time it prepared the bid, and significantly higher than the defined standard. Rather than assume that Walmart utilization would increase significantly between 2011 and 2012, causing a precipitous drop in cost sharing, Actuarial Rx assumed that cost sharing would stay the same as it had for 2011. Under that internal assumption, preferred utilization for LICS and non-LICS members would be 17 percent and 76 percent, respectively. As a result, Humana expected the value of the benefit to be substantially less than the defined standard, contrary to its representation to CMS.

3. Humana's Bids for the 2013 Contract Year Were Knowingly False or Fraudulent

154. Humana continued its fraudulent scheme the following year. On February 19, 2012, Milliman cautioned that the member utilization at Walmart that Humana could expect in 2013 was significantly lower than the member utilization that Humana had used in prior bids and was proposing for 2013 for both LICS and non-LICS members.

155. On May 17, 2012, Humana held a meeting to discuss the 2013 Walmart Plan bid. A PowerPoint prepared for the meeting admitted that actual cost sharing in the ICL phase tracked Humana's budget assumptions and not its bid assumptions: "2011 and 2012 actual 35%, driven by non-preferred pharmacy use." Humana again valued the excess cost sharing at \$7 in additional capitation revenue: "Reducing to 25% = \$7 PMPM net liability." Only weeks away from submitting the 2013 bid, Humana knew that cost sharing under the Walmart Plan was consistently and significantly higher than the defined standard and that Humana was profiting as a result.

Humana planned at the meeting to reduce cost sharing from 35 percent to 28.3 percent through internal "commitment to increase preferred utilization," with the "Remainder of ICL reduction [from 28.3 percent to 25 percent] through improved benefits." To move "from 35% to 28.3% cost share," Humana had to assume that preferred utilization would soar from 13 percent to 63 percent for LICS members and from 63 percent to 90 percent for non-LICS members. Thus, Humana would continue to rely primarily on a steep rise in preferred utilization, not improved benefits, to meet the actuarial equivalence requirement, notwithstanding that actual experience did not support that improbable assumption and that Humana did not use that same assumption for its internal budget projections.

- 47 -

6

8 9

12 13

11

1415

1617

18

1920

21 22

23

2425

26

2728

157. Humana's bids followed the strategy discussed at the meeting and the same strategy Humana had applied in 2012: Humana assumed that preferred usage would increase to 60 percent and 90 percent for LICS and non-LICS members, respectively.

158. In its internal documents, Humana justified the increased preferred utilization in the bids partly on the basis of seven business initiatives, or "campaigns," which would supposedly increase preferred utilization by 29.7 percent for LICS members and 11.1 percent for non-LICS members: "LIS Phone Number Sweepstakes," "Auto Assign Welcome Letter," "WM Calendar," "SSrx Savings Message," "Guidance Alert Savings," and "Additional VAIS." Humana knew that such results for these initiatives were fictional. For example, Humana knew that mailings such as the "Auto Assign Welcome Letter" do not change member behavior significantly, particularly among low-income members. Nonetheless, Humana assumed for purposes of the bids that the "Auto-Assign Welcome Letter" would increase preferred utilization among LICS members by 5 percent in 2013. Similarly, the "LIS Phone Number Sweepstakes" offered prizes if LICS members provided Humana with their phone numbers, which Humana could then call to solicit the members about filling prescriptions at Walmart. For the bid, Humana claimed that obtaining the phone numbers would result in a 9.9 percent increase in preferred utilization among LICS members, even though Humana knew that it had not increased preferred utilization among the many LICS members whose phone numbers it already possessed. Humana well understood that it had no basis for projecting a vastly different result to support the cost sharing numbers in its bid.

159. Based in part on its fraudulent utilization numbers, Humana represented in the BPT and certified to CMS that the Walmart Plan was actuarially equivalent to defined standard coverage. Based upon those representations, CMS approved the 2013 bid.

assumptions about utilization and representations about actuarial equivalence were false. When it prepared its 2013 budget from the Regular Model, Humana estimated that the Walmart Plan's effective coinsurance percentage for the Walmart Plan would be 33.2 percent. Humana based that estimate on the assumption that preferred utilization would stay the same for LICS members (18 percent) and decrease for non-LICS members (70 percent) compared to the 2012 budget.

4. Humana's Bids for the 2014 Contract Year Were Knowingly False or Fraudulent

On January 7, 2013, the PDP Strategy Team met to discuss strategy for Humana's 2014 PDP bids. The attendees at the meeting included Susan Diamond, Carl Koontz, David Pottschmidt, Matthew Hayes, and Lazar Ivetic. In connection with the meeting, Humana prepared a PowerPoint presentation entitled "2014 PDP Strategy." In a slide titled "Member Cost Share Issue Driven by Higher Non-Preferred Utilization," Humana acknowledged that member cost sharing under the Walmart Plan had been significantly higher than 25 percent in both 2011 and 2012, and again calculated the additional profits that Humana had received:

A basic alternative plan must have 25% member cost share in the initial coverage phase.

The current Walmart plan member cost share is higher than 25%, due to more non-preferred utilization than expected.

In 2011, the higher member cost share translated to approximately \$7 pmpm.

162. In considering how to meet the actuarial equivalence requirement, the PDP Strategy Team conceded that Humana was unlikely to increase preferred utilization because it had been "difficult to motivate members to change behavior, especially LIS members who have no financial incentive to change." Humana further admitted that the percentage of LICS beneficiaries enrolled in the plan had risen each year, making it even less likely that Humana would be able to achieve the necessary changes to member behavior to make the plan actuarially equivalent.

- 163. Though Humana did not expect to increase preferred utilization, it also did not want to improve benefits. Humana noted that improving benefits "[c]reates premium and/or margin pressure." Improving benefits would also risk Humana's relationship with Walmart. If Humana improved preferred benefits, the Walmart Plan might intrude on a new, enhanced coverage PDP that Humana was developing with Walmart (the Walmart Enhanced Plan). And if Humana improved non-preferred benefits, Walmart would have less reason to give Humana discounts on covered drugs, because members would have less reason to shop at Walmart.
- 164. Notably, Humana resisted improving preferred benefits in the Walmart Plan because it wanted non-LICS members (who mostly used preferred benefits) to switch to the Walmart Enhanced Plan, leaving the Walmart Plan primarily with LICS members. Through this strategy, Humana intended to actually reduce the number of Walmart Plan members who used preferred pharmacies. (Humana was successful in this regard. Preferred utilization in fact dropped from 69 percent in 2013 to 62 percent in 2014 because of non-LICS members leaving the Walmart Plan for the Walmart Enhanced Plan.)
- 165. Humana therefore turned to "[a]dditional mitigation tactics" to meet the actuarial equivalence requirement, even though these approaches had never worked. During the January 7, 2013 meeting described above, Humana admitted that its "Campaigns Designed to Increase Preferred Utilization Have Had Limited Impact to Date." Among the "limited impact" campaigns were "Preferred utilization guidance alerts," "Walmart calendar with VAIS coupons and preferred messaging," and "SmartSummaryRx preferred utilization messaging." Humana also identified "additional initiatives that did not yield improvements in preferred utilization," including the "Auto-assign welcome newsletter," "Outbound educational calls," and "RightSource direct mail using actual packaging and pill bottles."
- 166. On May 14, 2013, shortly before submitting its bid, Humana noted in a presentation that year-to-date actual cost sharing in the ICL for the 2013 contract

