

MAR 18 2005



**Comprehensive Cancer Centers  
OF NEVADA**

*Exceptional Care, Centered Around You.*

March 14, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

To Whom It May Concern:

As a practicing oncologist for twenty years, I see the possible initiation of a purchase and distribution plan for chemotherapy, from a remote site/pharmacy, as the most dangerous change YET suggested for Medicare cancer patients.

First, the hazards of shipping drugs across the country from an off-site vendor, with non-secure refrigeration and packing issues is fraught with dangers: especially contamination and drug instability. Secondly, the experience with the Kansas City pharmacist tampering doses and profiteering is bound to be repeated nationally in this system with less quality control because of the sheer volume.

Lastly, patients will have to return more often to out-patient centers, and have to pay TWICE the co-pays to receive chemotherapy: one day to see the physician and check lab tests, a second day to receive the drug prepared somewhere else. For many Medicare patients, who have a hard enough time getting transportation, this will be an additional incentive to postpone or even cancel a needed treatment. Imagine a patient coming twice a week, every week to a physician's office to receive treatment that should be done in just one day!!

I hope this issue will be re-considered for not just the inconvenience and expense the senior citizens will go through, but the dangers and potential abuse such a CAP would introduce nationwide! Thank you for your efforts on our patients' behalf.

Sincerely,

Paul E. Michael, M.D.  
Medical Oncologist

jp

www.cccnevada.com

**MEDICAL ONCOLOGISTS**

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**EXECUTIVE DIRECTOR**

William P. Moore II

**SERVICES OFFERED**

Chemotherapy  
Radiation Therapy  
Pediatric Oncology  
Hematology  
Clinical Research  
(UCLA, USON, CCOPI)  
Stem Cell Transplantation  
Positron Emission Tomography  
Diagnostic CT  
Nuclear Medicine  
Onsite Pharmacy  
Onsite Laboratory  
Therapeutic Phlebotomy  
Social Services  
Medical Massage  
Nutritional Counseling  
Community Support Groups  
Nursing Care  
Hydration  
IMRT  
Gamma Knife  
High Dose Rate Brachytherapy  
Prostate Brachytherapy  
Intravascular Brachytherapy  
Stereotactic Radiosurgery

**LOCATIONS**

3730 South Eastern Avenue  
Las Vegas, Nevada 89109  
702-952-3400

10001 South Eastern Avenue  
Suite 108  
Henderson, Nevada 89052  
702-952-3444

9280 W. Sunset Rd., Ste 100  
Las Vegas, Nevada 89148  
702-952-1251

2650 North Tenaya Way  
Suite 208  
Las Vegas, Nevada 89128  
702-952-2140

655 Town Center Drive  
Las Vegas, Nevada 89144  
702-233-2200

3059 S. Maryland Pkwy., Ste 202  
Las Vegas, Nevada 89109  
702-732-0971

US Oncology Affiliated Network

**Section IV. Oncology Drug / Regimen Based Time In Motion Survey**

**\*Please Write Clearly\*** Site \_\_\_\_\_ Date \_\_\_\_\_ Page \_\_\_\_\_  
 Observer \_\_\_\_\_

Are you observing a regimen Yes or No \_\_\_\_\_  
 if yes, which regimen? \_\_\_\_\_

New Patient? Yes or No \_\_\_\_\_  
 Study Patient? Yes or No \_\_\_\_\_

Regimens represented by drug list include:  
 AC, gemcitabine ± cisplatin or carboplatin, RCHOP, FOLFOX.  
 Provide Codes for drugs observed: \_\_\_\_\_

Were any of the selected drugs produced in Batch? Yes or No \_\_\_\_\_  
 if yes which drug(s)? \_\_\_\_\_  
 Other Drugs Observed: \_\_\_\_\_

Start Time	Stop Time	Order Review by RPh	Collect patient data	Evaluate AB	Manage AB	MD consult'n	Other HCP consult'n	Patient consult'n	Insurer consult'n	Order entry	Oral premed adm'n	Product verification	Compound'g	Product'n check	Drug Information	Patient counseling	CR	Continuity of care	Prod. Spec. Handlg	PharmD	Pharm Tech	Other Comments		
1																								
2																								
3																								
4																								
5																								
6																								
7																								
8																								
9																								

**Appendix 5:  
Fixed Costs Per Site**

	Alabama		Utah		Virginia		Wisconsin		ALL SITES	
	TOTAL	PER DOSE	TOTAL	AVG P						
<b>Storage</b>										
Facilities Cost	\$680.00	\$0.03	\$4,875.00	\$0.82	\$5,167.00	\$0.16	\$5,668.50	\$0.33	\$16,590.50	
<b>Total</b>	<b>\$680.00</b>	<b>\$0.03</b>	<b>\$4,875.00</b>	<b>\$0.82</b>	<b>\$5,167.00</b>	<b>\$0.16</b>	<b>\$5,668.50</b>	<b>\$0.33</b>	<b>\$16,590.50</b>	
<b>Space Rental</b>										
Annual Cost	\$19,639.77	\$0.70	\$3,857.00	\$0.65	\$28,163.40	\$0.86	\$9,111.25	\$0.53	\$60,771.42	
<b>Total</b>	<b>\$19,639.77</b>	<b>\$0.70</b>	<b>\$3,857.00</b>	<b>\$0.65</b>	<b>\$28,163.40</b>	<b>\$0.86</b>	<b>\$9,111.25</b>	<b>\$0.53</b>	<b>\$60,771.42</b>	
<b>Inventory Management</b>										
Labor Cost	\$33,878.00	\$1.20	\$8,331.00	\$1.40	\$39,986.00	\$1.23	\$8,853.00	\$0.52	\$91,048.00	
Inventory Value	\$106,009.40	\$3.75	\$21,860.51	\$3.66	\$44,509.92	\$1.36	\$30,567.81	\$1.79	\$202,947.64	
<b>Total</b>	<b>\$139,887.40</b>	<b>\$4.95</b>	<b>\$30,191.51</b>	<b>\$5.06</b>	<b>\$84,495.92</b>	<b>\$2.59</b>	<b>\$39,420.81</b>	<b>\$2.31</b>	<b>\$293,995.64</b>	
<b>Insurance Management</b>										
Labor Cost	\$235,996.00	\$8.36	\$43,050.00	\$7.22	\$289,536.00	\$8.87	\$64,575.00	\$3.78	\$633,157.00	
<b>Total</b>	<b>\$235,996.00</b>	<b>\$8.36</b>	<b>\$43,050.00</b>	<b>\$7.22</b>	<b>\$289,536.00</b>	<b>\$8.87</b>	<b>\$64,575.00</b>	<b>\$3.78</b>	<b>\$633,157.00</b>	
<b>Waste Management</b>										
Labor Cost	\$3,170.00	\$0.11	\$25,827.00	\$4.33	\$2,059.00	\$0.06	\$18,659.00	\$1.09	\$49,715.00	
Annual Drug Waste	\$58,923.00	\$2.09	\$2,500.00	\$0.42	\$35,000.00	\$1.07	\$15,000.00	\$0.88	\$111,423.00	
Other Costs	\$38,320.00	\$1.36	\$0.00	\$0.00	\$88,784.00	\$2.72	\$71,253.00	\$4.17	\$198,357.00	
<b>Total</b>	<b>\$100,413.00</b>	<b>\$3.56</b>	<b>\$28,327.00</b>	<b>\$4.75</b>	<b>\$125,843.00</b>	<b>\$3.86</b>	<b>\$104,912.00</b>	<b>\$6.15</b>	<b>\$359,495.00</b>	
<b>Payroll</b>										
Payroll Cost	\$305,565.00	\$10.82	\$147,172.48	\$24.67	\$351,876.00	\$10.78	\$377,580.00	\$22.12	\$1,182,193.48	
<b>Total</b>	<b>\$305,565.00</b>	<b>\$10.82</b>	<b>\$147,172.48</b>	<b>\$24.67</b>	<b>\$351,876.00</b>	<b>\$10.78</b>	<b>\$377,580.00</b>	<b>\$22.12</b>	<b>\$1,182,193.48</b>	
<b>Equipment</b>										
Hood Cost	\$3,100.00	\$0.11	\$1,250.00	\$0.21	\$1,200.00	\$0.04	\$1,061.00	\$0.06	\$6,611.00	
Venting Cost	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$600.00	\$0.04	\$600.00	
Inspections	\$1,200.00	\$0.04	\$350.00	\$0.06	\$1,100.00	\$0.03	\$350.00	\$0.02	\$3,000.00	
Computer	\$4,500.00	\$0.16	\$3,000.00	\$0.50	\$3,000.00	\$0.09	\$3,000.00	\$0.18	\$13,500.00	
Fax	\$250.00	\$0.01	\$250.00	\$0.04	\$250.00	\$0.01	\$250.00	\$0.01	\$1,000.00	
Phone	\$150.00	\$0.01	\$100.00	\$0.02	\$150.00	\$0.00	\$100.00	\$0.01	\$500.00	
Dispensing	\$13,452.00	\$0.48	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$13,452.00	
Telecom Cost	\$1,800.00	\$0.06	\$1,944.00	\$0.33	\$4,003.00	\$0.12	\$2,330.00	\$0.14	\$10,077.00	

Total	\$24,452.00	\$0.87	\$6,894.00	\$1.16	\$9,703.00	\$0.30	\$7,691.00	\$0.45	\$48,740.00
<b>Supplies</b>									
Annual Cost	\$98,122.00	\$3.48	\$135,943.00	\$22.79	\$77,382.00	\$2.37	\$40,102.00	\$2.35	\$351,549.00
Total	\$98,122.00	\$3.48	\$135,943.00	\$22.79	\$77,382.00	\$2.37	\$40,102.00	\$2.35	\$351,549.00
<b>Shipping</b>									
Annual Cost	\$0.00	\$0.00	\$0.00	\$0.00	\$74,288.00	\$2.28	\$0.00	\$0.00	\$74,288.00
Total	\$0.00	\$0.00	\$0.00	\$0.00	\$74,288.00	\$2.28	\$0.00	\$0.00	\$74,288.00
<b>Info Resources</b>									
Annual Cost	\$1,200.00	\$0.04	\$500.00	\$0.08	\$500.00	\$0.02	\$500.00	\$0.03	\$2,700.00
Total	\$1,200.00	\$0.04	\$500.00	\$0.08	\$500.00	\$0.02	\$500.00	\$0.03	\$2,700.00
GRAND TOTAL	\$926,155.17	\$32.80	\$400,809.99	\$67.19	\$1,046,954.32	\$32.08	\$649,560.56	\$38.05	\$3,023,480.04

**Appendix 6:**

**Observed Chemotherapy Drugs, Regimens, and Supportive Agents**

Chemotherapy Agents	Number of Observations per Agent			
	Alabama	Virginia	Utah	Wisconsin
Carboplatin	12	12	10	15
Cisplatin	12	8	12	19
Cyclophosphamide	13	8	14	25
Docetaxel	3	14	9	10
Doxorubicin	12	10	14	22
Fluorouracil	21	14	15	12
Gemcitabine	10	8	14	14
Herceptin	10	11	7	12
Irinotecan	8	19	11	11
Leucovorin	14	14	15	10
Oxaliplatin	4	12	10	11
Paclitaxel	15	10	11	15
Rituximab	12	12	11	17
Topotecan	3	2	1	9
Vincristine	3	9	8	12
<b>Total Observations</b>	<b>152</b>	<b>163</b>	<b>162</b>	<b>214</b>

Concomitant Agents	Number of Observations per Agent			
	Alabama	Virginia	Utah	Wisconsin
Darbepoetin	20	14	10	12
Decadron	68	3	58	57
Dolasetron	3	8	53	87
Epoetin	0	6	4	8
Filgrastim	0	4	0	5
Granisetron	68	0	8	0
Ondansetron	0	0	3	0
Pamidronate	5	11	0	2
Pegfilgrasim	7	4	6	5
Zoledronate	8	8	11	12
<b>Total Observations</b>	<b>179</b>	<b>58</b>	<b>153</b>	<b>188</b>

