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Medicare Part D Administrator Survey

Potential Cost Impacts Resulting from CMS Guidance on "Special Protections for Six Protected Drug Classifications" and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275)

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The Academy of Managed Care Pharmacy engaged Milliman to act as an independent third party for them for the purpose of 1) collecting quantitative and qualitative rebate cost impact information from a number of large Medicare Part D program administrators[1] and 2) reporting summaries of that data. The data were collected through a survey instrument (see Attachment 1). We have now completed our collection and summarization. Those results are discussed below and can be seen in more detail on Attachment 2. The issues the survey targeted involved 1) the impact on drug cost and use that is due to the CMS Guidance requiring special protections for six specific drug classifications and 2) the potential impact on future drug cost and use, if similar protections were afforded to other classes of drugs as might occur under Section 176 of MIPPA. We described the purpose to the surveyed organizations as follows:

"The purpose of this survey is to determine the extent to which these restrictions affect the ability of managed care organizations (MCOs) to manage utilization and cost within these 6 drug classes by reducing the power to negotiate maximum rebates or other effects. Second, we are interested in your opinions regarding the anticipated impact of extending the protections of the 6 drug classes of clinical concern to other drug classes."

It should be noted that the survey focused solely on the question of the simple costs associated with the conduct of customary drug benefit management practices. As we discussed, AMCP understands that clinical outcomes related to the use of the drug therapies in the six "protected classes" are of greatest importance and advised us that its views on clinical issues have been

[1] Part D program administrator – terminology used to refer to Part D plan sponsors and/or organizations that administer the Part D benefit for multiple Part D plan sponsors.

expressed in previous communications to policy makers. The results of our survey are therefore solely intended to inform about the cost outcomes of the Medicare rules related to Part D protected classes.

Regulations Prior to Enactment of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)

Under a regulatory guidance previously issued by the Centers for Medicare and Medicaid Services (CMS), Medicare Part D plan formularies must include "all or substantially all drugs" in "six classes of clinical concern." Drugs in these classes can be subject to copayment tiering, but Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to steer alternatives within these classes for enrollees who are currently taking a drug. However, plans may use these standard drug management approaches for members that are starting drugs in these classes for the first time, often referred to as "new starts."

CMS reviews all Medicare Part D prescription drug formularies to assure that beneficiaries have access to all medically necessary treatments and are not discriminated against due to specific health conditions. During this review, formularies are assessed as to whether they are compliant with CMS's policy that virtually all drugs in six classes of clinical concern be included on the formulary. The six drug classes receiving the special protections under the CMS guidance are immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. The apparent purpose of this policy is to ensure that those who are already taking drugs from these six classes (and may be stabilized on them) will not be denied treatment or discouraged from continuing their current treatment due to drug management techniques such as step therapy, quantity limitations, formulary limitations and prior authorization.

Section 176 of MIPPA

In enacting Section 176 of MIPPA, Congress sought to statutorily recognize the approach taken by the CMS guidance as to the six protected drug classes by authorizing CMS to establish a regulatory review process for the purpose of identifying those drug classes (presumably including the six classes identified in the CMS regulatory guidance) for which a Part D plan would be required to include all drugs on its formulary and limit its utilization management processes. The pertinent portion of MIPPA is in Attachment 3.

Survey Population

The survey respondents were senior staff members of Medicare Part D program administrators. Five Part D program administrators of varying size participated in the survey. These five administrators currently have over 11 million Medicare Part D enrollees, approximately 43% of the total number of Part D enrollees (see Attachment 4 for Part D membership statistics as of 1/1/08). Of these 11 million members, the proportion of low income subsidy members ranged from 16% to 68% among the five survey respondents. The average weighting for the 5 Part D administrators in this survey yielded 38% low-income beneficiaries versus 37% in the overall Medicare population covered under Part D. [2]

Drug Spend and Management

The six protected drug classes make up between 16.8% and 33.2% of total drug spend among those surveyed. The Part D program administrators all commented on the fact that allowing the classes to be protected limited their ability to effectively negotiate lower costs with manufacturers since it is known that these drugs must be represented in the formulary. The survey respondents also commented that the restrictions on enforcing step therapy or quantity limits to only those who are newly starting therapies in these classes hinders their ability to manage utilization. The survey polled how common utilization management mechanisms such

[2] Based on: LIS – Eligible Medicare Beneficiaries with Medicare Prescription Drug Coverage, as of January 2008. Available at: www.statehealthfacts.org\comparetable.jsp?ind=312&cat=6

as step therapy, quantity limits and/or prior authorization are imposed on new starts in the six protected drug classes. The majority of the plans that were surveyed have some sort of limitation on antidepressants and antipsychotics. More details are available in Attachment 2.