5 6

7

11

12

13 14

15

16

17

18 19

20

21 22

23

24

25 26

27

28

1 vear was 31 percent, "driven by non-preferred pharmacy use." Thus, Humana knew that the bids would be significantly different from its then-current experience.

167. Despite realizing no increases in preferred utilization over the past two years, and despite admitting that increases were unlikely given its experience and membership, Humana again used bid assumptions to misrepresent the Walmart Plan as actuarially equivalent.

168. In the 2014 bid, Humana assumed that preferred utilization by LICS and non-LICS members would increase to 37 percent and 81 percent, respectively. Humana represented in the BPT and certified to CMS that the Walmart Plan was actuarially equivalent to defined standard coverage on the basis of those assumptions. Based on that representation, CMS approved the bids and renewed Humana's Part D contract.

169. In its simultaneous internal forecast, of which CMS was unaware, Humana concluded that preferred utilization would not change from the 2013 budget projection. Humana based its budget projection on the assumption that preferred usage by LICS and non-LICS members would be 17 percent and 70 percent, respectively.

170. Subsequently, on or about October 21, 2013, Humana prepared the Utilization Procedure, described supra ¶¶ 119–121, reflecting its practice of using more aggressive assumptions about preferred utilization in its bids for the Walmart Plan than it used for its actual projections for its budget. At the time that Humana prepared the Procedure, it had known for years that the Walmart Plan was not actuarially equivalent based on its actual results. Based on that experience, Humana knew that the effect of using different and more "aggressive" assumptions in the bids was that Humana would falsely represent to CMS that the Walmart Plan met Part D requirements that it did not in fact meet.

5. Humana's Bids for the 2015 Contract Year Were Knowingly False or Fraudulent

bid. On May 15, 2014, Humana admitted in an internal presentation that year-to-date actual cost sharing in the ICL phase in 2014 was 31.1%, "driven by non-preferred pharmacy use and dual demo delays." Humana also admitted that the rate of non-LICS members in the Walmart Plan was dropping due to the Walmart Enhanced Plan: "Must be mindful of 42% NLI and potential loss/migration." Despite this trend, Humana once again identified "[i]ncrease preferred/mail use" as a method to "mitigate" the effective coinsurance percentage in the bid. Humana knew that such an increase would not occur based on its experience, particularly now that it expected the percentage of non-LICS members in the plan to fall. Thus, Humana again planned to misrepresent member utilization of preferred pharmacies in its 2015 bids.

172. For the 2015 contract year, however, Humana additionally planned to misrepresent what it expected the low-income premium subsidy benchmark to be in a key market, Florida. CMS only auto-assigns LICS members to PDPs that have premiums below a certain benchmark. Humana expected that the Walmart Plan premium would be below the benchmark in Florida, such that the Walmart Plan would continue to receive Florida auto-assignments, but planned to represent to CMS in the Florida bid that the benchmark would be lower than the planned premium, which would mean that the Walmart Plan would not receive auto-assignments. The bid would therefore include far fewer LICS members than Humana expected to receive in Florida, making it easier for Humana to represent in the bid that the Walmart Plan was actuarially equivalent in that key state. In its May 15, 2014 internal presentation, Humana identified this scheme as one of its "[m]ethods to mitigate" the cost-sharing issue, admitting internally: "Have planned

a FL premium that stays under the benchmark <u>but are assuming in the bid we go</u> over (as we are close)" (emphasis added).

173. On May 22, 2014, approximately one week before the 2015 bids were submitted, Humana prepared an actuarial valuation for the Walmart Plan using the Regular Model, which Humana uses for its budget. In the Regular Model, Humana assumed that LICS members would use preferred pharmacies RightSource and Walmart for 16 percent of their utilization, and that non-LICS members would use RightSource and Walmart for 69 percent of their utilization. Based on those assumptions, Humana estimated that the effective coinsurance percentage for the Walmart Plan would be 28.8 percent in the ICL phase, which is higher than the defined standard.

174. In addition to the utilization assumption, Humana used a different estimated membership in the Regular Model than it intended to submit in its 2015 bid. For its internal "budget membership," Humana assumed that 62 percent of its membership would be LICS members, 38 percent would be non-LICS members, and the overall preferred utilization would be 32 percent. For its "bid membership," Humana assumed that 45 percent of its membership would be LICS members, 55 percent would be non-LICS members, and the overall preferred utilization would be 41 percent. Since LICS members are less likely to use preferred pharmacies than non-LICS members, the false assumption in the bids would allow Humana to assume an increase in preferred utilization.

175. In the bid, Humana represented that the Walmart Plan was actuarially equivalent to the defined standard. Humana made that representation by assuming that LICS members would use preferred pharmacies for 30 percent of their drug spending (compared to Humana's internal assumption of 16 percent) and that non-LICS members would use preferred pharmacies for 77 percent of their spending (compared to 69 percent internally). Humana knew that the bids were false and that

- 53 -

1 | 2 | 3 |

5 6 7

the Walmart Plan would not be actuarially equivalent to the defined standard, as its internal utilization and membership estimates for that year showed.

176. In the bid that was specific to Florida (Contract No. S5584, Plan ID 105), Humana additionally represented that LICS member-months in that state would decrease from 2,181,671 in 2014 to 150,000 in 2015 because of the loss of auto-assignments. Humana did not in fact expect to lose its LICS membership in Florida at the time it submitted its bid and never budgeted for the serious financial consequences of such a loss. When CMS later set the benchmark for 2015, the Walmart Plan was below the benchmark in Florida, just as Humana had expected.

177. When Humana prepared its budget projections in the early fall of 2014, it again used the Regular Model, rather than the assumption submitted to CMS and estimated that the effective coinsurance percentage in the ICL phase would be 28 percent. The estimate relied on the assumption that preferred utilization by LICS and non-LICS members would be 16 percent and 62 percent, respectively, which was consistent with historic experience.