Drug Regimens	Number of Observations per Regimen			
	Alabama	Virginia	Utah	Wisconsin
Fluorouracil + Leucovorin	4	3	1	0
Fluorouracil + Leucovorin + Irinotecan	4	0	0	0
Doxorubicin + Cyclophosphamide	7	7	4	11
Carboplatin + Paclitaxel	6	3	1	0
Cyclophosphamide + Vincristine + Doxorubicin	0	0	1	1
Cisplatin + Docetaxel	1	0	0	0
Cisplatin + Paclitaxel	3	0	0	0
Irinotecan + Leucovorin + Fluorouracil infusion	0	4	0	0
Oxaliplatin + Leucovorin + Fluorouracil bolus + Fluorouracil infusion	4	3	4	8

Oxaliplatin + Gemcitabine	0	1	0	0
Gemcitabine + Carboplatin	2	0	0	1
Gemcitabine + Cisplatin	0	0	1	3
Rituximab + Cyclophosphamide + Vincristine + Doxorubicin	1	2	9	11
Regimen Indicated with Nothing Named	1	0	4	1
<b>Total Observations</b>	<b>33</b>	<b>23</b>	<b>25</b>	<b>36</b>

**Appendix 7:**  
**Summary of Time-and-Motion Analysis Raw Data**

Practice ID	Type	Drug Observation Data					
		Activity	Number of Observations	Sum of Minutes	Sum of Hours		
Alabama	Pharm Tech	Compounding	162	364.6	6.1		
		Order Entry	6	9.2	0.2		
		Product Verification	1	0.7	0.0		
		Production Check	3	0.8	0.0		
	PharmD	Collect Patient Data	23	20.1	0.3		
		Compounding	31	77.7	1.3		
		Insurer Communication	1	1.1	0.0		
		Manage AE	2	22.7	0.4		
		MD Consultation	1	0.9	0.0		
		Oral Premed Administration	3	2.1	0.0		
		Order Entry	120	191.2	3.2		
		Order Review By RPh	122	228.9	3.8		
		Other HCP Consultation	22	61.1	1.0		
		Product Special Handling	13	32.9	0.5		
		Product Verification	18	12.7	0.2		
		Production Check	190	106.0	1.8		
		Utah	Pharm Tech	Collect Patient Data	4	26.2	0.4
				Compounding	122	1243.6	20.7
				Insurer Communication	1	3.7	0.1
				Oral Premed Administration	3	3.5	0.1
Order Entry	7			20.7	0.3		
Order Review By RPh	3			52.4	0.9		
Other HCP Consultation	3			6.0	0.1		
Patient Communication	2			7.0	0.1		
PharmD	Product Verification		2	0.4	0.0		
	Production Check		1	0.5	0.0		
	Collect Patient Data		129	693.5	11.6		
	Compounding		1	1.2	0.0		
	Drug Information		3	8.5	0.1		
	Evaluate AE		1	1.0	0.0		
	MD Consultation		11	31.0	0.5		
	Oral Premed Administration		92	169.6	2.8		
	Order Entry		125	529.2	8.8		

<b>Virginia</b>	<b>Pharm Tech</b>	Order Review By RPh	143	1021.6	17.0
		Other HCP Consultation	25	28.6	0.5
		Patient Communication	14	54.5	0.9
		Product Verification	32	33.7	0.6
		Production Check	132	331.5	5.5
		Compounding	187	639.9	10.7
		Collect Patient Data	3	25.2	0.4
		Compounding	3	7.6	0.1
	<b>PharmD</b>	Evaluate AE	2	2.3	0.0
		MD Consultation	2	2.3	0.0
		Order Entry	117	247.2	4.1
		Order Review By RPh	128	255.2	4.3
		Other HCP Consultation	15	32.2	0.5
		Patient Counseling	10	5.3	0.1
		Product Special Handling	141	97.8	1.6
		Product Verification	215	117.7	2.0
<b>Wisconsin</b>	<b>Pharm Tech</b>	Production Check	169	106.4	1.8
		Compounding	153	764.7	12.7
		Product Verification	153	768.9	12.8
		Production Check	1	0.8	0.0
	<b>PharmD</b>	Collect Patient Data	134	321.3	5.4
		Continuity Of Care	14	70.2	1.2
		Drug Information	5	23.7	0.4
		Evaluate AE	1	2.7	0.0
		Insurer Communication	5	33.1	0.6
		Manage AE	1	2.7	0.0
		MD Consultation	17	44.9	0.7
		Order Entry	157	348.5	5.8
		Order Review By RPh	150	351.8	5.9
		Other HCP Consultation	12	28.6	0.5
		Patient Communication	69	292.2	4.9
		Patient Counseling	65	329.5	5.5
Product Verification	1	0.8	0.0		
Production Check	149	355.4	5.9		

<b>Direct Pharmacist One Day Observation Data</b>				
<b>Practice ID</b>	<b>Activity</b>	<b>Number of Observations</b>	<b>Sum of Minutes</b>	<b>Sum of Hours</b>
<b>Alabama</b>	Collect Patient Data	4	2.6	0.0
	Compounding	21	46.4	0.8
	Insurer Communication	1	1.1	0.0
	Interruption	14	15.3	0.3

**Utah**

Order Entry	30	62.5	1.0
Order Review By RPh	32	62.1	1.0
Other	45	229.8	3.8
Other HCP Consultation	25	34.2	0.6
Patient Communication	1	1.5	0.0
Product Special Handling	2	2.3	0.0
Product Verification	20	19.7	0.3
Production Check	21	26.3	0.4
CE	1	17.3	0.3
Collect Patient Data	36	91.2	1.5
Drug Information	11	47.4	0.8
Interruption	7	39.2	0.7
MD Consultation	5	7.2	0.1

**Virginia**

Oral Premed Administration	21	40.1	0.7
Order Entry	21	38.9	0.6
Order Review By RPh	57	134.1	2.2
Other	21	61.1	1.0
Other HCP Consultation	34	81	1.4
Patient Communication	4	11.9	0.2
Product Verification	19	33.4	0.6
Production Check	18	49.3	0.8
CE	3	17.4	0.3
Collect Patient Data	1	8.4	0.1
Continuity Of Care	2	8.1	0.1
Drug Information	7	24.4	0.4
MD Consultation	12	82	1.4

**Wisconsin**

Order Entry	33	237.7	4.0
Order Review By RPh	33	233.9	3.9
Other	36	183.8	3.1
Other HCP Consultation	22	99.8	1.7
Product Special Handling	5	57.3	1.0
Product Verification	15	149.3	2.5
Production Check	16	150.1	2.5
Collect Patient Data	17	33.6	0.6
Compounding	1	3.4	0.1
Continuity Of Care	14	43.7	0.7
Evaluate AE	1	2.8	0.0
Insurer Communication	4	18.3	0.3
Interruption	2	0.9	0.0
Manage AE	1	2.8	0.0
MD Consultation	11	22.7	0.4

**Appendix 8. Counts of Persons and Infusions by HCPCS Code.**

Chemotherapy Procedure Code (HCPCS)	Unweighted Counts		Projection to Population with Medicare and Commercial Supplemental Insurance		Projection to Total Medicare Population	
	Persons	Infusions	Persons	Infusions	Persons	Infusions
C9205-Oxaliplatin	9	30	193	741	583	2,432
J0640-Leucovorin Calcium Injection	787	8,408	12,154	132,415	32,721	351,443
J9000-Doxorubic HCl 10 Mg VI Chemo	589	2,172	9,076	32,850	24,750	90,212
J9001-Doxorubicin HCl Liposome Inj	112	316	1,637	4,504	4,796	13,144
J9045-Carboplatin Injection	1,453	6,415	21,928	97,648	59,389	263,194
J9060-Cisplatin 10 Mg Injection	222	765	3,579	12,518	9,411	31,961
J9062-Cisplatin 50 Mg Injection	215	785	3,281	12,137	8,592	31,416
J9070-Cyclophosphamide 100 Mg Inj	129	460	2,003	7,441	5,318	20,364
J9080-Cyclophosphamide 200 Mg Inj	35	84	484	1,217	1,285	3,273
J9090-Cyclophosphamide 500 Mg Inj	99	320	1,442	4,807	3,836	12,670
J9091-Cyclophosphamide 1.0 Grm Inj	79	254	1,149	3,678	3,108	9,919
J9092-Cyclophosphamide 2.0 Grm Inj	11	20	155	266	394	668
J9093-Cyclophosphamide Lyophilized	329	1,050	4,944	15,706	13,784	43,703
J9094-Cyclophosphamide Lyophilized	141	473	2,204	7,400	6,194	21,248
J9095-Cyclophosphamide Lyophilized	219	683	3,514	11,224	9,921	31,754
J9096-Cyclophosphamide Lyophilized	289	931	4,433	14,298	12,226	40,114
J9097-Cyclophosphamide Lyophilized	52	174	736	2,484	1,976	6,708
J9170-Docetaxel	849	5,040	12,869	76,849	35,333	211,862
J9190-Fluorouracil Injection	1,341	11,998	20,653	187,448	56,202	507,111
J9201-Gemcitabine HCl	872	5,405	13,244	81,693	36,769	226,345
J9206-Irinotecan Injection	398	3,004	6,155	47,212	16,223	123,198



12258

MAR 21 2005

Signal Point Hematology/Oncology, Inc.

Cheryl A. Skinner, M.D. • Albert S. Malcolm, M.D.

March 7, 2005

**RE: Competitive Acquisition Program Proposed by CMS**

To Whom It May Concern:

I'm writing this letter in comment to the proposed Competitive Acquisition program as I'm reading it outlined from CMS. I am an oncologist who has been in practice for 20 years and I think I have reasonable experiences to offer as far as the delivery of drugs to patients with oncology diagnoses. We see patients in the office for treatments. I think private oncology office practices for patients represent the appropriate site of care and represent a lower cost setting. There are times when we do fairly emergent therapies for patients. Obviously a program where I have to register patients and acquire the drug would hamper this ability to respond quickly to the patients needs.

As far as the comment that I could use drugs from my inventory. Because of the recent national and international experiences with drugs that have been tampered with, my malpractice carrier has stated that if I accept responsibility for the drugs from a wholesaler, required by an insurance plan without control of the drug inventory then my malpractice rates go up. I would think that I would have to maintain a separate drug inventory which would complicate the services that I deliver in my office. I also do not maintain individual drugs for individual patients so this kind of inventory process required under CAP would be a demand beyond my practice ability. I do not have barcode capabilities as most computer programs are not accepting that at present.

I have concern about the patient's care overall. We do a lot to help with secondary insurance billing and out of pocket expenses for patients. It doesn't sound like that kind of personalized service is going to be provided to these patients. The secondary dollar amounts can add up very quickly with oncology drugs. I'm already starting to see patients who are opting out of fairly treatable and even curable disease processes because of concerns about expenditures. These patients are often on limited income and have finite financial reserves that spouses have to live on when the oncology patient expires. I think these are all problematic areas as far as your proposed CAP service, i.e. my malpractice rate will go up, the complexity of the services delivered in my practice are going to mean more personnel time and expense and ultimately my concern that patients

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are going to opt out of treatments because of the monetary consequences. I think this is a very dangerous proposal that is going to clearly interfere with the current and appropriate delivery of patient care. I think patients will suffer with this proposal.

Sincerely yours,



Cheryl A. Skinner, M.D.