Rebates

The majority of the surveyed Part D program administrators that provided us with responses negotiated their own rebate contracts with pharmaceutical manufacturers. The survey reflects an overall opinion that rebates on these six protected classes of drugs would be increased (by up to 15% for certain drug classes) if the Medicare protection was removed. Below is a summary of estimated rebate % improvement by class:

Table 1 – Estimated Rebate Increase with Elimination of Protection of Six Classes

Drug Class	Estimated change in rebate %	Average % Change*
Antidepressants	+3% to +13%	+10%
Antipsychotics	+2% to +12%	+10%
Antiretrovirals	0% to +14%	+9%
Antineoplastics	0% to +13%	+9%
Immunosuppressants	0% to +15%	+11%
Anticonvulsants	+3% to +15%	+11%

* Average % change in rebate means % change in total dollars. For example, if a drug class had an average rebate of 30%, an average % change of 10% would result in a 40% rebate if the mandate was removed. See Table 3 for more details.

Regarding rebates, several manufacturers pay higher rebates for low income versus non-low income beneficiaries.

Additional Protected Classes

The survey also addressed the potential for additional drug classes being added to the protected class list. The potential classes that we asked about were antihyperlipidemics, proton-pump inhibitors (PPIs), antidiabetics and antihypertensives, which today represent a significant component of the drug spend for those over 65 years of age. If these drugs were added to the protected class list, the surveyed respondents estimated the percent change in the rebates would be in the following ranges:

Table 2 – Change in Rebates for Selected Classes if Additional Protections Were Imposed

Drug Class	Estimated change in rebate %	Average % Change*
Antihyperlipidemics	-35% to -3%	-15%
PPIs	-40% to -5%	-31%
Antidiabetics	-20% to -5%	-8%
Antihypertensives	-30% to -3%	-9%

* Average % change in rebate means % change in total dollars. For example, if a drug class had an average rebate of 40%, an average % change of 10% would result in a 30% rebate if a mandate was imposed. See Table 4 for more details.

Similar to responses to the survey questions on the currently protected drug classes, pharmaceutical manufacturers are expected to offer lower rebates to Part D program administrators for any newly protected classes because they would know that these drugs would have to be offered on the formularies. Generally all Part D program administrators are concerned about the addition of more drug classes to the protected list. They worry that it may become more difficult to manage utilization and also possibly result in an increase in the use of more expensive drugs.

It should be noted that any additional protected classes would result in lower rebates which would result in higher claims cost, which would likely be reflected in higher member premiums and/or government liabilities. Conversely, the removal of any drug class protections would result in higher rebates and therefore lower claims costs, which would likely be reflected in lower member premiums and/or government subsidies.

Potential Cost Impact

Based on the survey results and Milliman's *2008 Ages 65 and Over Health Cost Guidelines*,[3] the following is an estimate of savings loss impact for the six currently protected drug classes and four therapeutic classes that could potentially be protected under Section 176 of MIPPA.

The estimated loss in rebates for the six protected drug classes is shown in Table 3.

Table 3 - Potential Lost Rebate Savings in the 6 Protected Classes *

Drug Class	2008 Brand Cost PMPM at WAC	Current Rebates on Brand Drugs	Potential Rebates without Protection	Estimated Cost Impact	Average % Change
Antidepressants	$4.86	$0.65	$1.14	$0.48	10%
Antipsychotics	$2.42	$0.16	$0.41	$0.25	10%
Antiretrovirals	$0.10	$0.00	$0.01	$0.01	9%
Antineoplastics	$5.89	$0.11	$0.63	$0.51	9%
Immunosuppressants	$1.38	$0.04	$0.20	$0.16	11%
Anticonvulsants	$2.37	$0.13	$0.39	$0.26	11%
Total	$17.02	$1.10	$2.77	$1.68	10%

* Rebate and drug class percentages of total were provided by the survey respondents.