178. Based on the bids' false representations of actuarial equivalence, and Humana's false certification to CMS of actuarial equivalence, CMS approved the bids and renewed Humana's Part D contract.

6. Humana's Bids for the 2016 Contract Year Were Knowingly False or Fraudulent

179. Humana continued to misrepresent the value of the Walmart Plan in its bids for the 2016 contract year, notwithstanding renewed warnings from Milliman. On February 13, 2015, Milliman provided Humana with preliminary bid projections for 2016. Milliman warned that while "ICL cost sharing for the Walmart Basic plan is close to 25.5% . . . current projected Walmart retail use is significantly higher than historical use, and the ICL cost sharing is closer to 26.5% in aggregate based on historical levels. . . . We will also need to discuss projected future increases in

10

12 13

11

15

16

14

17 18

19

20

21

Walmart use on this product since historical levels have remained fairly constant despite programs aimed at increasing preferred network use."

- 180. Milliman repeated the warning on March 9, 2015, during the second round of bid development, writing that "We will need to discuss projected future increases in Walmart use on this product since historical levels have remained fairly consistent despite programs aimed at increasing preferred network use." Milliman observed that Humana's assumed usage at RightSource "seems aggressive given that use has remained relatively flat or even decreased in recent years." Due to its concerns, Milliman added the issue to the agenda for its next meeting with Humana: "Many of Humana's assumptions for preferred network use and mail order use on the Walmart Basic product are significantly different from historical data. We would like to understand how Humana plans to justify these increases given several years of relatively consistent experience."
- 181. On May 8, 2015, Humana estimated through the Regular Model that the effective coinsurance percentage in the ICL phase would be 28.2 percent. Humana assumed LICS and non-LICS members would use preferred pharmacies for 15.4 percent and 60.5 percent of their spending, respectively. By contrast, on May 6. 2015, Match Milliman listed the effective coinsurance percentage in the ICL phase at 27.2 percent, with LICS and non-LICS use of preferred pharmacies at 27. percent and 75.9 percent, respectively.
- As in prior years, Humana justified the increase in preferred utilization 22 In Match Milliman and the bids on the basis of several business initiatives. 23 Humana's exclusion of the increases from the Regular Model meant not only that it 24 did not expect the increases to occur, but more particularly that it did not expect the 25 business initiatives to have any effect. Reflecting that expectation, Humana simply 26 recycled the initiatives from the 2015 bid, assuming large results for 2016 even as it 27 saw no results from the initiatives and had no reason to believe such results were 28 bossible. The initiatives for the 2015 and 2016 bids were largely identical:

2015	2016
Walmart In-Store Customer Service Pilot	Return to Growth After 2014 Anomaly
Increased WM H&W Engagement and Media Spend	Increased WM H&W Engagement and Media Spend
Increased WM MTM Opportunities	Increased WM MTM Opportunities
RightSource Rebranding Effort	RightSource Rebranding Effort
Expand Scope of RS Sales Education to Delegated Agents	Expand Scope of RS Sales Education to Delegated Agents
Increase Service Ops Support for Guidance Alerts	Increase Service Ops Support for Guidance Alerts
For the 2015 hid Humana assumed signifi	igant ingresses in professed utilization

For the 2015 bid, Humana assumed significant increases in preferred utilization from the initiatives. Humana claimed, for example, that the initiatives would increase LICS member usage at RightSource by 4.9 percent and usage at Walmart by 10.1 percent. Humana's actual results, however, showed no appreciable changes between the preparation of the 2015 and 2016 bids.

183. For 2016, Humana relied on most of the same campaigns, replacing "Walmart In-Store Customer Service Pilot" with "Return to Growth After 2014 Anomaly." Even though the initiatives had produced no results to date, Humana again assumed significant increases in utilization from the initiatives, including increases among LICS members of 9 percent and 6.3 percent at RightSource and Walmart, respectively. Humana knew the initiatives were no more likely to increase utilization in 2016 than they were in 2015. Despite having assumed that those initiatives would increase utilization for two consecutive bid cycles, Humana did not expect them to realize results in the coming year (if ever).

184. The internal work papers that purported to support the initiatives reflect the fact that Humana did not expect the initiatives to actually yield results. For most of the assumptions in its bids, Humana prepares detailed worksheets that document the actuarial basis for each assumption. The worksheets supporting the utilization initiatives, by contrast, are hastily compiled window dressing, lacking detail and containing errors that do not occur elsewhere in Humana's actuarial work. For

- 56 -

example, the "Increased WM H&W Engagement and Media Spend" initiative relied on a worksheet in which the relative percentage of prescriptions filled at the four different pharmacy types added up to 114 percent, not 100 percent. Humana also assumed the same usage increases from the initiative in both 2015 and 2016, and did not correct the error. Humana did not share these worksheets with Milliman, which may not have incorporated Humana's assumptions into the bids had it seen that they acked bona fide support.

- 185. Notwithstanding Humana's business initiatives, actual utilization of preferred pharmacies has been significantly lower than Humana's assumptions and has remained constant or declined each year. Indeed, the only time when utilization of a preferred pharmacy increased in any respect was in 2012, when spending among LICS members at RightSource increased from 3 percent to 4 percent.

 Because Humana has consistently assumed large increases in utilization on the basis of business initiatives, without ever coming close to realizing those assumptions, it knows its initiatives do not actually support the increases assumed in its bids.
- 186. Nonetheless, in the bids that Humana submitted to CMS for 2016, Humana once again based its bids on significant increases in preferred utilization by LICS and non-LICS members. The assumptions Humana incorporated into the bids (31 percent and 79 percent, respectively) were much higher than the assumptions in the Regular Model (15.4 and 60.5 percent), and higher even than the Match Milliman assumptions from early May (27 percent and 75.9 percent). On the basis of these fabricated assumptions, Humana represented in its bids that the Walmart Plan met the actuarial equivalence requirement. Based on that representation, CMS approved the 2016 bids and renewed Humana's Part D contract.
- 187. On September 28, 2015, as Humana was finalizing the assumptions in its budget projections, Relator emailed Carl Koontz that the bid had assumed utilization increases in 2016 at RightSource and Walmart as a result of planned business initiatives, and asked for "an update on these initiatives and their impacts"

and whether "you recommend we put [them] into 2016 Budgets." Mr. Koontz instructed Relator to leave the bid assumptions out of the budget. According to Mr. Koontz:

 Most of the initiatives haven't really had time to have an effect yet. . . . Given potential the variability [sic] and the fact that we can already achieve our profit requirements, I don't think we should build those Ux increases into the budget (which would just increase our profit target). If the increases don't materialize as planned, we would have some serious budget issues in the middle of the merger. I think it's better to be conservative and go with the 2015 experience.