Cc: ASCO  
ACC  
Members of Congress

CAS:bms



Austin Travis County  
Mental Health Mental Retardation Center

MAR 30 2005

Centers for Medicare and Medicaid Services  
Department on Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244-8010

Sirs:

I am the Director of Medical and Clinical Management Services at the Austin Travis County Mental Health and Mental Retardation Center in Austin, Texas. In my position, I am not only the direct supervisor of 12 physicians, but am also part of the executive management team of our Center with responsibility for Utilization Management, Quality Management and the Pharmacy Program. I am uniquely positioned in this agency to comment upon the Medicare Competitive Acquisition Program for Part B Drugs.

I strongly support the implementation of the Competitive Acquisition Program. Community mental health centers are working hard to create efficiencies in order to press funds into direct care for patients. Consolidating the reimbursement process for Part B drugs into Specialty Pharmacy Providers would allow economies of scale. By reducing the financial risks to our Center, we are better equipped to maintain access to the best treatment options for our patients with severe and persistent mental illnesses.

Please include psychiatric medications in the Competitive Acquisition Program. These are very expensive and debilitating psychiatric conditions. Insuring access to effective care is an ultimate cost savings to the country. Further, I urge you to include these psychiatric medications at the outset of the program rather than waiting for some period of time. You should create the appropriate category for psychiatric medications. Finally, in order to assure continuity of treatment, you should not allow the Specialty Pharmacy Providers to discontinue provision of the medications due to copays not collected.

I look forward to expanded opportunities for successful treatment of our patients with severe and persistent psychiatric illnesses with the inclusion of psychotropic medications under the Competitive Acquisition Program of Medicare Part B.

Sincerely,

James R. Van Norman, MD  
Director, Medical and Clinical Management Services

APR - 6 2005



# Oregon Health & Science University

*School of Medicine, Department of Psychiatry*

3181 S.W. SAM JACKSON PARK ROAD, UHN80 • PORTLAND, OR 97239-3098 • (503) 494-7514 • FAX: (503) 494-6152

April 05, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P, Box 8010  
Baltimore, MD 21244-8010

**RE: Long-acting injectable antipsychotic medications should be a pharmacy benefit rather than "buy and bill"**

Adherence to a prescribed regimen of medication is a challenge for all of us, whenever we need to take medication. This is especially true for medications that need to be taken over a long period of time, and for which the person taking the medication has little subjective awareness of missed doses, for example, antihypertensives, cholesterol lowering agents, and antipsychotic medications.

Individuals with chronic psychotic disorders have especial difficulty with medication adherence due to factors associated with their illness. Some of these factors have to do with particular cognitive deficits in planning, sequencing and monitoring behavior. Others may relate to partial insight into the nature of their illness and the benefits of medication treatment. Assured medication compliance is thus a challenge, but is an essential element in the process of recovery and the prevention of relapse.

Use of long-acting injectable ("depot") antipsychotic medication provides a level of medication adherence that is often unattainable with oral medication, and is thus an excellent alternative to oral medication for many individuals with psychotic disorders. Two of the older "typical" antipsychotics have been available for years in this type of formulation: haloperidol decanoate and fluphenazine decanoate. More recently the first of the newer, preferred "atypical" antipsychotics has become available as a long-acting injectable: risperidone long-acting injectable, which uses a dissolving microsphere delivery system.

Access to these medications is crucial to maximizing treatment outcomes and avoiding relapse and costly hospitalizations. The current "buy and bill" approach to funding these medications is often a barrier to access in community mental health programs and other treatment facilities. To promote access to these useful medications, I urge you to provide long-acting injectable antipsychotics as a pharmacy benefit rather than on a "buy and bill" basis.

William H. Wilson, MD  
Professor of Psychiatry  
Director of Inpatient Psychiatry

C:

Gina Firman, Executive Director  
Oregon Association of Community Mental Health Centers  
1201 Court Street NE, Suite 201  
Salem OR 97301

Catherine Gaylord  
Washington CMH Council  
600 Stewart Street, Suite 520  
Seattle WA 98101



APR - 4 2005

5

# NAMI South Carolina

29 March 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244-8010

On behalf of the National Alliance for the Mentally Ill- SC, I am writing to strongly urge that mental health medications be eligible for the Competitive Acquisition Program (CAP) on January 1, 2006.

These medications are a critical lifeline for people with mental illnesses. We are very concerned that without access to CAP, the current buy and bill system will act as a disincentive for many physicians to obtain Part B drugs. Our mental health system is like many others- it is under-funded, it is in crisis, and these tough economic times are only making the situation worse. Not including mental health medications in the CAP is a challenge we can do without.

Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink that reads "J. David Almeida".

J. David Almeida  
Executive Director

**NAMI South Carolina**

P.O. Box 1267 ★ Columbia, South Carolina 29202  
HelpLine: (800) 788-5131 OR (803) 733-9591 ★ PH: (803) 733-9592  
FX: (803) 733-9533 ★ E-Mail: [namiofsc@logicsouth.com](mailto:namiofsc@logicsouth.com) ★ [www.namisc.org](http://www.namisc.org)

# Communicare



MICHAEL D. ROBERTS, Ph.D., Executive Director

152 Highway 7 South  
Oxford, Mississippi 38655  
(662) 234-7521  
FAX (662) 236-3071

APR - 4 2005

March 29, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

Dear Sirs:

I am writing in regard to the Competitive Acquisition Program. Communicare is the community mental health center serving Northern Mississippi. We provide treatment for mentally ill persons in seven counties.

As I understand it, CMS is considering the therapeutic categories and medications to be included in the CAP. I would urge that psychotic medications be included.

Community mental health centers in Mississippi are severely under funded by the State, which continues to prioritize expenditures on State inpatient facilities. We have identified approximately 300 patients who will lose Medicaid coverage as of January 1, 2006. Most of them will remain covered by Medicare. We are seeking resources to enable continued care of these patients after January 1, 2006. Inclusion of them in the Competitive Acquisition Program would be of great assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Roberts", written over a horizontal line.

Michael D. Roberts, Ph.D.  
Executive Director

clc

APR - 4 2005

**NAMI Contra Costa**, 1110 St. Francis Drive, Concord, CA, 94518  
925-676 5771 Fax: 925-476 1444 E Mail: xnamicc@aol.com  
[www.namicontracosta.org](http://www.namicontracosta.org)

March 30, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: [REDACTED]  
[REDACTED]  
[REDACTED], 21244-8010

**SUBJECT: Include Mental Health Therapies in the CAP, Phase I**

We at NAMI Contra Costa, the tenth largest affiliate in the nation feel that it is a matter of great importance that mental health medications be included in the Competitive Acquisition Program, Phase I. Making these changes insure patients will receive their medications, because the specialty pharmacy provider vendors will maintain product availability.

The serious and chronic mental illnesses are as life shattering as any physical illness including cancer. Normal life experiences are taken away when these disorders strike. The only chance of some normalcy is an effective medication. To deny the patient the one thing that can give some sort of life is unthinkable.

In the last year we have seen many of our most intractable, medication non-compliant patients make significant progress. To have these injectables become unavailable, and they would, would be devastating

Please be certain the mental health medications are included in the Competitive Acquisition Program.

Cordially,



David Kahler  
President  
NAMI Contra Costa  
DK:avw

APR - 7 2005



**NAMI**

# NAMI Massachusetts

April 5, 2005

RE: Psychiatric Medications

Dear Center for Medicare and Medicaid Services;

The National Alliance for the Mentally Ill of Massachusetts (NAMI-Mass) is a grassroots family based advocacy and education group dedicated to improving the quality of life for people affected by mental illness. We would like to address mental health medications in your upcoming drug benefit changes. We are concerned that decisions may adversely affect some individuals with mental illness and family members if the policies does not allow for flexibility for the individuality of each mental health patient.

- Some patients do not have the same therapeutic affects from generic medication as compared to trademarked medications. In addition, some psychiatric patients believe that a change in medication will harm them and this belief in and of itself can create a self-fulfilling prophecy where the patient deteriorates. Hospitalization is clearly more expensive than medication.
- Clinicians already speak of being inundated with paperwork and regulations. Clearly there is a need for regulations; however, we hope that this policy does not create additional or unneeded barriers to treatment.
- The professionals who work directly with the patients are the best suited to determine the most appropriate clinical needs of the individual patients. We believe that the decision of which medication to prescribe at any given time should ultimately lie with the clinician.
- Selecting the right medicine for a patient is a complex decision – one that is best made by the treating health care professional. No medicine works exactly like another – “therapeutically equivalent” in many cases does not mean therapeutically *equal*. Each medicine is different and each patient is different. The brain is a complex organ and it is not unusual to find that response to medication differs from person to person, even if the diagnosis is the same. Therefore, to impose a “one size fits all” medication policy is unsound, unsafe, and unfair to a population that struggles daily with their illness.
- The value of a particular medicine cannot be measured by its price. It is measured by how well it treats a particular patient when delivered at the right time and at the right dose. Saving money in the pharmaceutical budget through

**NAMI Massachusetts ★ The State's Voice on Mental Illness**

400 West Cummings Park, Suite 6650 ★ Woburn, MA 01801

PH: 781-938-4048 ★ FX: 781-938-4069 ★ E-Mail: namimass@aol.com

www.namimass.org

National Alliance For The Mentally Ill ★ NAMI ★ National Alliance For The Mentally Ill ★ NAMI ★ National Alliance For The Mentally Ill

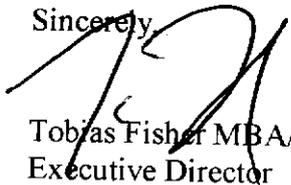
shortsighted restrictions does not necessarily translate to reduce spending generally, as each change in treatment may require additional doctor visits, medical testing and monitoring. Prescription medicines are a single component in the spectrum of health care services, and still account for only about 10% of the health care dollar.

For these reasons we urge you to do the following when implementing the new drug benefit.

1. Include Psychiatric Medications in CAP (Competitive Acquisition Programs). It is unlikely you would see any cost savings from doing otherwise.
2. Include Psychiatric Medications in Phase I on January 1, 2006
3. Include a Mental Health Drug Category in Part B, which would include all forms of mental health drugs including long-acting injectable medications.
4. Insure seamless reimbursement procedures so that providers do not have uncollectibles or dis-incentives for administering vital mental health medications.

As family members, caretakers and people with mental illness, we are very concerned at the prospect of the new drug benefit that will roll out next year. Access to vital psychiatric medications is essential to patients with mental illness and family members. All anti-psychotics, antidepressants, and anticonvulsants used for the treatment of mental illness should be made available. We believe that individuals with brain disorders must have access to treatments that have been recognized as effective by the FDA and/or NIMH. We strongly oppose measures that limit the availability and right of individuals with brain disorders to receive treatment with "new generation" medications. Policies that do not allow flexibility for the patient and the complexities of the human brain can be detrimental and ultimately cost more. We look forward to your response.

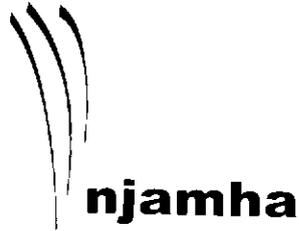
Sincerely,



Tobias Fisher MBA/MSW,  
Executive Director

March 30, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244



Dear Members of the Centers for Medicaid and Medicare Services:

Thank you for the welcome opportunity to provide our comments and insights in relation to the proposed Competitive Acquisition Program (CAP) rules under current consideration that were issued by the Centers for Medicare and Medicaid Services on February 25 and which appeared in the *Federal Register* on March 4, 2005. The New Jersey Association of Mental Health Agencies, Inc. (NJAMHA) is honored and privileged to speak on behalf of New Jersey's mental health providers (both hospital-based and freestanding) in order to facilitate the development of an effective and efficient Medicare reimbursement plan. We at NJAMHA appreciate that our comments and recommendations will be seriously considered and weighed.

Based in Mercerville, New Jersey, the New Jersey Association of Mental Health Agencies, Inc. (NJAMHA) is a statewide trade association representing the needs of nonprofit behavioral health provider organizations. Founded in 1951, NJAMHA represents 125 hospital-based and freestanding mental health agencies throughout New Jersey that employ more than 50,000 people and collectively treat more than one million incidences of mental illness and substance abuse annually. NJAMHA's mission is to champion opportunities that advance its members' ability to deliver accessible, quality, efficient and effective integrated behavioral health care services to mental health consumers and their families.