WAC=wholesale acquisition cost; approximately 80% of average wholesale price (AWP)[4]

For the 11 million members represented in this survey, the approximate current loss in rebates is estimated to be $222 million per year or $511 million per year for the CMS reported 25.4 million members covered by Part D.

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[3] The Milliman, Inc. *Health Cost Guidelines – Ages 65 and Over* provide a flexible but consistent basis for the estimation of claim costs and premium rates for a wide variety of health benefit plans. These *Guidelines* can be used to estimate future claim levels, evaluate past experience and establish interrelationships between different health benefit plans for populations ages 65 and over. Claim costs included in this edition of *Ages 65 and Over* are representative of claims incurred on July 1, 2008.

These *Guidelines* are developed as a result of Milliman's continuing research on health care costs and are updated periodically. These *Guidelines* are continually monitored as we use them in measuring the experience or evaluating the rates of our clients and as we compare them to other data sources.

The *Guidelines* are a cooperative effort of many Milliman health actuaries and represent a combination of their experience, research, and judgment. An extensive amount of data is used in developing these *Guidelines*, including published and unpublished data. In most instances, assumptions are based on our evaluation of several data sources and, hence, not specifically attributable to a single source.

[4] AWP – Average Wholesale Price represents the average of prices wholesalers publish for their customers. AWP does not represent the actual cost of drugs to pharmacies. This is a reference price PBMs and pharmacies have traditionally used for pricing prescriptions, with PBMs typically negotiating discounts off of AWP for their plan sponsor customers.

WAC – Wholesale Acquisition Cost is the reported cost that wholesalers pay to a manufacturer for drug products. WAC, reported by manufacturers, may not represent actual acquisition price because wholesalers may obtain discounts through volume purchases or special deals.

The cost before rebate is based on Milliman's *2008 Ages 65 and Over Health Cost Guidelines* (HCGs). We adjusted the average wholesale price (AWP) from the HCGs by an estimated 20% reduction to have all dollars expressed on the basis of wholesale acquisition cost (WAC).

The estimated potential lost rebates due to imposing the CMS protections for the four selected classes are shown in Table 4 below.

Table 4 - Savings Lost with Additional Protections Imposed on Selected Classes *

Drug Class	2008 Brand Cost PMPM at WAC	Current Rebates on Brand Drugs	Potential Rebates after Protection	Estimated Cost Impact	Average % Change
Antihyperlipidemics	$26.44	$7.05	$2.95	-$4.09	-15%
PPIs	$13.69	$6.48	$2.18	-$4.30	-31%
Antidiabetic	$11.23	$2.05	$1.17	-$0.87	-8%
Antihypertensives	$19.81	$4.06	$2.21	-$1.85	-9%
Total	$71.18	$19.63	$8.52	-$11.11	-16%

* Rebate and drug class percentages of total were provided by the survey respondents.

Using the reported 11 million members from this survey, the potential loss in rebates for the four additional classes would be approximately $1.5 billion per year, or $3.4 billion per year for the estimated 25.4 million members covered by Part D.

Note that the amounts in Tables 3 and 4 may be understated since the HCGs are based on a Non-Institutional, Non-Medicaid (NINM) population and low income beneficiaries use more drugs in general than the NINM population.

Caveats

It should first be noted that our firm signed non-disclosure agreements with all of the respondents with the promise to protect their individual company responses, including company-specific data. We have prepared this brief report as an aid in understanding the cost implications of the current treatment of the six protected drug classes and the possible future expansion of the protections to other classes. Our report may not be appropriate for any other use. The statistics that are cited within the report represent a combination of actual Part D program administrator claims experience and their expert opinions regarding the possible effects of the restrictions on

the various drug classes. The statistics are therefore estimates and must be viewed in that light. The actual impact for the entire Part D program of the protections on each drug class is unknown. The results could vary substantially from what we have reported for a variety of reasons. For example, while our sample represents 43% of all Medicare Part D beneficiaries in 2008, we do not have survey responses from all Part D plan administrators; so we can only assume that those not surveyed would experience much the same range of results as those that responded to our survey.

About Milliman

Milliman is among the world's largest independent actuarial and consulting firms, with revenues of $522 million in 2007. Founded in Seattle in 1947, Milliman currently has 48 offices in key locations worldwide. Its staff of 2,100 people includes more than 1,000 qualified consultants and actuaries. Milliman is owned and managed by approximately 300 principals – senior consultants whose selection is based on their technical, professional and business achievements.