7 8

188. Thus, Humana assumed in the bids that RightSource and Walmart utilization would increase, but excluded that assumption from the budget because the initiatives to achieve it (which had been relied upon in the Part D bids for several years) had not had time to materialize and were too "variable."

189. In sum, Humana has misrepresented the actuarial value of the Walmart Plan each year it has sought and obtained a Part D contract. Humana knows that the cost sharing amounts in its bids, which have been unchanged and consistently inaccurate, are false and not indicative of what Humana expects to occur and which have in fact occurred. The cost sharing estimates from Humana's Regular Model and budget projections, which are prepared by the same personnel at the same time, reflect Humana's true estimate of cost sharing in each contract year. In no year has Humana budgeted for the Walmart Plan to meet the actuarial equivalence requirement and in no year has the Walmart Plan achieved actuarial equivalence.

Yet each year Humana has certified to CMS that the Walmart Plan is actuarially

equivalent and that the information in the bids is accurate, complete and truthful.

190. Over the life of the Walmart Plan, Humana's false representations of actuarial equivalence in order to obtain Part D contracts have resulted in Humana providing benefits worth approximately \$412 million less than the defined standard. The assumptions amount to roughly one quarter of Humana's total underwriting margin during that period, giving Humana a strong motive to continue its scheme year after year.

C. Humana's Violations of the False Claims Act

- 191. Through this fraudulent scheme, Humana has presented or caused to be presented false claims for payment and made, used or caused to be made or used false records and statements material to false or fraudulent claims for payment.
- that the Walmart Plan is actuarially equivalent to the defined standard, when Humana has known, recklessly disregarded, or acted in deliberate ignorance of the truth that the benefits set forth in the bids were worth far less than the defined standard. Actuarial equivalence is a condition of obtaining a Part D contract. Had CMS known that the representation of actuarial equivalence was false and that the information in the bids was not accurate, complete and truthful, Humana would not have received the contract. As a result of the fraudulently induced contracts, the claims for payment submitted under the contract were false.
- 193. Humana has made and used false statements and records material to false or fraudulent claims for payment in that it falsely represented that the benefits identified in the bids were the benefits that Humana would make available to beneficiaries and that they complied with CMS requirements. At the time it made its representations, Humana knew that it would provide beneficiaries with benefits significantly lower than the defined standard and that the benefits it would offer that did not comply with CMS regulations. Humana falsely certified in each contract that the information in the Walmart Plan bids was accurate, complete, and truthful.
- 194. Humana has presented or caused to be presented false claims, and made or used false records and statements material to false claims, by submitting enrollment and PDE records to CMS for beneficiaries enrolled in the Walmart Plan. The enrollment records that Humana submitted to CMS claimed payment for the provision of actuarially equivalent benefits to the enrolled beneficiary during the contract year. Those claims for payment were false because the benefits for which Humana claimed payment were worth less than the defined standard required under

2.1

the contract. Similarly, Humana claimed payment from CMS based on PDE records that were false because they claimed payment for benefits that were worth less than the defined standard required by the contract and not entitled to payment from CMS. The PDE records further claimed payments for LICS subsidies that were higher than the subsidies that CMS would have paid under the defined standard or an eligible plan. Humana has known, recklessly disregarded, or deliberately ignored the truth that it claimed payment for benefits that were worth less than the defined standard and for LICS subsidies that were higher than the defined standard. CMS would not have approved payment to Humana had it known that the enrollment and PDE records claimed payment for benefits that were worth less than the defined standard and/or claimed payment for excessive LICS costs.

195. Humana has also caused Milliman to make or use false statements or records material to false claims when it submitted actuarial certifications to CMS for the Walmart Plan that falsely represent that Humana's bids comply with applicable laws, rules, bid instructions, and current CMS guidance. For each of the years that it has submitted PDP bids, Humana has known that the bids do not accurately reflect the value of its proposed benefits and that the true value of those benefits does not comply with CMS requirements, and has withheld the relevant true information from Milliman, demonstrating that Humana did not believe the bid representations.

196. Humana's misrepresentations were material to CMS's decision to award Part D contracts to Humana and to make direct subsidy and LICS payments to Humana pursuant to those contracts. Actuarial equivalence is a condition of obtaining a Part D contract and of being paid under the contract.

197. Humana also knowingly made and used false records or statements material to an obligation to pay or transmit money to the government and knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay the government by failing to make payments to the government for LICS subsidy payments to which Humana was not entitled.

1 **COUNT I** 2 FALSE CLAIMS ACT 31 U.S.C. \S 3729(A)(1)(A)–(B), (G) 3 198. Relator realleges and incorporates by reference the allegations 4 5 contained in paragraphs 1 through 197 above as though fully set forth herein. 199. This is a claim for treble damages and penalties under the False Claims 6 7 Act, 31 U.S.C. § 3729, et seq., as amended. 200. Defendant knowingly presented, or has caused to be presented, false or 8 fraudulent claims for payment to the United States, in violation of 31 U.S.C. 10 § 3729(a)(1)(A). 201. Defendant knowingly made or used, or caused to be made or used, false 11 records or statements material to false or fraudulent claims, in violation of 31 U.S.C. 12 13 § 3729(a)(1)(B). 202. Defendant knowingly made, used, or caused to be made or used, a false 14 record or statement material to an obligation to pay or transmit money or property to 15 the United States, and knowingly concealed or knowingly and improperly avoided 16 or decreased an obligation to pay or transmit money or property to the Government, 17 in violation of 31 U.S.C. § 3729(a)(1)(G). 18 203. The Government, unaware of the falsity of the records, statements, and 19 claims that Defendant made or caused to be made, paid and continues to pay claims 20 that would not be paid but for Defendant's illegal conduct. 21 204. Defendant has damaged, and continues to damage, the United States in 22 23 a substantial amount to be determined at trial. 24 205. Additionally, the United States is entitled to the maximum penalty of 25 up to \$11,000 for each and every violation alleged herein. PRAYER 26 WHEREFORE, Relator prays for judgment against Defendant as follows: 27 28 - 61 -

COMPLAINT

1	1. That Defendant cease and desist from violating the False Claims Act,			
2	31 U.S.C. § 3729, et seq.;			
3	That this Court enter judgment against Defendant in an amount equal to			
4	three times the amount of damages the United States has sustained because of			
5	Defendant's actions, plus the maximum civil penalty permitted for each violation of			
6	the False Claims Act;			
7	 That Relator be awarded the maximum amount allowed pursuant to 			
8	§ 3730(d) of the False Claims Act;			
9	4. That Relator be awarded all fees, costs, and expenses incurred in			
10	connection with this action, including attorneys' fees, costs, and expenses; and			
11	That Relator recover such other relief as the Court deems just and			
12	proper.			
13	JURY DEMAND			
14	Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby			
15	demands a trial by jury.			
16				
17	Dated: January 19, 2016			
18	By: Chille			
19	CLAIRE M. SYLVIA (SBN 138990)			
20	csylvia@pcsf.com EDWARD H. ARENS (SBN 259155)			
21	earens@pcst.com PHILLIPS & COHEN LLP			
22	100 The Embarcadero, Suite 300 San Francisco, California 94105			
23	Tel: (415) 836-9000 Fax: (415) 836-9001			
24	Attorneys for Qui Tam Plaintiff			
25				
26				
27				
28	- 62 -			
	COMPLAINT			
{00067353, 4 }	d .			