To begin with, the current Medicare reimbursement system for physicians, which is covered under Medicare's Part B benefit, has deterred many mental health providers from dispensing much-needed psychiatric drugs and has resulted in the reduction of therapy sessions. Under the current "buy and bill" reimbursement system, mental health providers are burdened with the problem of having to pay for necessary medication up-front without any safeguards against claims rejections. When a claim rejection occurs (this is not uncommon in the mental health field), the mental health provider is left with bad debt and must limit the amount of medication and therapy services offered. Not only does this prevent mental health providers from effectively treating consumers, but it also serves as a further deterrent to future services as

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New Jersey Association of Mental Health Agencies, Inc.

providers are unlikely to offer drugs or therapy when the chances for reimbursement are questionable at best, non-existent at worst.

Similarly, even when Medicare claims are reimbursed partially or fully, mental health providers are still losing money. Though the Medicare Modernization Act (MMA) has tried to correct this situation by changing the basis for reimbursement from 95% of the average wholesale price to 106% of the average sales price, mental health providers continue to have to advance funds for treatment services without a guarantee of reimbursement. As with a rejected claim, partial and full coverage under the current Medicare reimbursement system are problematic to mental health providers, so they have no other option but to limit access to treatment.

Associated with the difficulties of reimbursement is the issue of billing. Many providers cite frustration with Medicare billing as a reason for their challenge in offering medications and therapy to their patients. Unable to navigate the complex billing system, they are routinely denied claims. This unfortunate consequence of the Medicare system is common among providers nationwide.

For mental health providers, the unintended consequences of the current Medicare reimbursement plan are easy to discern, but for mental health consumers, the population that is most the most vulnerable and important in this discussion, the negative implications are paramount. Without access (or faced with limited access) to effective medications, therapy and services, individuals with mental illness are left largely untreated. Several studies have shown that this leads to increased emergency hospital visits and increased incarcerations, which costs the states millions of dollars every year. The human and fiscal costs of not treating mental illness far outweigh the costs of treatment, and this fact must be imbedded into any new Medicare proposal.

In light of these observations on the current Medicare reimbursement system for physicians and its effects on mental health consumers, NJAMHA and its supporters have much to add to the topic of reimbursement reform. We support the proposed CAP rule, but strongly urge that wording be added to include psychiatric drugs, including injectable antipsychotics, into Phase I of the program, which is scheduled to begin January 1, 2006, owing to the fact that the longer the current system is in place, the higher the risk of providers incurring debts, cutting back services and patients going untreated.

NJAMHA applauds the fact that the CMS has not excluded drugs from the program that are unlikely to result in significant savings or are likely to cause patient access difficulties, and we endorse and support additional regulations that protect psychiatric drugs from any future exclusion. **We also back the proposition to create a category solely comprised of mental health drugs, which will aid mental health providers in obtaining effective medication and drugs.**



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**Director, IT Project**

John A. M.D.

New Jersey Association of Mental Health Agencies, Inc.



A category dedicated to injectable drugs is a necessary and vital step toward reimbursement reform and will serve as a catalyst to more effective treatment methods. Guaranteeing that mental health providers will be reimbursed for injectable drugs will protect them from paying up-front for medication without any safety net and will enable them to direct and focus their attention on what matters the most, the health and well-being of their patients.

Finally, NJAMHA is supportive of CMS's recognition of the problematic cycle of rejected claims and reduced services, but desires new rules to be added that will prevent the discontinuation of medication and therapy because of lack of reimbursement.

NJAMHA hopes that these recommendations will help to restructure the Medicare reimbursement system so that the ultimate beneficiaries, mental health consumers, will not encounter obstacles in obtaining the necessary medications to effectively treat their mental illnesses. If the realistic concerns providers have about the potential of not being reimbursed for medication are eliminated, access problems for mental health consumers will be greatly alleviated. Thank you once again for this opportunity to comment on the proposed CAP rule.

Sincerely,  
  
Debra L. Wentz, Ph.D.  
Chief Executive Officer

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**Director, IT Project**

Jim A. Neri

New Jersey Association of Mental Health Agencies, Inc.



# NAMI-NEW YORK STATE

National Alliance for the Mentally Ill - New York State

260 Washington Avenue • Albany • New York 12210 • email:naminys@naminys.org  
Phone: 518.462.2000 • Hotline: 1.800.950.3228 • Fax: 518.462.3811 • http://www.naminys.org

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## Executive Director

J. David Seay, JD

March 30, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
P. O. Box 8010  
Baltimore, MD 21244-8010

Dear Sir/Madam:

I am writing about the notice of proposed rulemaking published in the March 4, 2005, *Federal Register* concerning the "Medicare Competitive Acquisition Program" (CAP) for Part B drugs. I submit the following comments on behalf of the National Alliance for the Mentally Ill of New York State (NAMI-NYS) and our 5,000 members and 58 local affiliate organizations across the State of New York.

Our comments are as follows:

- Include psychiatric drugs in the CAP program from the beginning. The present system has inherent within it certain barriers to access that the CAP would solve. If categories or groupings of drugs are used under CAP, we urge you to create a group or category that would include medications used to treat any diagnosis included within the DSM-IV (revised), including the "long-acting" or injectable antipsychotic medications.
- Discourage discontinuation of therapy by vendors by crafting a reimbursement process that adequately addresses the handling of co-pays and other payment issues that can imperil continuity of therapy.

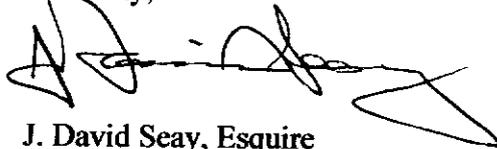
NAMI-NYS is a 23 year old, grass-roots membership organization representing persons with serious and persistent mental illnesses and their families. Our mission is to improve the lives of all New Yorkers affected by mental illness. We accomplish this through carefully crafted programs of support, education and advocacy. We are part of the national NAMI movement, the nation's largest mental health advocacy organization.



Centers for Medicare and Medicaid Services  
March 30, 2005  
Page two

We thank you for the opportunity to offer our comments and we urge you to take them under serious consideration.

Cordially,

A handwritten signature in black ink, appearing to read "J. David Seay", written over a horizontal line.

J. David Seay, Esquire  
Executive Director



Quality In Care • Excellence In Service

March 31, 2005

Center for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8010  
Baltimore, MD 21244-8010  
ATTN: CMS-1325-P

Dear Administrator:

I am requesting that Mental Health injectables be part of the Competitive Acquisition Program of 2006.

Presently, we are encountering difficulty with obtaining some of these medications for our most chronically ill clients. For instance, Risperdal Consta requires "buy and fill" for medicare patients, which leaves a clinic such as ours financially exposed. As a result, we have to limit the number of clients that can benefit from this intramuscular medication.

Therefore, I am requesting that all Mental Health injectables be included in Phase I. Thank you for your consideration in this matter.

Sincerely,

A handwritten signature in black ink that reads "Luis J. Bird, M.D.".

Luis J. Bird, M.D.  
Medical Director

LJB/bjl

cc: Mathew J. Elavumkal  
Chief Executive Officer

100 West Lehigh Avenue, Philadelphia, PA 19133-4097 • 215-203-3000 • Fax: 215-203-3011 • TDD: 800-654-5984

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# MADISON CENTER AND HOSPITAL

APR 12 2005

403 E. MADISON STREET • SOUTH BEND, INDIANA 46617 • 574/234-0061 • TOLL-FREE 877/234-0061 • FAX 574/288-5047 • www.madison.org

April 7, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attn.: CMS-1325-P  
P. O. Box 8010  
Baltimore, MD 21244-8010

Re: Competitive Acquisition Program (CAP) Proposed Rule

To Whom It May Concern:

The purpose of this letter is to provide public comment on the Centers for Medicare and Medicaid Services (CMS) CAP proposed rule.

It is my recommendation that CAP include psychiatric drugs, including long-acting, injectible anti-psychotics. It is also my recommendation that psychiatric drugs be included in Phase I of the program.

I believe that inclusion of psychiatric drugs in the CAP program will alleviate barriers to access inherent in the current system. By replacing the current buy and bill system for providers with the specialty pharmacy provider vendors proposed under CAP, those barriers will be alleviated and enable more patients in need of valuable mental health medications to access them.

If I may provide any additional information, please do not hesitate to contact me at (574) 283-2107.

Sincerely,

John I. Twardos  
Chief Operating Officer

JT/dr

*Accredited by the Joint Commission on Accreditation of Healthcare Organizations*

MADISON CENTER  
FOR CHILDREN  
701 N. NILES AVENUE  
SOUTH BEND, INDIANA 46617  
574/234-0061  
FAX 574/283-1129

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574/266-8480  
FAX 574/266-5118

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2349 LAKE AVENUE, SUITE 202  
PLYMOUTH, INDIANA 46563  
574/935-3770  
FAX 574/935-3788

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574/283-0581  
FAX 574/283-4022

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533 N. NILES AVENUE  
SOUTH BEND, INDIANA 46617  
574/283-1104  
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13

*Central Pennsylvania*  
**Hematology & Medical Oncology**  
*Associates, P.C.*

APR 12 2005

John D. Conroy, Jr., D.O., F.A.C.P., F.A.C.O.I.  
Scott G. Barnes, D.O., F.A.A.O.I.  
Michael E. Klein, M.D.  
Li Min Isaac Liu, M.D.

Joyce A. McCorkle, R.N.  
*Practice Manager*

*Affiliated with:*



April 4, 2005

Centers for Medicare and Medicaid Services  
Department of Health & Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore MD 21244-8014

To Whom It May Concern:

We are a Community Oncology office in Pennsylvania. Listed below are our concerns with the proposed CAP program:

1. Each time a patient enters our office for chemotherapy, they are evaluated. We perform a CBC to check the blood counts, we evaluate any new diagnostic testing reports, and we assess the patient's tolerance to the protocol that they are receiving. It is very common to change drugs and or doses for patients just prior to their chemotherapy. This evaluation is necessary and changes are medically necessary. We are confused as to how we could preorder drugs per patient. We would be forced to reschedule patients often.
2. The chemotherapy may be discontinued the day the patient has it scheduled due to hospital admission, dehydration, low blood counts, intolerance, patient is put on Hospice, etc. We are concerned that this will develop into much unnecessary waste and actually increase the cost of cancer care in the USA.
3. What would we do with drugs sent for specific patients but unused. These drugs are toxins and we will not be able to ship them back to the vendor or use them for another patient. We again believe this will cause unnecessary waste and increase in the cost of delivering cancer care.
4. Will drugs be premixed? This causes us much alarm as to the stability of the drugs premixed.
5. The physician's responsibilities of giving insurance information to the CAP vendor, notifying the vendor of drugs wasted, maintaining an inventory for each CAP drug received, using the prescription number on every claim, communicating to the vendor the specific prescription number and the dose administered, etc. will be very timely and costly to the Community Oncologist.

6. This process will greatly increase our overhead costs without reimbursement for the costs to the practice.
7. Making the physician practices responsible to ensure that the Medicare beneficiaries are not confused by the billings is yet more cost to the practice. Are we to be paid for the education of your beneficiaries?
8. Timely delivery would be an issue. We need to keep our schedules accurate. How far in advance would we have to order to have our drugs delivered on time for the scheduled patients? Can you ensure prompt delivery?
9. Quality control and liability are major concerns for our practice.
10. Are liability insurance carriers going to cover us for such a program?
11. Will this program meet our State Pharmacy Regulations?
12. How will you control counterfeit drugs?

As you can see we have many concerns about the CAP program.