Through consulting practices in employee benefits, healthcare, investment, life insurance and financial services, and property and casualty insurance, Milliman serves the full spectrum of business, financial, government, union, education, and nonprofit organizations. In addition to its consulting actuaries, Milliman's body of professionals includes numerous other specialists, ranging from clinicians to economists.

Milliman has consulted with many of the Part D program administrators and has provided consulting services to Medicare Risk contractors since the inception of the risk program in the mid 1980's.

Attachment 1

Milliman Medicare Part D Questionnaire Regarding "Special Protections for Six Protected Drug Classifications"

(Transmitted to survey participants on July 9, 2008).

Under a guidance issued by the Centers for Medicare and Medicaid Services (CMS), Medicare Part D plan formularies must include "all or substantially all drugs" in "six classes of clinical concern." Drugs in these classes can be subject to copayment tiering but "Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to steer alternatives within these classes for enrollees who are currently taking a drug." [2007 Final Guidelines]. However, plans may use these standard drug management approaches for any members that are starting therapies using drugs in these classes for the first time, often referred to as "new starts". Congress is considering 2 alternative legislative proposals: to either codify the CMS guidance as to the 6 specific classes or to give CMS authority to establish a regulatory review process for the purpose of identifying drug classes for which a Part D plan would be required to include all drugs on its formulary. Language in the House bill refers to "special protections for six protected drug classifications."

The purpose of this survey is to determine the extent to which these restrictions affect the ability of managed care organizations (MCOs) to manage utilization and cost within these 6 drug classes by reducing the power to negotiate maximum rebates or other effects. Second, we are interested in your opinions regarding the anticipated impact of extending the protections of the 6 drug classes of clinical concern to other drug classes.

Note that this survey is focused solely on the question of the simple costs associated with the conduct of customary drug benefit management practices. AMCP considers the clinical outcome issues related to the use of the drug therapies in the 6 "protected classes" to be of premier importance and that opinion on these issues have been expressed and debated previously. The results of the present survey will help inform about the cost outcomes.

1. What is the name of your MA-PD/PDP managed care company? Please fill in the line below

_____

2. Is your MCO a **PDP**, **MA-PD** or **both**? (please highlight the answer that applies)

3. Do you do all or most of your company's rebate contract negotiating with pharmaceutical manufacturers? **Yes or** No (please highlight one), If no, who does?

_____

4. What is the approximate number of Medicare members covered under your MA-PD and/or PDP programs? (please fill in the blank provided) _____

5. What is the approximate proportion of your Medicare Part D membership that is Low-Income Subsidy (LIS)?

_____ % (please fill in the blank provided)

6. Please complete the data in the following table based on your personal experience in negotiating rebate contracts with drug manufacturers, including your estimate of the absolute %-point change (up or down) in rebate contract terms (based on WAC) that you would expect in an <u>environment</u> in which these 6 drug classes did <u>not</u> have this mandate? Please indicate in the last 2 columns which of the 3 utilization management tools are used in your Medicare and Commercial business segments (QL=quantity limits; ST=step-therapy; PA=prior authorization).

Drug class	% share of total Medicare drug benefit spend, based on Plan allowed $	% Brand share of class	%-point change in Medicare rebates if there was no Medicare mandate	Medicare QL, ST or PA	Commercial QL, ST or PA
Antidepressants					
Antipsychotics					
Antiretrovirals					
Antineoplastics					
Immunosuppressants					
Anticonvulsants					

7. Please describe, on the lines below, how the Medicare guidance for these 6 classes affects your use of managed care tools.

_____

_____

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8. If the rebate contract terms (i.e., % rebates) are different for any sub-blocks of your business, such as PDP versus MA-PD business, or low income versus non-low income, please describe the differences on the lines below.

_____

_____

_____

_____

_____

9. Are your Medicare rebates generally **higher, lower**, or the **same** than your commercial rebates? (please highlight one)

10. Are your Medicare rebates **higher, lower,** or the **same** than commercial rebates for the six classes in question? (please highlight one)

11. Please describe how the rebate contract terms for the drugs in the 6 "Classes of Clinical Concern" for Medicare are different as compared with these 6 classes in your commercially insured and other business. If the rebate contract terms are different for your PDP versus MA-PD business or low income versus non-low income, please complete this table for the sub-classes that are different.