EXHIBIT 1

CONTRACT WITH APPROVED ENTITY PURSUANT TO SECTIONS 1860D-1 THROUGH 1860D-43 OF THE SOCIAL SECURITY ACT FOR THE OPERATION OF A VOLUNTARY MEDICARE PRESCRIPTION DRUG PLAN

CONTRACT (<<CONTRACT !D>>)

Between

Centers for Medicare & Medicaid Services (hereinafter referred to as "CMS")

And

<<CONTRACT NAME>>

(a Prescription Drug Plan Sponsor, hereinafter referred to as "PDP Sponsor")

CMS and PDP Sponsor, an entity that has been determined eligible to operate a Voluntary Medicare Prescription Drug Plan by the Administrator of CMS under 42 CFR §423.503, agree to the following for the purposes of §§1860D-1 through 1860D-43 (with the exception of §§1860D-22(a) and 1860D-31) of the Social Security Act (hereinafter referred to as "the Act").

Article I Voluntary Medicare Prescription Drug Plan

- A. PDP Sponsor agrees to operate one or more Medicare Voluntary Prescription Drug Plans (hereinafter referred to as a "PDP"), as described in its application and related materials submitted to CMS for Medicare approval, including but not limited to all the attestations contained therein and all supplemental guidance, and in compliance with the provisions of this contract, which incorporates in its entirety the Solicitation for Applications for Medicare Prescription Drug Plan 2016 Contracts, released on January 14, 2014 (hereinafter collectively referred to as "the contract"). PDP Sponsor also agrees to operate in accordance with the regulations at 42 CFR Part 423 (with the exception of Subparts Q, R, and S), §§1860D-1 through 1860D-43 (with the exception of §§1860D-22(a) and 1860D-31) of the Act, and the solicitation, as well as all other applicable Federal statutes, regulations, and policies. This contract is deemed to incorporate any changes that are required by statute to be implemented during the term of this contract and any regulations or policies implementing or interpreting such statutory or regulatory provisions.
- B. CMS agrees to perform its obligations to PDP Sponsor consistent with the regulations at 42 CFR Part 423 (with the exception of Subparts Q, R and S), §§1860D-1 through 1860D-43 of the Act (with the exception of §§1860D-22(a) and 1860D-31) and the solicitation, as well as all other applicable Federal statutes, regulations, and policies.
- C. CMS agrees that it will not implement, other than at the beginning of a calendar year, regulations under 42 CFR Part 423 that impose new, significant regulatory requirements on PDP Sponsor. This provision does not apply to new requirements mandated by statute.
- D. If PDP Sponsor had a contract with CMS for Contract Year 2014 under the contract ID number designated above, this document is considered a renewal of the existing contract. While the terms of this document supersede the terms of the 2014 contract, the parties' execution of this contract does not extinguish or interrupt any pending obligations or actions that may have arisen under the 2014 or prior year contracts.
- E. This contract is in no way intended to supersede or modify 42 CFR, Part 423. Failure to reference a regulatory requirement in this contract does not affect the applicability of such requirements to PDP Sponsor and CMS.

Article II Functions to be Performed by PDP Sponsor

A. ENROLLMENT

 PDP Sponsor agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as described in 42 CFR, Part 423, Subpart B.

- 2. PDP Sponsor agrees to comply with the prohibition in 42 CFR 423.104(b) on discrimination in beneficiary enrollment.
- 3. PDP Sponsor shall conduct Part D-related enrollment activities between October 15 and December 7 of the year prior to the contract year.
- 4. PDP Sponsor shall accept enrollment applications during the first 45 days of a contract year from beneficiaries who have elected to disenroll from a Medicare Advantage plan and enroll in the Medicare fee-for-service program.

B. PRESCRIPTION DRUG BENEFIT

- 1. PDP Sponsor agrees to provide the basic prescription drug coverage as defined under 42 CFR §423.100 and, to the extent applicable, supplemental benefits as defined in 42 CFR §423.100 and in accordance with Subpart C of 42 CFR Part 423. PDP Sponsor also agrees to provide Part D benefits as described in PDP Sponsor's bid(s) approved each year by CMS (as referenced in Attachment A, to be replaced each year upon renewal of the contract to reflect the Sponsor's approved bids for the succeeding contract year).
- 2. PDP Sponsor agrees to calculate and collect beneficiary premiums in accordance with 42 CFR §§423.286 and 423.293.
- 3. PDP Sponsor agrees to maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality assurance activities related to the delivery of Part D services as required by 42 CFR §423.505(b)(25).
- 4. PDP Sponsor agrees to provide applicable beneficiaries applicable discounts on applicable drugs in accordance with the requirements of 42 CFR Part 423 Subpart W.

C. DISSEMINATION OF PLAN INFORMATION

- 1. PDP Sponsor agrees to provide the information required in 42 CFR §423.48.
- PDP Sponsor acknowledges that CMS releases to the public summary reconciled Part D
 Payment data after the reconciliation of Part D Payments for the contract year as provided
 in 42 CFR §423.505(o).
- 3. PDP Sponsor agrees to disclose information to beneficiaries in the manner and the form specified by CMS under 42 CFR §§423.128 and 423 Subpart V-Part D Marketing Requirements, and the Medicare Marketing Guidelines for Medicare Advantage-Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs).
- 4. PDP Sponsor certifies that all materials it submits to CMS under the File and Use Certification authority described in the Medicare Marketing Guidelines are accurate, truthful, not misleading, and consistent with CMS marketing guidelines.

D. QUALITY ASSURANCE/UTILIZATION MANAGEMENT

- PDP Sponsor agrees to operate quality assurance, drug utilization management, and medication therapy management programs, and to support electronic prescribing in accordance with Subpart D of 42 CFR Part 423.
- 2. PDP sponsor agrees to address complaints received by CMS against the Part D sponsor as required in 42 CFR §423.505(b)(22) by:
 - (a) Addressing and resolving complaints in the CMS complaint tracking system; and
 - (b) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the Part D plan's main Web page.
- 3. PDP Sponsor agrees to maintain a Part D summary plan rating score of at least 3 stars as required by 42 CFR §423.505(b)(26).
- 4. PDP Sponsor agrees to pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year. 42 CFR §423.505(b)(27).