In addition, please note that we have patients who are not Medicare recipients, thus we will be continuing our present processes with those patients. This will cause us to need additional space for organization of two programs.

Ordering drugs, inventory, waste, quality control, drug preparation, etc. are all real costs to a practice. The CAP program will increase these costs.

This program may cause delay in treatment to our patients.

This program may cause access to care to be greatly diminished.

Thank you for your attention to this matter.

Sincerely,  
The Physicians and Staff of  
Central Pennsylvania Hematology and Medical Oncology Associates, PC

# Riverside Community Care

THE HELP YOU NEED CLOSE TO HOME

APR 12 2005

April 1, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P. O. Box 8010  
Baltimore, MD 21244-8010

Attention: CMS-1325

Gentlepersons:

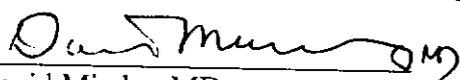
It has been recently brought to our attention that there is pending strategy that will have a major impact on our most vulnerable and needy patients who are eligible for Medicare Part B benefits. We would like to go on record with the following strong concerns:

1. Psychiatric Drugs should be included in the Competitive Acquisition Program to keep these as accessible as any other evidently crucial medications.
2. Psychiatric Drugs should be included in Phase I of CAP to alleviate barriers to access that are inherent in the current system. This is equally underscored by
3. the need to include a Mental Health Drug Category including long-acting injectible anti-psychotics.

These are medications vital to the maintenance in the community of many of our most needy and impaired patients. Without them, these individuals are likely to suffer emotional and social deterioration that can be tragic and costly for them, their families and the community.

We are all working to ensure the availability of the healthiest and most effective treatments to enable at-risk individuals to live productive lives in the least restrictive environments. Our team of prescribers hopes that you will consider our concerns and act accordingly for the benefit of our often unhappily compromised clientele.

Sincerely,  
Staff of Riverside Community Care @ Upton

  
David Mirsky, MD

  
Stephanie Davidoff, MD

  
Mark Strecker, MD

  
Kimberly Lovett, MD

  
Susan Stevens, APRN, BC *APRN, BC*

Riverside Outpatient Center at Upton • Riverside Day Treatment at Upton

206 Milford Street • Upton, MA 01568 • Tel 508-529-7000 • Fax 508-529-7024

www.riversidecc.org

APR 12 2005

15

Name *Patricia Paredes*  
St. Luke's House, Inc.  
6040 Southport Dr  
Bethesda, Maryland 20814

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, Maryland 21244-8010

April 7, 2005

I am writing to convey several essential comments on Medicare Part B-Competitive Acquisition of Outpatient Drugs and Biologicals.

Our private, not for profit Outpatient Mental Health Clinic serves those consumers who struggle with serious and persistent mentally illnesses such as schizophrenia. Nearly half of our consumers are eligible for Medicare Part B. Long acting, non self-administered injectable medications (e.g. Risperdal Consta) are often the most clinically effective symptom management strategy. Currently, the only option under which such drugs may be obtained is the Buy and Bill process, one which is very expensive, administratively burdensome, and financially risky for both non profit providers and needy consumers alike.

I strongly urge you to include all of the mental health therapeutic categories and psychiatric drugs in the proposed Competitive Acquisition Program, Phase I, scheduled to be effective January 1, 2006. Please ensure that the rule also prevents discontinuation of therapy the vendors selected. Such measures will improve consumer access to care by simplifying the reimbursement process.

Thank you for your serious and thoughtful consideration.

Sincerely,

Name *Patricia E Paredes APRN IBC*



# Mental Health Association in Michigan

APR 12 2005

16.

Greg Dziadosz, Ph.D.  
Board Chair

Mark Reinstein, Ph.D.  
President and CEO

April 8, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244-8010

Dear CMS Personnel:

As Michigan's oldest advocacy organization for persons experiencing mental illness, we appreciate the opportunity to comment on the proposed rule published March 4th (CMS-1325-P) for the Competitive Acquisition Program (CAP) in Medicare Part B.

We commend the proposed rule for not exercising the MMA option of barring mental health drugs from CAP. We believe, however, that more needs to be done in a final rule to recognize the importance of mental health medications to many individuals' lives.

We respectfully suggest that a final rule specify the inclusion of mental health medications under CAP effective January 2006; the establishment of a mental health drug category for specialty pharmacy vendors to offer under Part B CAP; and the development of consumer-friendly guidelines for dealing with co-pay and other reimbursement issues in ways that promote, rather than disrupt, continuity of care.

The above steps will make it less burdensome for physicians to prescribe needed Part B mental health medications; allow such medications to be managed more efficiently through specialty pharmacy approaches as soon as possible; and recognize that mental health treatment is highly dependent on psychopharmacology, yet involves significant medication compliance challenges that neither consumers nor society can afford to have exacerbated.

Thank you for your thoughtful consideration of our views.

Sincerely,

Mark Reinstein, Ph.D.  
President & CEO



**VALLEY  
MENTAL  
HEALTH**

VALLEY STOREFRONT  
AND SAFE HAVEN

550 West 700 South  
Salt Lake City, Utah 84101  
(801) 537-7537  
FAX: (801) 363-3140

Program Manager:  
Mitzy Stewart

17  
APR 12 2005

Hello, my name is Lucille Anderson and I work as an License Practical Nurse in a community mental health center (CMHC) in Salt Lake City, Utah. I am writing to express my concern , as I foresee issues that will arise pertaining to access to care. Specifically, non-self administered medications, such as Prolixen, Haldol Deconate, and Risperdal Consta.

I'm concerned about a CMHC needing to purchase and subsequently bill to obtain these medications for patients, as most clients have insufficient funds to cover these costs. CMHC's are often strapped financially, this could possibly produce a credit risk as they will have to assume the financial responsibility for these such medications

Most importantly to me, is my concern that there will be less that optimal care given to those who need it. By this I mean that there will be instances where the medicine is chosen by ease of access, not efficacy or what is in the patients best interest.

This could also increase a need for resources and staff to do billing, inventory, and patient tracking.

Thank you for your time,

*Lucille Anderson LPN*

Lucille Anderson LPN

April 12, 2005

APR 18 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
ATTN: CMS1325-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

Dear CMS,

I thank you for the opportunity to comment on the Competitive Acquisition Program. As a practicing medical oncologist, I believe that the proposed Competitive Acquisition Program does not serve a patient's best interest and detracts from quality of care.

This system as designed is extremely cumbersome. It does not allow for flexibility of same day treatment decisions for non-emergent situations. This inflexibility detracts from the overall quality of care by limiting the options for patients with cancer. Specifically, treatment decisions cannot be made in a timely fashion and subsequently require a built-in delay of several days for changes in therapy. This will ultimately lead to long-term delays in care for patients. Furthermore, this system does not allow appropriately for the dosage reductions that are frequent in cancer therapy. Additionally, it is unclear as to who pays for unused chemotherapy that is wasted through no fault of anyone's (e.g.: unexpected death or a natural disaster such as we have with hurricanes in our area).

The billing system is cumbersome. The ordering process is cumbersome. Coverage of indigent care (such as patients with no co-pay insurance) becomes a difficult issue, in so far as who covers the cost of the chemotherapy. The administrative work caused by the system is an unfunded mandate from the government. The payment coverage of denials of claim processes as well as the appeals process is not clear. Furthermore, the "acceptable threshold" for denials of a physician's services is also unclear.

In general, this system is quite cumbersome. It does not allow flexibility of same day treatment decisions for non-emergent patients, and overall detracts from the quality of care by limiting the options of patients with a built-in delay.

I thank you for the opportunity to comment on this proposed program. I do not recommend its implementation. More time needs to be spent to work out the mechanisms so that patients are not penalized.

Sincerely,



Lawrence B. Holt, MD  
LBH/pjh



APR 18 2005

19



DEPARTMENT OF MENTAL HEALTH, RETARDATION AND HOSPITALS  
ELEANOR SLATER HOSPITAL – FORENSIC SERVICE

P.O. BOX 8269  
CRANSTON, RHODE ISLAND 02920  
TEL. (401) 462-2013  
SECURE FAX (401) 462-1497

April 13, 2005

Center for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244-8010

To Whom It May Concern:

I am writing to urge CMS to include injectable psychiatric medications in the Competitive Acquisition Program beginning January 1, 2006. These medications include Risperdal Consta, Haldol Decanoate, Prolixin Decanoate, in addition to short acting injectable Zyprexa and Geodon. These medications, especially the long acting injectables are crucial in the practice of psychiatry, as they are effective in helping to manage some of the most severely ill psychiatric patients. These individuals, often as a result of their illness, are unable to take oral medications on a regular basis. Regular use of these medication can help to keep these individual safe in the community and avoid costly hospitalizations.

There is a significant problem in obtaining these medications for many Medicare patients. Mental Health Centers in Rhode Island do not buy and bill medication for these patients, because of the many problems entailed in this process. If a patient has Medicaid, he is much more likely to receive an injectable. This decision is not always based on clinical considerations, as it involves the ability to access the medication. Allowing these medications to be included in this new program would save money for Medicare (through lower hospitalizations) and add no significant cost to the program.

The treatment of persons with serious mental illness is often an afterthought in the design and implementation of medical benefits. I urge you to avoid discriminating against this group and include injectable antipsychotic medications in the CAP program on January 1, 2006.

Thank you for your consideration of this matter.

Sincerely,

Barry W. Wall, M.D.  
Director, Forensic Service  
Eleanor Slater Hospital



April 12, 2005

**Michael A. Fiori, M.D.**  
Assistant Clinical Professor  
Brown Medical School  
Department of Psychiatry & Human Behavior

APR 18 2005



Center for Medicare and Medicaid Services Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244-8010

Dear Sirs,

I am writing to urge CMS to include long acting injectable psychiatric medications in the Competitive Acquisition Program beginning January 1, 2006. These medications include Risperdal Consta, Haldol Decanoate, and Prolixin Decanoate; these long acting injectables are crucial in the practice of psychiatry, as they are effective in helping to manage some of the most severely ill psychiatric patients. These individuals, often as a result of their illness, are unable to take oral medications on a regular basis, and the regular use of these medications can help to keep patients safe in the community and avoid costly hospitalizations.

There is a significant problem in obtaining these medications for many Medicare patients. Mental Health Centers like The Providence Center do not buy and bill medication for these patients, because of the many problems entailed in this process. If a patient has Medicaid, he is much more likely to receive an injectable. This decision is not always based on clinical considerations, as it involves the ability to access the medication. By allowing these medications to be included in this new program, it would likely save money for Medicare (through lower hospitalizations) and add no significant cost to the program.

The treatment of persons with serious mental illness is often an afterthought in the design and implementation of medical benefits. I urge you to avoid discriminating against this group and include long acting injectable antipsychotic medications in the CAP program on January 1, 2006.

Thank you for your consideration of this matter.

Respectfully,

Michael A. Fiori MD  
Clinical Assistant Professor of Psychiatry, Brown University

Need to include Psychiatric Drugs under Competitive Acquisition Program. (CAP)

Reference - Proposed rule that would implement CAP -

Following are some comments on the issues

- ① Inclusion of psychiatric drugs - do not exclude psychiatric drugs from CAP
- ② Inclusion of psychiatric drugs in Phase 1 - Please for sure include psychiatric drugs in the initial stages of CAP to alleviate barriers to access
- ③ Inclusion of mental health drug category - CMS needs to create a category that includes mental health drugs, including long-acting injectable anti psychotics
- ④ Ensure rule prevents discontinuation of therapy by vendors - CMS needs to work out reimbursement processes for vendors, so that they can continue their service.

I appreciate this opportunity to comment and advocate for inclusion of therapy for those with mental illness in the CAP.

