

# United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

April 29, 2008

## **Via Electronic Transmission**

Kerry Weems  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Acting Administrator Weems:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the Medicare and Medicaid programs. As Ranking Member of the Committee, I have a responsibility to protect these programs and the more than 80 million beneficiaries who receive health care through them. This responsibility includes monitoring the Centers for Medicare and Medicaid Services (CMS or Agency) and its reimbursement to states through the Medicaid Drug Rebate Program.

Recently, my Committee staff found some troubling disparities when comparing data downloaded from the CMS website in December 2007 (12/07) to data downloaded on April 11, 2008 (04/08). In particular, they compared the national State Drug Utilization Data for the Medicaid Drug Rebate Program for the drugs Avandia, Dytan, Guaifexen, Oyster-Cal-D, and Vytorin and found that the total amount reimbursed in 2006 for the five products, collectively and individually, dropped sharply between 12/07 and 04/08. In addition, much of the data reviewed by my staff show large differences in the numbers reported between the two download dates for the same quarter.

I am concerned not only about the significant disparities in the numbers reported in the State Drug Utilization database, but also by the lack of notice to the public regarding any material updates to the drug utilization and reimbursement figures. Had my staff not examined the data at two different points in time, they would not have been aware of those changes either.

Attached is a spreadsheet with examples of some of those differences. Specifically, the spreadsheet reveals instances where total reimbursements for the five drugs during periods of 2006 as posted on 12/07 exceeded the amounts posted on 04/08 by at least a multiple of 10 (Attachment 1). In addition, I have included below summary examples derived from Attachment 1, which highlight the most dramatic differences in the same data for each drug from the two download dates (04/08 and 12/07):

FDA Name	Codes				# of Prescriptions		Total Reimbursed	
	Label	Product	Package Size	Period	04/08	12/07	04/08	12/07
AVANDIA	29	3159	13	20063	33,500	1,010,000	\$4,428,000	\$98,024,000
DYTAN 25MG	63717	570	4	20061	3,500	353,500	\$99,000	\$58,599,000
GUAIFENEX	58177	208	4	20063	5,500	105,500	\$58,000	\$12,557,000
DYST-CAL-D	182	4439	10	20063	90,500	568,000	\$378,000	\$84,071,000
VYTORIN 10	66582	315	31	20063	14,500	775,500	\$1,308,000	\$18,903,000

The national State Drug Utilization Data shows how much Medicaid paid for outpatient drugs each quarter of each year. The federal government and the public rely on CMS's accurate reporting of this type of information. Not only is it important for budgetary and research purposes, but also critical for ensuring that taxpayer money is spent appropriately. This incident raises questions about the data's overall reliability.

CMS reports that it has limited resources to monitor the accuracy of the information submitted individually by the states. In addition, according to CMS's initial explanation for the discrepancies, Tennessee and Washington had submitted incorrect data that corrupted the database, and the drop in numbers reflect the removal from the State Drug Utilization database of data reported by those two states. Even if one were to accept that the database continues to be updated as information is submitted by the states, at some point, the information for 2006, for example, should be complete and static.

Therefore, I request that CMS examine its drug utilization data systems and provide a response to the following questions:

- 1) Reliability of the data:
  - a. Was the change in prior year data (12/07 numbers) caused only by the erroneous numbers submitted by Tennessee and Washington?
  - b. While CMS does not independently validate the data submitted by the states, does the Agency conduct periodic checks of the state drug utilization database for errors? If so, how frequently?
  - c. How did CMS detect the errors reported by Tennessee and Washington?
  - d. Were decisions about Medicaid reimbursement based on this data?
  - e. Please confirm that the numbers posted on CMS's website as of April 2008 are the most complete and accurate numbers available.
  - f. What steps, if any, is CMS taking to ensure the reliability of the data in its systems?
  - g. Who is responsible for maintaining, monitoring and adding data to CMS's database?

- h. How do users of the data evaluate the completeness and accuracy of the data?
- i. How can users determine if there have been material updates, additions or deletions to the database at any given time period?

2) Reimbursements made to states:

- a. How much did CMS, in fact, reimburse the states for Avandia, Dytan, Guaifenex, Oyster-Cal-D, and Vytarin during each quarter of 2006?
- b. Do the erroneous numbers reported by Tennessee and Washington reflect the actual amounts that CMS reimbursed the two states? If so, has CMS recouped the reimbursements that were made to the two states based on the 12/07 data? If not, why not? What mechanisms exist for CMS to recoup mistaken payments?

I am confident that my concern for this matter reflects yours. Please provide a response to this letter by no later than May 13, 2008. Also, I would appreciate a briefing for my staff on this issue at your earliest convenience. All formal correspondence should be sent electronically in PDF format to [Brian\\_Downey@finance-rep.senate.gov](mailto:Brian_Downey@finance-rep.senate.gov) or via facsimile to (202) 228-2131. Should you have any questions regarding this matter, please contact Angela Choy or Eben Roberts of my Committee Staff at (202) 224-4515.