Describe the segments in the blank spaces provided in the title. If more than two segments, please add additional tables.

Business segment 1_____

Drug class	Medicare rebate as % of brand drug cost (WAC)	% Brand share of class	Commercial/other rebate % of brand drug cost (WAC)	% Brand share of class
Antidepressants				
Antipsychotics				
Anitretrovirals				
Antineoplastics				
Immunosuppressants				
Anticonvulsants				
Anti-hyperlipidemics				
PPIs				
Anti-diabetics				
Antihypertensives				
All other drug classes				

Business Segment 2_____

Drug class	Medicare rebate as % of brand drug cost (WAC)	% Brand share of class	Commercial/other rebate % of brand drug cost (WAC)	% Brand share of class
Antidepressants				
Antipsychotics				
Anitretrovirals				
Antineoplastics				
Immunosuppressants				
Anticonvulsants				
Anti-hyperlipidemics				
PPIs				
Anti-diabetics				
Antihypertensives				
All other drug classes				

12. Are you concerned that additional drug classes will be added to the list of 6 classes of clinical concern? **Yes** or **No**? (please highlight one and explain why on the lines below)

_____

_____

_____

_____

_____

13. Do you believe that adding additional drug classes to the "list of 6" would likely **raise**, **lower**, or **not change** rebates for the classes that are added? (please highlight one)

14. Do you believe that adding additional drug classes to the "list of 6" would likely **raise**, **lower,** or **not change** utilization of higher cost drugs? (please highlight one)

15. Please provide your estimate of the impact of adding drug classes to the list of protected classes in the table below.

%-point change in Medicare rebates

if there <u>was</u> a Medicare mandate

Drug class	Estimated %-point change in WAC + or (-)
Anti-hyperlipidemics	
PPIs	
Anti-diabetics	
Antihypertensives	
All other classes (excl. the 6 classes)	

Attachment 2
Summary of Survey Responses

Survey Question Number	Questions	Summary of Responses (Based on five responses)					
2	PDP, MA-PD or both?	4 answered Both, 1 answered PDP Only					
3	Do you do all or most of your company's rebate contract negotiating with pharmaceutical manufacturers?	4 answered Yes, 1 answered No					
4	Medicare members covered	Total Members Surveyed = 11,035,000					
5	Proportion of Medicare Part D membership that is LIS	Average % of Population Low Income = 38%					
	Drug Class	Antidepressants	Antipsychotics	Antiretrovirals	Antineoplastics	Immunosuppressants	Anticonvulsants
6	Range of Total Medicare Drug Benefit Spending	2.32% - 4.30%	4.35% - 11.85%	1.80% - 5.10%	1.45% - 7.83%	0.20% - 0.62%	2.95% - 6.49%
	Range of Brand Share Drug Spend of Class	54.53% - 74.31%	94.74% - 97.20%	98.62% - 99.20%	86.15% - 97.50%	81.20% - 90.11%	60.19% - 86.08%
	Range of Change in Medicare Rebates if no mandate	3.00% - 13.00%	2.00% - 12.00%	0.00% - 14.00%	0.00% - 13.00%	0.00% - 15.00%	3.00% - 15.00%
	Medicare Pharmacy Util Mgmt Tool Responses by Drug Class *	3 QL 1 Yes; 1 QL,ST,PA	3 QL 1 No; 1 QL,ST,PA	2 QL 3 No/None	1 QL; 1 QL,ST,PA; 1 PA; 1 None; 1 Some	1 QL; 1 PA; 1 PA, BvD 2 No/None	2 QL; 1 QL,ST,PA 1 Some; 1 QL,PA 1 Some
7	Description of how Medicare guidance for these 6 classes affects use of managed care tools. Responses Listed to the right.	"We lack the ability to negotiate as there are limited controls that we as a plan can put in place that allows us to negotiate better pricing from the manufacturer. In a lot of cases this manufacturers do not even have a contact person calling on our organization." "Limits our ability to effectively manage net cost of category and limits negotiation leverage." "Somewhat limiting." "CMS requirements mandate that plans not implement any utilization management tools for the antiretrovial class. With regards to the other 5 classes, we are able to implement QLs, but PA and ST edits are limited to new starts only." "The protected classes allowed pharmaceutical manufacturers to not offer significant rebates because they know that their products had to be represented on formulary. The protected classes also did not really allow for step edits or prior authorizations since we had to insure that members were not turned away at the pharmacy."					
8	Differences in rebate contract terms for sub-blocks of business (ie PDP vs MA-PD; low income vs non-low income) Responses Listed to the right.	"Several manufacturers pay higher rebates for beneficiaries in low income versus non low income ." "No difference between MA-PD and PDP rebates. A few manufacturers offer enhanced rebates for LIS members on select drugs." "Not different." "Our contracts do not differentiate between PDP and MA-PD. However, we do have a couple of contracts that give higher rebates for LIS members versus non-LIS members. These contract (LIS vs NonLIS) cut across many different therapeutic classes." "Rebates for LI members were only slightly higher for very few products within the protected category. Only one manufacturer, in the 6 categories noted above, was willing to provide improved rates for LI members. Pharmaceutical manufacturers were avoiding offering rebates in some categories as they began to realize that LICS members were not subject to the copay differentials. They determined that their strategies would be to target those physicians who serviced a large LICS population and encourage the use of their products where the member was not subject to the copay differential, which increases the costs to the government and the plan."					