Jane Baxter  
4641 Chalmers Drive  
Nashville, TN 37215

APR 18 2005

*Thomas D. Lee, M.D.*  
*Consulting Psychiatrist*  
*Cornerstone Services, Inc.*  
800 Black Road  
Joliet, Illinois 60435  
Ph. 815.774.3244  
Fax 815.478.5510

April 11, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244-8010

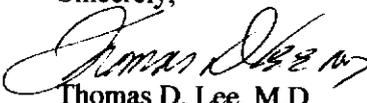
To Whom It May Concern:

I am writing today to offer commentary as a mental health provider on the issue of the proposed Competitive Acquisition Program with regard to the issue of whether injectable long acting antipsychotic medications will be included in the categories of medication which will be available through the CAP program. I am a psychiatrist who works primarily with the indigent patient population, including many schizophrenic and schizoaffective patients who are in grant funded supportive living arrangements through Cornerstone Services, Inc. in Joliet, Illinois. This is a population who benefits greatly from the availability of long acting injectable antipsychotic medications because of improved compliance and stability, less need for polypharmacy for symptom control and a reduced burden of medication side effects. Due to financial constraints, it is difficult for many community mental health agencies to purchase medications to have available for administration and wait for reimbursement. In addition, staff time and resulting costs are being directed toward procuring medication, obtaining prior approval for medication use and completing complicated billing procedures when this staff time could be otherwise directed toward direct patient care. Because of these issues there are currently significant barriers in many community health care settings preventing the provision of consistent access to care for mental health care consumers.

I would request that you strongly consider that all appropriate mental health therapies be included in the CAP program from the initial phase of the program (beginning 1/6/06). This inclusion would allow for improved consumer access to care. It is estimated that up to 40% of consumers afflicted with schizophrenia are Medicare eligible and this population represents conservatively 1% of the general population. It is my hope that you will consider my input regarding these issues when determining policy with regards to the CAP program administration. I strongly believe that inclusion of mental health therapies will significantly contribute to improved access to care for consumers.

Thank you for your openness to accepting provider comments in regards to this issue. I would be glad to be available for further input if it would be of assistance to you.

Sincerely,



Thomas D. Lee, M.D.  
Ph. (815)774-3265

APR 18 2005

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## Midwest Psychiatry

*...dedicated to promoting wellness and recovery in psychiatric care since 1989.*

April 6, 2005

Centers for Medicaid and Medicare Services  
Department of Health and Human Services  
Attn: CMS-1325-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

Dear Sir or Madam:

I am writing in request for CMS to include mental health category in the CAP. There are certain second and third generation antipsychotic medications that are now available in injectable form for long-acting treatment of psychotic illness, including schizophrenia.

These medicines are proving effective, but the funding of them currently involves the clinic paying for them, and then trying to get reimbursed. Many of these clinics are in the inner city, where funds are very limited. It would be most helpful if these could be obtained via prescription through the pharmacy, still administered and supervised by these clinics. Please consider this request.

Sincerely,



Thomas F. Richardson, M.D.  
Board Certified Psychiatrist



**THE CENTER  
For  
HEALTH CARE  
SERVICES**

APR 18 2005

3031 IH 10 West  
San Antonio, Texas 78201  
(210) 731-1300  
FAX (210) 731-1315

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April 11, 2005

Centers for Medicare & Medicaid Services  
Department of Health & Human Resources  
Attention CMS-1325-D  
P.O. Box 8010  
Baltimore, Md 21244-8010

Leon Evans  
*Executive Director*

Charles H. Boone  
*Chief Operating Officer*

Richard A. Treviño, Jr.  
*Interim Chief Financial Officer*

Dear Sir/Madam:

Pedro Ruggero, M.D.  
*Chief of Staff, Medical Services*

As an MHMR psychiatrist I think it would be important to include long acting injectable antipsychotic in the Competitive Acquisition Program.

Sincerely,

Pedro Ruggero, M.D.  
Chief of Staff

H:2

APR 18 2005

April 11, 2005

In reference to: CMS - 1325 - P

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

Dear Sir:

My name is Jim Clarke. I am the Practice Manager for three oncologists in Coos Bay, Oregon. The percentage of Medicare/Medicaid patients in their practice exceeds 65%. Many Medicare patients have no Medicare Supplemental insurance plans and they find it hard, if not impossible, to pay their bills now or in the near future.

I have some general comments before I get into some details. Our practice has been severely impacted by the SAP + 6% changes brought on by legislation. We are yet to see a payment from most Medicare co-insurance companies for January billings. Introducing a 3<sup>rd</sup> party vendor, CAP, removes treatment from a Doctor/Patient relationship. We change treatment regimes based on test and doctor/patient discussion. The time frame is often hours not 5 or more days between regime changes. And the thought that a vendor can inventory, order, ship, bill, collect for treatments more efficiently than our own nurses and staff at the clinic is very, very doubtful. And I seriously doubt if the vendor can take into account the empathy needed to successfully deliver chemotherapy and the necessary support without adding additional stress to the patient and their families.

Specific comments to "Categories of Drugs to be Included under the CAP"

I believe in starting small and building on success. Therefore, I support the logic in 'Begin with Specialties That Use Fewer Part B-Covered Drugs'. Learning where and what the problems are improve the process and expand the program. If you should choose another option, I would again suggest going with a limited number of drugs and expand after the problems, if any, are satisfactorily worked out.

Specific comments to "Claims Processing Overview"

The CAP program is aiming to be cost neutral for the physician practice. One must be extremely skeptical of one sentence in 28 pages that write off practice expenses with one statement. Substantial extra work will be required to communicate orders to the vendor, verify the drug was given, made changes and emergency changes as directed. All the time keeping the vendor informed. An additional tracking system will be needed to include

each patient as a separate inventory. Additional space will be necessary to store the individual patient's physical inventory, including additional refrigeration space. This comes at a substantial cost to the practice. The only savings to the practice is the loss the practice experience for uncollected bills the patient does not pay. Is Medicare going to reimburse the vendor for these losses? Medicare doesn't do this for the physician. So I hope the vendor is willing to accept these losses. They are huge. The vendor will need to hire additional employees to manage what we already managed locally at the clinic. This doesn't made economic sense. And the vendor is expected to save Medicare money. If this is actually true than, the vendors and drug companies should pass the saving on to the doctors, and give the doctors the lowest possible drug cost. That is where the savings (drug cost) is to be made not in duplicating what already is in place and works well (our office and clinic processes for order, storing, giving, tracking, and billing and collections).

As you can see, I am less than enthusiastic about CAP, and don't believe for a minute these rules, as proposed, will save Medicare the dollars they hoped. There are only two issues here, "how to save Medicare money" and "collecting the patient financial responsibility". Medicare could negotiate drug prices with the drug companies and allow Doctor's, or their GPO's, to purchases these drugs for Medicare patients. This would be simpler and cost saving upfront and immediate. Collecting patient's co-pays is really a separate issue that these rules do not adequately address.

Thank you for the considering these comments.

Sincerely,



Jim Clarke  
Practice Manager  
cc: Community Oncology Alliance



APR 18 2005

April 12, 2005

Centers for Medicare & Medicaid Services  
 Department of Health and Human Services  
 Attention: CMS-1325-P  
 P.O. Box 8010  
 Baltimore, MD 21344 - 8010

Dear Sir or Madame:

I am writing to comment on the Competitive Acquisition Program ("CAP") as part of the Medicare Modernization Act 2006 and the impact it could have for patients we serve at the Recovery Behavioral Health Clinic at Health Care For The Homeless - Milwaukee. We serve a large percentage of patients with Medicare and Medicaid coverage who currently rely on the Medicaid benefit to obtain psychiatric medications that allow them to function in the community and avoid hospitalization and extreme functional impairment. If Mental Health Services, particularly psychiatric medications in both pill and injectable form, are not included as a pharmacy benefit from implementation, there will be additional barriers put in place that would complicate patient access to necessary treatment.

For our patients eligible for Medicare now or in the foreseeable future, which may be up to on third of our caseload, a second option to the current "buy and bill" would improve patient access to care and significantly simplify the reimbursement process. Please consider consumer's needs regarding Mental Health medications as a pharmacy benefit option and improving access to care in CAP.

Sincerely,

*Timothy Wildrick*  
 Timothy Wildrick - Clinic Coordinator

2139 Silas Deane Highway  
Suite 205  
Rocky Hill, CT 06067  
(860) 257-8066 • (860) 257-8074 FAX

Sophie Tworkowski, LCSW, MPH, President  
Stephen A. Karp, MSW, Executive Director  
naswct@conversent.net

April 12, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
PO Box 8010  
Baltimore, MD 21244-8010

RE: CMS-1325-P: Medicare Part B – Competitive Acquisition of Outpatient Drugs and Biologicals

To Who It May Concern:

On behalf of the National Association of Social Workers, CT Chapter that represents over 3600 members we offer the following comments on the above referenced proposed rule.

As social workers most of our members are directly involved with the provision of mental health services. In fact approximately two-thirds of all mental health services in the United States are provided by clinical social workers. These services include therapeutic treatment, case management and information & referral. Social workers are well versed in all aspects of mental health care and based on this knowledge we provide these comments.

Psychiatric medications are a key part of effectively treating patients with mental illness. While social workers provide the talk therapy side of treatment we also work closely with psychiatrists to assure that the correct medication regimen is available. **Thus we strongly support inclusion of psychiatric medications, including long-acting injectable antipsychotics** into the Competitive Acquisition Program (CAP). We also **strongly recommend that psychiatric medications be included right from the initial start of CAP.**

In order to facilitate an effective start-up under CAP for psychiatric medications we recommend that CMS create a category that includes mental health drugs, including long-acting injectable antipsychotics. This latter point is particularly important as new injectable medications are coming onto the market that have shown excellent results and should be encouraged by easing of access issues.

It has been documented and is well understood by our members that portions of patients with mental illness have difficulty with medication compliance. To the degree that medications can be administered that is long lasting this will clearly be advantageous to

the patient and will reduce acute episodes of illness. Such medications are now becoming available and it is essential that they be covered under CAP. Otherwise the barriers to use of these medications will limit their usage, to the detriment of persons with mental illness.

We also encourage CMS to address how vendors should handle uncollectible copays and other reimbursement issues that may interfere with the therapeutic regimen. Consistency of usage of medication is extremely important in the effective treatment of mental illness.

All too often in the past mental health services has been a stepchild of the health care field, despite the fact that physical and mental health are very closely tied together. When barriers exist to accessing mental health services patients end up utilizing increased physical health care services from providers who are not adequately trained to deal with the patients problems. This only leads to greater health care costs, unnecessary delays for patients in getting proper treatment and over utilization of care. We urge CMS to avoid this pitfall by including psychiatric medications, right from the start, in CAP.

Sincerely,

  
Stephen A. Karp, MSW  
Executive Director



APR 15 2005

4006 Beltline Road, Suite 115  
Addison, TX 75001

April 14, 2005 Specialty Group

Phone 972.490.5551  
Fax 972.490.5266

**By Hand Delivery**

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Comments on Medicare Program; Competitive Acquisition of  
Outpatient Drugs and Biologicals under Part B, 70 Fed. Reg. 10746  
(March 4, 2005) [CMS-1325-P]**

Dear Dr. McClellan:

AmerisourceBergen Specialty Group (“ABSG”) respectfully submits the following comments pertaining to the proposed rule issued by the Centers for Medicare and Medicaid Services (“CMS”) on the Competitive Acquisition of Outpatient Drugs and Biologicals under Medicare Part B (the “Proposed Rule”), 70 Fed. Reg. 10746 (March 4, 2005). The Proposed Rule implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) that concern the distribution and payment of drugs under the Competitive Acquisition Program (“CAP”). ABSG commends CMS for issuing guidance about the CAP and, in the spirit of cooperation, raises the issues set forth in this comment letter for CMS’s consideration.

ABSG focuses on the unique access, distribution, specialty pharmacy, reimbursement, and education needs associated with specialty and biotech products administered in the physician office setting. ABSG has a national footprint and provides unmatched experience and expertise across physician specialties. Among other things, we are the largest provider of goods and services to oncology and specialty physician practices and a top pharmacy provider to oncology.