E. APPEALS AND GRIEVANCES

PDP Sponsor agrees to comply with all requirements in Subpart M of 42 CFR Part 423 governing coverage determinations, grievances and appeals, and formulary exceptions and the relevant provisions of Subpart U governing reopenings.

F. PAYMENT TO PDP SPONSOR

- 1. PDP Sponsor and CMS agree that payment under this contract will be governed by the rules in Subpart G of 42 CFR Part 423.
- 2. PDP Sponsor agrees that it is bound by all applicable federal laws and regulations, guidance, and authorities pertaining to claims and debt collections. In the event that the government determines that PDP Sponsor has been overpaid, PDP Sponsor agrees to return those overpaid monies back to the federal government.

G. BID SUBMISSION AND REVIEW

If PDP Sponsor intends to participate in the Part D program for the next program year, PDP Sponsor agrees to submit the next year's bid, including all required information on premiums, benefits, and cost-sharing, by the applicable due date, as provided in Subpart F of 42 CFR Part 423 so that CMS and the Part D plan sponsor may conduct negotiations

regarding the terms and conditions of the proposed bid and benefit plan renewal.

H. STATE LAW AND LICENSURE REQUIREMENTS

- 1. PDP Sponsor agrees to comply with State law to the extent that it is not preempted by Federal law as described in Subpart I of 42 CFR Part 423.
- 2. PDP Sponsor agrees that where it is operating in a State using a waiver granted pursuant to 42 CFR §423.410, such waiver shall be valid for three consecutive program years. PDP Sponsor agrees that expiration of the licensure waiver (and the failure to obtain a license from the relevant State) may be the basis for CMS deleting from PDP Sponsor's service area those PDP Regions affected by the waiver expiration. CMS may terminate or non-renew PDP Sponsor's contract where the expiration of the waiver results in PDP Sponsor not being qualified to offer a PDP plan in any PDP Region.
- 3. PDP Sponsor agrees that where it is operating in a State using a waiver granted pursuant to 42 CFR §423.415, such waiver shall be valid for the period that the Secretary of the Department of Health and Human Services determines is appropriate for timely processing of PDP Sponsor's license application by the State, but in no case for more than one year only, beginning on January 1 of the contract year for which CMS granted the waiver.

I. COORDINATION WITH OTHER PRESCRIPTION DRUG COVERAGE

- PDP Sponsor agrees to comply with the coordination requirements with State Pharmacy Assistance Programs (SPAPs) and plans that provide other prescription drug coverage as described in Subpart J of 42 CFR Part 423.
- 2. PDP Sponsor agrees to comply with Medicare Secondary Payer procedures as described in 42 CFR §423.462.

J. SERVICE AREA AND PHARMACY ACCESS

- 1. PDP Sponsor agrees to provide Part D benefits in the service area for which it has been approved by CMS utilizing a pharmacy network and formulary approved by CMS that meet the requirements of 42 CFR §423.120.
- 2. PDP Sponsor agrees to provide Part D benefits through out-of-network pharmacies according to 42 CFR §423.124.
- 3. PDP Sponsor agrees to provide benefits by means of point of service systems to adjudicate prescription drug claims in a timely and efficient manner in compliance with CMS standards, except when necessary to provide access in underserved areas, I/T/U pharmacies (as defined in 42 CFR §423.100), and long-term care pharmacies (as defined in 42 CFR §423.100) according to 42 CFR §423.505(b)(17).

4. PDP Sponsor agrees to contract with any pharmacy that meets PDP Sponsor's reasonable and relevant standard terms and conditions according to 42 CFR §423.505(b)(18).

K. EFFECTIVE COMPLIANCE PROGRAM/PROGRAM INTEGRITY

- 1. PDP Sponsor agrees that it will develop and implement an effective compliance program that applies to its Part D-related operations, consistent with 42 CFR §423.504(b)(4)(vi).
- 2. PDP Sponsor agrees to provide notice based on best knowledge, information, and belief to CMS of any integrity items related to payments from governmental entities, both federal and state, for healthcare or prescription drug services that would have been reported as part of Table A. of the Business Integrity section of the PDP application. These items include any investigations, legal actions or matters subject to arbitration brought involving the sponsor (or sponsor's firm if applicable) and its subcontractors (excluding contracted network providers), including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. In providing the notice, the sponsor shall keep the government informed of when the integrity item is initiated and when it is closed. Notice should be provided of the details concerning any resolution and monetary payments as well as any settlement agreements or corporate integrity agreements.
- 3. PDP Sponsor agrees to provide notice based on best knowledge, information, and belief to CMS in the event the Sponsor or any of its subcontractors is criminally convicted or has a civil judgment entered against it for fraudulent activities or is sanctioned under any Federal program involving the provision of health care or prescription drug services.

L. LOW-INCOME SUBSIDY

PDP Sponsor agrees that it will participate in the administration of subsidies for low-income subsidy eligible individuals according to Subpart P of 42 CFR Part 423.

M. COMMUNICATION WITH CMS

PDP Sponsor agrees that it shall maintain the capacity to communicate with CMS electronically in accordance with CMS requirements.

N. BENEFICIARY FINANCIAL PROTECTIONS

PDP Sponsor agrees to afford its enrollees protection from liability for payment of fees that are the obligation of PDP Sponsor in accordance with 42 CFR §423.505(g).

O. RELATIONSHIP WITH FIRST TIER, DOWNSTREAM, AND RELATED ENTITIES

1. PDP Sponsor agrees that it maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of this contract with CMS.

<<CONTRACT_ID>>

- PDP Sponsor shall ensure that any contracts or agreements with first tier, downstream, and related entities performing functions on PDP Sponsor's behalf related to the operation of the Part D benefit are in compliance with 42 CFR §423.505(i).
- 3. PDP Sponsor agrees to act in accordance with 45 CFR Part 79 and agrees that it will not contract with or employ entities or individuals that are excluded by the Department of Health and Human Services, Office of the Inspector General or included on the Excluded Parties List System maintained by the General Services Administration.

P. CERTIFICATION OF DATA THAT DETERMINE PAYMENT

PDP Sponsor must provide certifications in accordance with 42 CFR §423.505(k).

Q. ENROLLMENT RELATED COSTS

PDP Sponsor agrees to payment of fees established by CMS for cost sharing of enrollment related costs in accordance with 42 CFR §423.6.