* QL = Quantity Limits ST = Step Therapy PA = Prior Authorization

Attachment 2
Summary of Survey Responses

Survey Question Number	Questions	Summary of Responses (Based on five responses)					
9	Are your Medicare rebates **higher**, **lower**, or the **same** in comparison to your commercial rebates?	4 answered Higher, 1 answered Lower					
10	Are your Medicare rebates **higher**, **lower**, or the **same** for the six classes in question?	2 answered Higher, 1 Lower, 1 Same, 1 answered "50% slightly better than commercial, 50% slightly less"					
11	**Drug Class (CMS Special Protection)**	Antidepressants	Antipsychotics	Antiretrovirals	Antineoplastics	Immunosuppressants	Anticonvulsants
	Range of Medicare rebate as % of brand drug cost (WAC)	3.03% - 17.11%	2.88% - 12.40%	0.82% - 2.95%	0.20% - 3.30%	0.01% - 7.20%	2.10% - 7.80%
	Medicare % Brand share of class	54.53% - 71.60%	94.70% - 97.97%	98.62% - 100.00%	86.15% - 95.33%	81.30% - 91.56%	42.87% - 86.10%
	Drug Class (Potential Protected Classes)	Antihyperlipidemics	PPIs	Antidiabetics	Antihypertensives	All other classes	
	Range of Medicare rebate as % of brand drug cost (WAC)	8.53% - 35.20%	13.62% - 54.66%	8.55% - 22.74%	8.19% - 29.40%	3.61% - 14.00%	
	Medicare % Brand share of class	44.45% - 85.30%	52.01% - 88.93%	72.40% - 88.20%	38.00% - 100.00%	73.69% - 79.28%	
12	Are you concerned that additional drug classes will be added to the list of 6 classes of clinical concern? Why? Responses Listed to the right.	"Yes, some manufacturers provide relatively low rebates for these drugs because they know there will be access for their medication regardless of the discount they will provide. If more classes are protected like this, it will limited the ability of the plan to put pressure on the manufacturer either increase their discount or offer a discount altogether. As stated earlier there are a number of branded manufacturers in the protected classes who do not even call on our account. One company in particular finally gave us the opportunity to present to senior executives after 18 months of just trying to get the company to call us back. After our meeting they informed us that it is not in their business plan to rebate in the HIV space." "No. Addition of more than 6 classes of clinical concern will greatly impact our ability to manage net drug cost, negotiate aggressive rebates and therefore impact member premiums and our ability to compete in Medicare D market place." "Yes. New legislative mandate opens the door for additional lobbying for more classes to be added." "Yes. The design and administration of this benefit is politically based - and therefore, lobbyists, etc, have influence." "Yes. Pharmaceutical Manufacturers are aware of whether or not their products are in the protected categories. They realize that they do not have to offe significant rebates since their products have unrestricted access since they are part of the "protected categories." Additional "protected classes" would significantly lower rebates from current levels. It will also not allow for utilization management tools to be used. Utilization Management is an effective way to assure that generics are used first line as clinically appropriate or that the branded Tier 2 products are used before the more costly (to the government) Tier 3 products are utilized. "					
13	Will adding additional drug classes to the "list of 6" **raise**, **lower**, or **not change** rebates for the classes that are added?	All answered Lower					
14	Will adding additional drug classes to the "list of 6" **raise**, **lower**, or **not change** utilization of higher cost drugs?	4 answered Raise, 1 Answered Not Change					
	Drug Class	Antihyperlipidemics	PPIs	Antidiabetics	Antihypertensives	All other classes	
15	Estimated Range of %-point change in WAC	-35.00% to -3.00%	-40.00% to -5.00%	-20.00% to -5.00%	-30.00% to -3.00%	-10.00% to 0.00%	