ABSG supports CMS’s efforts to implement a safe, controlled, and efficient CAP. Towards that end, ABSG has reviewed the Proposed Rule and has given full consideration to the unique operational and economic factors associated with the design and development of the CAP. Our comments address the following areas of the Proposed Rule:

- Overview of the CAP;
- Categories of Drugs to be Included under the CAP;

- Competitive Acquisition Areas;
- Statutory Requirements Concerning Claims Processing;
- Claims Processing Overview;
- Dispute Resolution;
- Contracting Process – Quality and Product Integrity Aspects;
- Bidding Entity Qualifications; and
- CAP Bidding Process – Evaluation and Selection.

## **I. Overview of the CAP**

ABSG commends CMS for issuing the Proposed Rule and requests that CMS continue to issue formal and informal guidance in the upcoming months to further clarify and refine CAP requirements. Moreover, CMS should continue its efforts to educate and solicit input from interested parties through “Open Door” sessions and other appropriate venues.

## **II. Categories of Drugs to be Included under the CAP**

### **A. “Incident To” Drugs**

In the Proposed Rule, CMS proposes that the CAP would apply only to Part B drugs that are furnished “incident to” a physician’s service because the specific mechanisms described under Section 1847B of the MMA relate to the provision of and payment for drugs provided in this manner. However, CMS notes that the MMA provides for the CAP to cover all Part B drugs that are not paid on a cost or prospective payment basis. Therefore, under the language of the MMA, the CAP covers a wider range of Part B drugs than just those administered “incident to” a physician’s service. CMS is soliciting comments on its proposed limitation of the CAP to Part B drugs furnished “incident to” a physician’s service.

ABSG supports CMS’s proposal to limit the CAP to drugs that are administered “incident to” a physician’s service. As CMS points out in the Proposed Rule, the purpose of the CAP is to provide physicians with an alternative mechanism for supplying covered Part B drugs to Medicare beneficiaries. Therefore, ABSG believes that it is appropriate for CMS to limit the program to physician-administered drugs and not include Part B drugs furnished in other settings.

### **B. Phasing In CAP Drugs by Physician Specialty**

The Proposed Rule sets forth several alternatives for phase-in of the CAP with respect to drug categories. The alternatives include: (1) phasing in the CAP by initially including all drugs typically administered by oncologists; (2) beginning the phase-in with some set of drugs typically administered in physician offices by other specialties (i.e., urologists); or (3) implementing the CAP for all Part B drugs that are furnished incident to a physician’s service.

ABSG supports phasing in the CAP by initially including only those drugs administered by a physician specialty other than oncology (e.g., urology). By starting with a narrower specialty, CMS would be able to truly phase-in the CAP, allowing the agency to identify and remedy any operational issues. We believe this would reduce physician confusion, thereby ensuring the long-term success of the CAP. ABSG believes that CMS should exclude oncology drugs from the initial CAP phase-in because non-oncology specialties typically utilize fewer drugs than oncology. ABSG is concerned that beginning with oncology drugs would not represent a true "phase-in" of the program. Further, ABSG is well aware that oncologists have been subject to numerous payment and policy changes for Part B drugs as a result of MMA and feels strongly that they should not also be asked to be the first to put into practice the CAP before potential operational issues are addressed. In fact, if CMS decides that oncology drugs should be included in the initial CAP phase-in, ABSG believes that it would be more equitable to include all drugs administered incident to a physician's service and otherwise limit the CAP (e.g., by limiting the geographic regions where the CAP initially is made available, as discussed below).

### **C. Determination of Drug Categories**

ABSG supports the adoption of narrowly defined drug categories for cost-effective management of the CAP. Broader drug categories would place additional burdens on CAP vendors by requiring them to bid on and supply all drugs within each category. This burden could limit the participation of entities as CAP vendors and hinder the potential for cost-savings under the program.

ABSG requests that CMS provide additional clarification concerning specific issues associated with CMS's establishment of drug categories. As an initial matter, the reference in proposed section 414.908(d) only to multi-source drugs leaves it unclear as to whether both single source and multiple source drugs will be covered under the CAP. ABSG supports the inclusion of both.

CMS also proposes to require CAP vendors to bid on all HCPCS codes within each drug category. If CMS includes this requirement in the final rule, ABSG recommends that, when CMS creates the drug categories, it give careful attention to how its selection of HCPCS codes will promote the use of multi-source drugs, which often have a relatively lower ASP compared to their therapeutically equivalent single-source counterparts. That is, when there is more than one HCPCS code that covers drugs used to treat the same disease or condition and one HCPCS code includes only a single-source drug while another includes a multi-source drug, CMS should, if clinically appropriate, include both drug categories and specifically include the HCPCS code that is inclusive of the multi-source drug. Such inclusion has the potential to result in cost-savings under the CAP and would be supportive of CMS's program goals.

In addition, with respect to oncology, in order to promote the reduction of costs to the Medicare program, ABSG recommends that the final rule permit CAP vendors to utilize formulary controls with respect to supportive care drugs. We recommend that CMS define such drugs based on specific HCPCS codes, and permit CAP vendors to provide only one (1) drug representative of each category to CAP participants. Under these formulary controls, the CAP vendor could assure the delivery of products at a lower cost, and participating physicians could select CAP vendors, in part, based on a bundle of available supportive care drugs.

### **III. Competitive Acquisition Areas**

We believe that for the long-term success of the CAP, CMS should establish a nationwide competitive bidding area; however, initial phase-in of the CAP should be on a limited geographic basis. A nationwide competitive bidding area would parallel the existing drug distribution system, maximize for all participants in the CAP those benefits achieved through economies of scale, and minimize the administrative burden on vendors and CMS. Nevertheless, ABSG recognizes that a nationwide competitive bidding area may be unfeasible in the initial stage of the CAP. We therefore support initially phasing in the CAP on a limited geographic basis with a limited number of CAP vendors participating. This initial limited implementation will provide a means for CMS to test and refine operational procedures, claims processing, and systems infrastructure, and address unforeseen implementation issues.

### **IV. Statutory Requirements Concerning Claims Processing**

ABSG urges CMS to clarify whether it intends CAP vendors are to operate as distributors or specialty pharmacies. It is apparent that CMS desires the low cost product logistics capabilities that are characteristic of distributors and the higher-cost, patient-specific billing capabilities that are characteristic of pharmacies. For example, CMS's interchangeable use of the terms "prescription" and "order" in the Proposed Rule is confusing and does not make a clear distinction.

ABSG believes clarification is necessary given that CAP vendors must comply with applicable state and federal laws, however distributors and pharmacies have separate and mutually exclusive operational, licensure, and regulatory compliance requirements. Further, the CAP vendor must have assurance that the characterization of its activities as a distributor or pharmacy, would be consistently applied by regulatory authorities, agencies, and taxing authorities. For example, a CAP vendor operating under a distribution model must have reliable assurance that its business would not be classified as a pharmacy by another local, state, federal, regulatory, or taxing authority. Moreover, it would be inequitable, and potentially expose the CAP to regulatory challenge, to allow CAP vendors to bid and subsequently operate under either a distribution or pharmacy model at their sole discretion.

To the extent that CMS anticipates the CAP Program will require the operational capabilities and functions of both a distribution and pharmacy model, as a potential solution, ABSG recommends that these functions could be segregated by the CAP vendor through a dual functioning Distribution Model. We recommend that this Distribution Model include an intake function related to receiving bulk orders, billing, and collections through an ordering and claims processing "clearinghouse;" and product shipment through a separate specialty distributor function.

As depicted in the flowchart attached hereto as Exhibit A, this model, which we refer to as the "Distribution Model," would require the CAP vendor to have two distinct roles. When functioning as an ordering and claims processing clearinghouse, the CAP vendor would be responsible for performing intake of all orders, data entry, validation, confirmation of coverage, and related collections information. The CAP vendor's clearinghouse function also would be responsible for de-identifying patient information and assigning a patient-specific order number

to protect the order from a HIPAA perspective and clarify the duties and responsibilities of the CAP vendor (i.e., the CAP vendor would not be considered a pharmacy).

A CAP vendor's specialty distribution function would be responsible for verification and coordination of orders with physicians to provide the most cost-effective and appropriate shipment of products. The order number assigned by the CAP vendor's clearinghouse function would be included with the product when shipped as a means to link the order to the patient. The CAP vendor's specialty distribution function would provide a data file to the clearinghouse function with shipping confirmation and tracking code information to support program documentation and tracking.

We believe there are advantages to such a dual role, Distribution Model approach. Most importantly, it would: (1) allow the CAP vendor to distribute orders to service physicians using only de-identified codes that could be traced through the clearinghouse, up the supply chain to CMS, and down the supply chain to the patient, and (2) clearly define the responsibilities of CAP vendors. Having a CAP vendor clearinghouse function under this model also would allow CAP vendors to handle product returns in a manner consistent with current models that reduce wastage because CAP vendors would not fill patient-specific prescriptions.

In a separate but related issue, ABSG requests that CMS modify the final rule to enable CAP vendors to operate under a "Service Model." In other words, while CMS would consider CAP vendors to be responsible for administering the CAP, they would not be at risk for payments from CMS and beneficiaries. Being at-risk for payment would require CAP vendors to confirm that each product they distribute would meet Medicare coverage guidelines and that the co-payment would be collectible. Therefore, CAP vendors would require access to Medicare coverage and coding guidelines to proactively confirm product use and covered diagnosis codes as part of the intake and ordering process. Additionally, CAP vendors would need to be able to secure a valid credit card (or its equivalent) for the patient co-payment before it could ship products, similar to how most mail order pharmacies work with private paying patients. Thus, we believe that CMS should modify the CAP Program so that the CAP vendor would collect drug reimbursement and beneficiary co-payments as an agent of Medicare, but would not be at risk for drug orders that do not meet coverage or other Medicare program requirements or for non-payment by beneficiaries of their co-payment obligations. This change would potentially lead to additional CAP bidders, enhance the long-term success and overall cost-effectiveness of the CAP, and is consistent with the current duties and responsibilities of distributors.

We also believe that this change would facilitate a CAP vendor's ability to collect co-payments because such payments would be viewed as a bona fide Medicare obligation versus billing of Medicare beneficiaries by an unknown third party CAP Vendor. This billing clarification is particularly important because CAP vendors would not have traditional provider relationships with patients that facilitate the collection of co-payments.<sup>1</sup>

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<sup>1</sup> A summary of the Distribution Model versus the Pharmacy Model, and a summary of ABSG's recommendations related to the adoption of a dual functioning Distribution Model and Service Model is attached as Exhibit B.

## **V. Claims Processing Overview**

### **A. Timing of Vendor Billing**

CMS proposes to make payments to CAP vendors for Medicare drugs after the drug is shipped, administered, and billed by the physician, and the claim is paid by the CMS carrier. Such a lengthy process would result in tremendous uncertainty for CAP vendors regarding when, and if, payment ultimately would be made for a drug and would complicate CAP vendor accounting and reporting under Sarbanes-Oxley and Generally Accepted Accounting Principles ("GAAP"). ABSG believes that this could unfairly discriminate against and limit the participation of public companies as CAP vendors.

In the final rule, CMS should provide for a more accelerated schedule of payments to CAP vendors. Specifically, CMS should require a physician to notify the CAP vendor within a strictly defined time-period (e.g., by 5:00 p.m. the next business day) upon administration of a drug and reimburse the CAP vendor upon receipt of such notification. Additionally, CMS should include in the final rule a provision authorizing a CAP vendor to bill for the total number of units shipped, even if a physician administers a lesser amount. Such clarification is necessary given the distribution role of CAP vendors (i.e., entities that fulfill medication orders).