R. PDP SPONSOR REIMBURSEMENT TO PHARMACIES

- If a PDP Sponsor uses a standard for reimbursement of pharmacies based on the cost of a drug, PDP Sponsor will update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of the drug.
- If the source for any prescription drug pricing standard is not publicly available, PDP Sponsor will disclose all individual drug prices to be updated to the applicable pharmacies in advance for their use for the reimbursement of claims.
- 3. PDP Sponsor will issue, mail, or otherwise transmit payment with respect to all claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only, or are located in, or contract with, a long-term care facility) within 14 days of receipt of an electronically submitted claim or within 30 days of receipt of a claim submitted otherwise.
- 4. PDP Sponsor must ensure that a pharmacy located in, or having a contract with, a long-term care facility will have not less than 30 days (but not more than 90 days) to submit claims to PDP Sponsor for reimbursement.

Article III Record Retention and Reporting Requirements

A. RECORD MAINTENANCE AND ACCESS

PDP Sponsor agrees to maintain records and provide access in accordance with 42 CFR §\$423.505 (b)(10) and 423.505(i)(2).

B. GENERAL REPORTING REQUIREMENTS

PDP Sponsor agrees to submit information to CMS according to 42 CFR §\$423.505(f) and 423.514, and the "Final Medicare Part D Reporting Requirements," a document issued by CMS and subject to modification each program year.

C. LICENSURE-RELATED REPORTING REQUIREMENTS

- If PDP Sponsor is operating under a CMS-granted licensure waiver in any State, PDP Sponsor agrees to notify CMS in writing of the State's disposition of the Sponsor's license application within ten business days of the date that it receives notice of the State's action.
- 2. For those States where PDP Sponsor is operating under a risk-bearing license, the Sponsor agrees to provide written notice to CMS of the State's non-renewal of the Sponsor's license within ten days of receiving notice of the State's action.
- 3. In the event that a State regulator imposes a sanction against PDP Sponsor or requires the implementation of a corrective action plan, the Sponsor agrees to provide written notice to CMS of such sanction or corrective action requirement (including basis for the sanction and/or timeline for corrective action) within ten days of receiving notice of the State's action.
- 4. In the event that there is a change in the status of PDP Sponsor's risk-bearing license in any State (e.g., suspension, revocation), the Sponsor agrees to provide written notice to CMS of the change in status (including basis for the change in status and effective date) within ten days of receiving notice of the State's action.
- 5. If PDP Sponsor is operating a Part D benefit under a CMS-granted waiver in every State in its service area, and the Sponsor is terminating or reducing the amount of an existing letter of credit obtained for the purposes of funding projected losses, the Sponsor shall provide written notice to CMS of such action 30 days prior to its effective date. PDP Sponsor agrees that it must obtain CMS approval prior to terminating or reducing the amount of a letter of credit obtained for the purposes of funding projected losses under Appendix IV of the PDP Solicitation.

D. CMS LICENSE FOR USE OF PLAN FORMULARY

PDP Sponsor agrees to submit to CMS each plan's formulary information, including any changes to its formularies, and hereby grants to the Government, and any person or entity who might receive the formulary from the Government, a non-exclusive license to use all or any portion of the formulary for any purpose related to the administration of the Part D program, including without limitation publicly distributing, displaying, publishing or

reconfiguration of the information in any medium, including www.medicare.gov, and by any electronic, print or other means of distribution.

Article IV HIPAA Provisions

- A. PDP Sponsor agrees to comply with the confidentiality and enrollee record accuracy requirements specified in 42 CFR §423.136.
- B. PDP Sponsor agrees to enter into a business associate agreement with the entity with which CMS has contracted to track Medicare beneficiaries` true out-of- pocket costs.

Article V Requirements of Other Laws and Regulations

PDP SPONSOR agrees to comply with (a) applicable Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§3729 et seq.), and the anti-kickback provision of § 1128B of the Act; (b) applicable HIPAA Administrative Simplification Security and Privacy rules at 45 CFR parts 160, 162, and 164; and (c) all other applicable Federal statutes and regulations.

Article VI Contract Term and Renewal

A. TERM OF CONTRACT

This contract is effective from the date of CMS' authorized representative's signature through December 31, 2016. This contract shall be renewable for successive one-year periods thereafter according to 42 CFR §423.506.

B. QUALIFICATION TO RENEW A CONTRACT

- In accordance with 42 CFR §423.507, PDP Sponsor will be determined qualified to renew its contract annually only if:
 - (a) PDP Sponsor has not provided CMS with a notice of intention not to renew in accordance with Article VII of this contract, and
 - (b) CMS has not provided PDP Sponsor with a notice of intention not to renew.
- 2. Although PDP Sponsor may be determined qualified to renew its contract under this Article, if PDP Sponsor and CMS cannot reach agreement on the bid under Subpart F of 42 CFR Part 423, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in Subpart N of 42 CFR Part 423.

Article VII Nonrenewal of Contract

A. NONRENEWAL BY PDP SPONSOR

- PDP Sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason as long as PDP Sponsor provides proper notice of the decision according to the required timeframes.
- 2. If PDP Sponsor does not intend to renew its contract, it must notify:
 - (a) CMS in writing by the first Monday of June in the year in which the current contract period ends;
 - (b) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. PDP Sponsor must provide, to enrollees, through this notice or outbound telephone calls, information on alternatives available for obtaining qualified prescription drug coverage within the PDP region, including Medicare Advantage-Prescription Drug plans, Medicare cost plans offering a Part D plan, and other PDPs, and must receive CMS approval of notices or scripts prior to their use.
- 3. If PDP Sponsor does not renew a contract CMS cannot enter into a contract with PDP Sponsor or with an organization whose covered persons, as defined in 42 CFR §423.507(a)(4), also served as covered persons for the nonrenewing sponsor for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.
- 4. If PDP Sponsor does not renew a contract, it must ensure the timely transfer of any data or files in accordance with CMS instructions.

B. NONRENEWAL BY CMS

- 1. CMS may determine that PDP Sponsor is not qualified to renew its contract for any of the following reasons:
 - (a) The reasons listed in 42 CFR §423.509(a) that also permit CMS to terminate the contract.
 - (b) PDP Sponsor has committed any of the acts in 42 CFR §423.752 that support the imposition of intermediate sanctions or civil money penalties under 42 CFR §423.750.
- 2. CMS will provide notice of its decision whether PDP Sponsor is qualified to renew its contract as follows:
 - (a) To PDP Sponsor by August 1 of the current contract year.