PART II—OTHER PROVISIONS

SEC. 175. INCLUSION OF BARBITURATES AND BENZODIAZEPINES AS COVERED PART D DRUGS.

(a) IN GENERAL.—Section 1860D–2(e)(2)(A) of the Social Security Act (42 U.S.C. 1395w–102(e)(2)(A)) is amended by inserting after ''agents),'' the following ''other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines),''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to prescriptions dispensed on or after January 1, 2013.

SEC. 176. FORMULARY REQUIREMENTS WITH RESPECT TO CERTAIN CATEGORIES OR CLASSES OF DRUGS.

Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended—

(1) in subparagraph (C)(i), by striking ''The formulary'' and inserting ''Subject to subparagraph (G), the formulary''; and

(2) by inserting after subparagraph (F) the following new subparagraph:

"(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

"(i) IDENTIFICATION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—Beginning with plan year 2010, the Secretary shall identify, as appropriate, categories and classes of drugs for which both of the following criteria are met:

"(I) Restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class.

"(II) There is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer.

"(ii) FORMULARY REQUIREMENTS.—Subject to clause (iii), PDP sponsors offering prescription drug plans shall be re-

quired to include all covered part D drugs in the categories and classes identified by the Secretary under clause (i).

"(iii) EXCEPTIONS.—The Secretary may establish exceptions that permits a PDP sponsor of a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under clause (ii) (or to otherwise limit access to such a drug, including through prior authorization or utilization management). Any exceptions established under the preceding sentence shall be provided under a process that—

"(I) ensures that any exception to such requirement is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents); and

"(II) includes a public notice and comment period.".

Subtitle F—Other Provisions

SEC. 181. USE OF PART D DATA.

Section 1860D–12(b)(3)(D) of the Social Security Act (42 U.S.C. 1395w–112(b)(3)(D)) is amended by adding at the end the following sentence: "Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) to contracts under this section under the preceding sentence—

"(i) may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate); and

"(ii) shall be made available to Congressional support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the program under this title.".

Attachment 4

Total Medicare Beneficiaries with Prescription Drug Coverage
As of January, 2008

Description	Beneficiaries with Drug Coverage (millions)
Medicare Beneficiaries Eligible for Part D	**44.20**
Medicare Part D	**25.40**
Medicare Stand Alone Drug Coverage (Part D)	17.39
Medicare Advantage with Drug Coverage (Part D)	7.63
Other Medicare health plan types	0.38
Medicare Retiree Drug Subsidy (RDS)	**6.66**
Other Drug Coverage	**7.53**
TRICARE Retiree Coverage	0.90
FEHBP Retiree Coverage	1.05
Veterans Affairs (VA) Coverage	1.59
Active Workers with Medicare Secondary Payer	1.20
Multiple sources of creditable coverage#	0.69
Other Retiree Coverage, Not Enrolled in RDS *	1.54
Medigap and other individual insurance*	0.21
State Pharmaceutical Assistance Programs*	0.02
Indian Health Service Coverage*	0.03
Other sources*^	0.30
Total Medicare Beneficiaries with Drug Coverage	**39.59**

Includes beneficiaries with more than one of the following: TRICARE, FEHPB, VA, Active Workers

*This information is only available at the national level.

^Includes: FEHBP Spouses and Dependents

Sources: CMS Management Information Integrated Repository (MIIR) January 18, 2008; Office of Personnel Management; Department of Defense; Department of Veterans Affairs; Indian Health Service; CMS Coordination of Benefits Database (COB); CMS Creditable Coverage Database; Information from Wisconsin State SPAP.