Sincerely,



Charles E. Grassley  
Ranking Member

Attachment

# Medicaid Drug Rebate Program - National Drug Utilization Data

(ATTACHMENT 1)

Label	FDA Name	Period	Package		# of Prescriptions			Total Reimbursed			Script/Reimbursed \$		
			Size	Product	04/08	12/07	Multiple	04/08	12/07	Multiple	04/08	12/07	Multiple
29	AVANDIA(RO	20063	13	3159	33,444	1,010,000	30	\$4,428,021	\$98,024,414	22	\$132	\$97	0.73
29	AVANDIA(RO	20063	18	3158	18,769	498,777	27	\$1,808,346	\$41,906,639	23	\$96	\$84	0.87
29	AVANDIA(RO	20063	20	3160	15,328	435,337	28	\$2,896,002	\$36,097,328	12	\$189	\$83	0.44
<b>AVANDIA(RO Total:</b>					<b>67,541</b>	<b>1,944,114</b>	<b>29</b>	<b>\$9,132,370</b>	<b>\$176,028,381</b>	<b>19</b>	<b>\$135</b>	<b>\$91</b>	<b>0.67</b>
63717	DYTAN 25MG	20061	4	570	3,596	353,601	98	\$99,350	\$58,599,494	590	\$28	\$166	6.00
63717	DYTAN 25MG	20061	6	571	3,983	183,983	46	\$190,335	\$71,690,335	377	\$48	\$390	8.15
63717	DYTAN 25MG	20062	4	570	3,393	373,393	110	\$104,914	\$33,704,914	321	\$31	\$90	2.92
63717	DYTAN 25MG	20062	6	571	3,143	883,143	281	\$160,384	\$41,060,384	256	\$51	\$46	0.91
63717	DYTAN 25MG	20064	6	571	2,551	102,553	40	\$149,249	\$65,649,432	440	\$59	\$640	10.94
<b>DYTAN 25MG Total:</b>					<b>16,666</b>	<b>1,896,673</b>	<b>114</b>	<b>\$704,232</b>	<b>\$270,704,560</b>	<b>384</b>	<b>\$42</b>	<b>\$143</b>	<b>3.38</b>
58177	GUAIFENEX	20063	4	208	5,406	105,368	19	\$57,718	\$12,557,301	218	\$11	\$119	11.16
58177	GUAIFENEX	20063	4	213	6,087	126,027	21	\$107,796	\$9,704,769	90	\$18	\$77	4.35
58177	GUAIFENEX	20063	4	214	1,542	151,530	98	\$15,433	\$1,615,286	105	\$10	\$11	1.07
58177	GUAIFENEX	20064	4	213	8,587	538,607	63	\$137,915	\$26,738,510	194	\$16	\$50	3.09
<b>GUAIFENEX Total:</b>					<b>21,622</b>	<b>921,532</b>	<b>43</b>	<b>\$318,862</b>	<b>\$50,615,867</b>	<b>159</b>	<b>\$15</b>	<b>\$55</b>	<b>3.72</b>
182	OYST-CAL-D	20063	1	418	1,168	451,154	386	\$5,493	\$4,605,441	838	\$5	\$10	2.17
182	OYST-CAL-D	20063	10	4439	90,501	568,261	6	\$377,710	\$84,071,443	223	\$4	\$148	35.45
182	OYST-CAL-D	20063	10	418	2,438	12,409	5	\$10,217	\$310,137	30	\$4	\$25	5.96
182	OYST-CAL-D	20063	89	4439	279	590,257	2,116	\$1,182	\$501,083	424	\$4	\$1	0.20
<b>OYST-CAL-D Total:</b>					<b>94,386</b>	<b>1,622,081</b>	<b>17</b>	<b>\$394,603</b>	<b>\$89,488,103</b>	<b>227</b>	<b>\$4</b>	<b>\$55</b>	<b>13.20</b>
66582	VYTORIN 10	20061	31	313	61,600	892,360	14	\$5,573,541	\$102,435,303	18	\$90	\$115	1.27
66582	VYTORIN 10	20062	31	311	7,694	437,797	57	\$681,808	\$34,690,115	51	\$89	\$79	0.89
66582	VYTORIN 10	20062	31	315	12,909	403,023	31	\$1,155,808	\$21,965,029	19	\$90	\$55	0.61
66582	VYTORIN 10	20062	54	313	2,034	732,051	360	\$186,117	\$13,087,588	70	\$92	\$18	0.20
66582	VYTORIN 10	20062	54	315	596	470,612	790	\$55,390	\$4,956,670	89	\$93	\$11	0.11
66582	VYTORIN 10	20063	31	312	56,871	119,991	2	\$5,167,689	\$103,728,317	20	\$91	\$864	9.51
66582	VYTORIN 10	20063	31	313	60,038	903,954	15	\$5,508,656	\$89,334,665	16	\$92	\$99	1.08
66582	VYTORIN 10	20063	31	315	14,414	775,554	54	\$1,307,970	\$18,903,180	14	\$91	\$24	0.27
66582	VYTORIN 10	20063	74	313	193	980,204	5,079	\$19,348	\$320,274	17	\$100	\$0	0.00
66582	VYTORIN 10	20063	82	312	293	180,303	615	\$33,235	\$934,075	28	\$113	\$5	0.05
66582	VYTORIN 10	20064	31	311	8,842	148,944	17	\$798,317	\$35,007,168	44	\$90	\$235	2.60
66582	VYTORIN 10	20064	31	315	15,985	496,146	31	\$1,458,235	\$20,272,109	14	\$91	\$41	0.45
66582	VYTORIN 10	20064	52	315	12	820,012	68,334	\$1,002	\$1,701,002	1697	\$84	\$2	0.02
66582	VYTORIN 10	20064	54	313	2,772	902,800	326	\$260,986	\$17,763,433	68	\$94	\$20	0.21
<b>VYTORIN 10 Total:</b>					<b>244,253</b>	<b>8,263,751</b>	<b>34</b>	<b>\$22,208,100</b>	<b>\$465,098,928</b>	<b>21</b>	<b>\$91</b>	<b>\$56</b>	<b>0.62</b>
<b>Five Drugs' Total:</b>					<b>444,468</b>	<b>14,648,151</b>	<b>33</b>	<b>\$32,758,166</b>	<b>\$1,051,935,838</b>	<b>32</b>			

Note: Above examples exhibit the significant disparities among 5 drugs. Totals do not represent 2006 drug totals. Meant for summary purposes only.