- (b) If CMS decides that PDP Sponsor is not qualified to renew its contract, to PDP Sponsor's Medicare enrollees by mail at least 90 calendar days before the end of the current contract year.
- (c) CMS will provide the notice described in (B)(2)(b) of this Article where a non-renewal results because CMS and PDP Sponsor are unable to reach agreement on the bid under 42 CFR Part 423, Subpart F.
- 3. CMS shall give PDP Sponsor written notice of its right to appeal the decision that the sponsor is not qualified renew its contract in accordance with 42 CFR §423.642(b).

Article VIII Modification or Termination of Contract

A. CONTRACT MODIFICATION OR TERMINATION BY MUTUAL CONSENT

- 1. This contract may be modified or terminated at any time by written mutual consent of the parties.
- 2. If this contract is terminated by mutual consent, PDP Sponsor must provide notice to its Medicare enrollees and the general public in accordance with CMS's instructions.
- As set forth in 42 CFR §423.508, if the contract is modified by mutual consent, PDP
 Sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification according to the process and timeframes specified by CMS.
- 4. If a contract is terminated under this section, PDP Sponsor must ensure the timely transfer of any data or files.
- 5. If a contract is terminated under this section, CMS cannot enter into a contract with PDP Sponsor or with an organization whose covered persons, as defined in 42 CFR §423.508(f), also served as covered persons for the terminating sponsor for a period of up to 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

B. TERMINATION OF CONTRACT BY CMS

CMS may terminate the contract in accordance with 42 CFR §423.509.

C. TERMINATION OF CONTRACT BY PDP SPONSOR

PDP Sponsor may terminate the contract only in accordance with 42 CFR §423.510.

Article IX Intermediate Sanctions

Page 11 of 14

<<CONTRACT ID>>

Consistent with Subpart O of 42 CFR Part 423, PDP Sponsor shall be subject to sanctions and civil money penalties.

Article X Severability

Severability of the contract shall be in accordance with 42 CFR §423.504(e).

Article XI Miscellaneous

A. DEFINITIONS

Terms not otherwise defined in this contract shall have the meaning given to such terms in 42 CFR Part 423.

B. ALTERATION TO ORIGINAL CONTRACT TERMS

PDP Sponsor agrees that it has not altered in any way the terms of the PDP contract presented for signature by CMS. PDP Sponsor agrees that any alterations to the original text that PDP Sponsor may make to this contract shall not be binding on the parties.

C. ADDITIONAL CONTRACT TERMS

PDP Sponsor agrees to include in this contract other terms and conditions in accordance with 42 CFR §423.505(j).

D. CMS APPROVAL TO BEGIN MARKETING AND ENROLLMENT ACTIVITIES

PDP Sponsor agrees that it must complete CMS operational requirements prior to receiving CMS approval to begin Part D marketing and enrollment activities. Such activities include, but are not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications (or contracting with an entity qualified to perform such functions on PDP Sponsor's behalf) and successfully demonstrating capability to submit accurate and timely price comparison data. To establish and successfully test connectivity, PDP Sponsor must, 1) establish and test physical connectivity to the CMS data center, 2) acquire user identifications and passwords, 3) receive, store, and maintain data necessary to perform enrollments and send and receive transactions to and from CMS, and 4) check and receive transaction status information.

E. Pursuant to §13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), PDP Sponsor agrees that as it implements, acquires, or upgrades its health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under §3004 of the Public Health Service Act, as amended by §13101 of the ARRA.

- F. PDP sponsor agrees to maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities) as required in 42 CFR §423.505(b)(23).
- G. Business Continuity: PDP Sponsor agrees to develop, maintain, and implement a business continuity plan as required by 42 CFR §423.505(p).

In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR PDP SPONSOR

<< CONTRACTING OFFICIAL NAME >>

Contracting Official Name

<<DATE STAMP>>

Date

<<CONTRACT NAME>>

<<ADDRESS>>

Organization

Address

Date

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

<<CYNTHIA TUDOR ESIG>>

<<DATE STAMP>>

Amy K. Larrick Acting Director Medicare Drug Benefit

and C & D Data Group,

Center for Medicare

EXHIBIT 2

CY 2016 Benefit Attestation

Please review the following information. If all of the information is correct, then electronically sign the benefit attestation.

Medicare Advantage Attestation of Benefit Plan

(Company Name)

Hxxxx

Date: 00/00/2015

Prescription Drug Plan Attestation of Benefit Plan

(Company Name)

Sxxxx

Date: 00/00/2015

I attest that I have examined the Plan Benefit Packages (PBPs) identified below and that the benefits identified in the PBPs are those that the above-stated organization will make available to eligible beneficiaries in the approved service area during program year 2016. I further attest that we have reviewed the bid pricing tools (BPTs) with the certifying actuary and have determined them to be consistent with the PBPs being attested to here.

PARAGRAPH FOR A/B ONLY COST

I attest that I have examined the Plan Benefit Packages (PBPs) identified below and that the benefits identified in the PBPs are those that the above-stated organization will make available to eligible beneficiaries in the approved service area during program year 2016.

(NOTE: ONLY DISPLAY THIS PARAGRAPH IF THE CONTRACTOR OFFERS AT LEAST ONE "800 SERIES" PLAN. THIS SAME ATTESTATION BELOW CAN BE USED FOR: ALL EMPLOYER/UNION DIRECT "E" CONTRACTS; ALL "S" AND "H" CONTRACTS THAT HAVE INDIVIDUAL AND "800 SERIES" PLANS; AND ANY "S" OR "H" CONTRACTS THAT ARE OFFERING ONLY "800 SERIES" PLANS IN 2016 (ENTITIES QUALIFIED TO ONLY OFFER "800 SERIES" PLANS IN 2016 ARE STANDALONE PDPS, NON-NETWORK PFFS AND MSA CONTRACTS)

I attest that I have examined the employer/union-only group waiver ("800 series") PBPs identified below and that these PBPs are those that the above-stated organization will make available only to eligible employer/union-sponsored group plan beneficiaries in the approved service area during program year

2016. I further attest we have reviewed any MA bid pricing tools (BPTs) associated with these PBPs (no Part D bids are required for 2016 "800 series" PBPs) with the certifying actuary and have determined them to be consistent with any MA PBPs being attested to here.

I further attest that these benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations and program guidance that CMS has issued to date and will issue during the remainder of 2015 and 2016, including but not limited to, the 2016 Call Letter, the 2016 Solicitations for New Contract Applicants, the Medicare Prescription Drug Benefit Manual, the Medicare Managed Care Manual, and the CMS memoranda issued through the Health Plan Management System (HPMS).

<< CONTRACTING OFFICIAL NAME >>

Contracting Official Name

<<DATE STAMP>>

Date

<<CONTRACT_NAME>>

Organization

<<ADDRESS>>
Address