In a related issue, ABSG suggests that CMS make full payment (including co-payment obligations) to the CAP vendor upon the drug delivery to the physician. We believe that this is the most appropriate policy and recognizes that the CAP vendor would have fulfilled its obligation to provide the drug to the Medicare beneficiary as requested by the physician.

If CMS finds it impractical to address beneficiary co-payments as outlined above, then ABSG recommends that CMS revise the proposed rule to authorize CAP vendors to bill the co-payment and coinsurance upon receipt of physician notification that drug administration has taken place. If such a policy is not adopted, CMS should specify in the final rule how it will facilitate beneficiary co-payment collection.

CMS's proposal to prohibit a CAP vendor from billing for co-payments until final payment of a claim by Medicare would be a significant change from the current practice of physicians billing for co-payments at the time of service. As written, the Proposed Rule causes a significant delay in payment to the CAP vendor and increases the risk of collection of the co-payment. With the passage of time, there is the likelihood that many beneficiaries would expire, move, or change or lapse coinsurance, which increases a CAP vendor's risk of nonpayment. Thus, delayed billing would significantly increase the risk of bad debt and increase collection-related efforts and costs potentially risking the solvency of the CAP vendor and viability of the CAP Program. Finally, the currently proposed co-payment billing process also would create significant issues with respect to Sarbanes-Oxley and GAAP for public companies. In addition, we recommend that the final rule allow CAP vendors to refuse to distribute products to patients who have a previous history of failing to fulfill their co-payment obligations. This ability would eliminate a significant amount of financial risks and uncertainty for CAP vendors.

## **B. Emergency Supply of Drugs**

ABSG has concerns about CMS's proposal that, in emergency situations, drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians. Permitting such use would ignore the fundamental fact that the CAP vendor, not the provider, owns the CAP drugs. Further, such a practice would raise diversion, inducement, program integrity, and drug quality concerns. From a claims processing perspective, such use would be difficult to track and could create a "mismatched claim" if the drug could not be traced to the original patient order. This confusion could result in a denial of payment to the CAP vendor. Further, permitting the emergency use of CAP drugs would complicate CAP vendor accounting and financial reporting.

In the final rule, CMS should prohibit physicians from using CAP drugs for any non-CAP purposes as well as for any patient other than the one dispensed to and identified by the PIN. ABSG recommends that CMS instead provide a procedure for physicians to maintain a separate supply of non-CAP drugs for emergencies and obtain reimbursement outside of the CAP program (i.e., under the ASP methodology) in such situations.

## **C. "Furnish As Written"**

CMS proposes to allow a physician to obtain a drug under the ASP methodology in "furnish as written" cases when medical necessity requires that a specific formulation of a drug be furnished to the patient and that formulation is not available under the CAP. If the carrier determines that the physician had not complied with furnish as written requirements and a specific NDC or brand name drug is found not to be medically necessary, the carrier could deny the claim for the drug and the administration fee.

ABSG believes that CMS should take steps to ensure that the use of the "furnish as written" provision is very limited to avoid undermining the fundamental drug category structure of the CAP system and jeopardizing the possibility for cost containment under the CAP system. All "furnish as written" orders should be processed under the ASP methodology. Moreover, CMS should ensure that the physician, and not the CAP vendor, is responsible for denials attributable to a physician's failure to comply with "furnish as written" requirements.

## **D. Administrative Burden**

CMS notes that some physicians have expressed concern that participation in the CAP would be administratively burdensome (e.g., involve additional clerical and inventory resources). We understand that CMS does not believe that the clerical and inventory resources associated with participation in the CAP would exceed those resources associated with the ASP methodology, and notes that the payment for such resources under the ASP methodology is bundled into the drug administration payment under the physician fee schedule. Therefore, CMS is not proposing to make a separate payment to physicians for the clerical and inventory resources associated with participation in the CAP.

ABSG recommends that CMS closely monitor physician clerical and inventory resources associated with the CAP during the phase-in period. If appropriate, CMS should provide for payments to cover additional costs associated with the CAP.

### **E. Prompt Submission of Claims**

ABSG believes that the proposed claims filing deadline of 14 days set forth in the Proposed Rule is excessive and should be revised. The 14 day time-period significantly increases the amount of cash the CAP vendor must invest to fund its receivable from Medicare and beneficiary co-payments. As discussed above, ABSG recommends that the final rule require physicians to notify CAP vendors of drug administration by 5:00 p.m. the next business day absent extenuating circumstances. The vendor could mitigate any burden on the physician office of such notification requirement through the provision of shipping confirmation and other data. ABSG further recommends that CMS narrowly define the circumstances under which a physician could submit a late claim. To promote compliance, the final rule should include a penalty for physicians who do not comply with the claims filing deadline in the absence of extenuating circumstances.

### **F. Local Coverage Policies**

ABSG recommends that CMS revise the final rule to limit the liability of CAP vendors for non-covered claims. The Proposed Rule would require physicians to determine whether a drug meets carrier standards for medical necessity. However, the CAP vendor, not the physician, would be liable for the loss if CMS denied coverage of the drug. ABSG strongly believes that it would be unreasonable for CAP vendors to have liability in this situation. CMS can address this situation by: (1) providing that a physician, and not the CAP vendor, would be liable for drug costs if the physician prescribes a drug to a Medicare beneficiary that does not meet coverage standards; (2) permitting the CAP vendor to validate Medicare coverage based on diagnosis coding information; or (3) creating a prior authorization process to confirm coverage before the CAP vendor distributes the drug.

### **G. Drug Storage**

ABSG is concerned that the drug storage provisions of the Proposed Rule do not include sufficient safeguards to protect the CAP Vendor's owned drug inventory when it is in the possession of the physician. CMS states that it does not believe that separate physical storage of CAP drugs is required. Instead, CMS is proposing that physicians participating in the CAP maintain a separate electronic or paper inventory for each CAP drug obtained. Under CAP, the CAP vendor would own and be responsible for properly accounting for drugs (*i.e.*, under GAAP and Sarbanes-Oxley) that are in the physician's possession, unlike under the current ASP methodology in which the physician owns the inventory. Thus, under the Proposed Rule, physicians (and the physicians' insurers) would not be at risk for product losses, and physician incentives to safeguard and track inventory would be diminished. Likewise, if the CAP drugs are not physically separated from the physician's general inventory, it is possible, due to negligence or design, for the CAP vendor's inventory to be administered to a private pay patient. In a worst-case scenario, a physician could intentionally use CAP inventory and/or unused portions of CAP inventory for non-CAP patients, and the CAP vendor would have no recourse or means of recoupment. This situation could be exacerbated if a physician amassed a large inventory of CAP vendor-owned drugs by placing an order for a beneficiary's entire course of treatment at one time.

ABSG recommends that the final rule require physicians to segregate and secure CAP drugs and observe all storage and handling instructions on the drug label. CMS should clarify that any unauthorized use or diversion of a CAP vendor's owned inventory for non-CAP purposes constitutes theft and may be pursued criminally by the CAP vendor. Further, CMS should not obligate CAP vendors to ship an order for a patient's full course of treatment at one time, because this would increase the time the drug is out of the control of the CAP vendor, while increasing the chances of wastage due to changes in treatment, patient death, poor storage conditions, and the like.

#### **H. Waste>Returns**

ABSG requests that CMS provide further guidance concerning wastage and returns. The Proposed Rule would require the CAP vendor to "assure that processing, handling, storage, and shipment of drugs and biologicals are adequate to maintain product integrity." Yet, in the case of an unused drug, CMS suggests that "the physician would notify the vendor and reach an agreement on how to handle the unused drug."

As there is no pre-existing financial relationship between the CAP vendor and physician to facilitate an arrangement to address returns, the mechanism to accomplish this is unclear. Further, ABSG suggests that introducing a direct financial relationship between the CAP Vendor and provider, particularly directly involving product, could raise concerns with respect to fraud, abuse, and inducement. Also, under the Proposed Rule, the CAP vendor essentially would be precluded from accepting returned drugs and subsequently redistributing them because the vendor would have no control over the drug's handling when it was out of the CAP vendor's possession and could not represent, upon redistribution, that the drug had been obtained from the manufacturer or from a distributor that acquired the drug directly from the manufacturer. Accordingly, the CAP vendor could not "assure that processing, handling, storage, and shipment of these returned drugs and biologicals are adequate to maintain product integrity." Moreover, if CMS contemplates using a patient-specific prescription (pharmacy model), unused drugs could not be returned for credit or redistribution in compliance with pharmacy law.

#### **VI. Dispute Resolution**

The Proposed Rule specifically prohibits CAP vendors from participating in the dispute resolution process and gives vendors no formal appeal rights with regard to denied claims. Instead, CMS encourages physicians, beneficiaries, and CAP vendors to use informal communication to resolve issues whenever possible. To that end, CMS would allow CAP vendors to track individual physician claims denials, and if the total dollar amount of vendor losses exceeds an "acceptable threshold," the vendor could ask the carrier to counsel the physician. Eventually, the vendor could ask the carrier to recommend a suspension of the physician's CAP participation agreement. CMS seeks comments on the appropriate amount for the vendor's loss threshold.

We are concerned that CMS is raising the concept that there is an acceptable threshold of losses for CAP vendors. To be clear, in today's operating and economic environment, there is no acceptable loss level for entities contemplating participation as CAP vendors. For instance, under the Proposed Rule, if a claim for an injection of Neulasta (J2505) is denied, the physician

would be at risk for only approximately \$19 in administration fees, and could choose not to file an appeal. On the other hand, the CAP vendor would be at risk of loss for approximately \$2,300 worth of drug and would not be able to file an appeal -- a significant loss for the CAP vendor which would likely require drug sales of over \$100,000 to recover. As a result, failure to provide a vendor appeal mechanism may discourage potential CAP vendor participation.

CMS should clearly signal to physicians that the agency expects that medication orders and/or prescriptions will be written for medically-necessary drugs and will comply with local medical policies, and that claims will be submitted in a timely manner. Moreover, CMS should remove references to the concept of an "acceptable threshold" of CAP vendor losses, and provide CAP vendors with the right to appeal denied claims as discussed in more detail below.

ABSG believes strongly that CAP vendors must have an independent, formal recourse to appeal denied claims, particularly in cases where a physician does not appeal a denial, and should not be obligated to provide services to a physician with a history of excessive denials. ABSG proposes that CMS give vendors the unilateral right to suspend service and/or deny new services to a physician who's denied claim performance is unacceptable to the CAP vendor. In addition, the claims carrier should automatically contact a physician about excessive claims denials and, ultimately, the case should be referred to CMS to determine whether the provider's privilege of CAP participation should be revoked. To further promote compliance, local carriers and CMS should publish physician claims denial statistics, as well as circumstances where there is a history of excessive denials and revocation.

The issues raised by the proposed appeals process underscore the importance of either providing CAP vendors with information on coverage determinations prior to CAP vendors filling drug orders, establishing a prior authorization process, or providing that the physician, not a CAP vendor, should be responsible for claims denials based on the physician's failure to follow medical necessity guidelines. Likewise, the physician, not the vendor, should be responsible for losses associated with physician errors or failure to file a claim in a timely manner.

Dispute Resolution is another area of the Proposed Rule that creates material issues with respect to GAAP and Sarbanes-Oxley compliance, in addition to creating real economic risks and confusion regarding whether CAP vendors will be operating under a pharmacy or distribution model. The concerns about this process reinforces our previous comments related to a Distribution Model (inclusive of a distinct clearinghouse function) and supports a Service Model approach where the CAP vendor is paid a fee for administrating the CAP instead of a model under which the CAP vendor assumes financial risk.

## **VII. Contracting Process-Quality and Product Integrity Aspects**

The Proposed Rule includes quality standards for drug products and vendors, including vendor capacity to acquire and deliver drugs; financial/solvency standards; and ability to assure the safe processing, handling, storage, and shipment of drug products. CMS references basic licensure and regulatory compliance standards as a minimum standard, and asks applicants to describe additional measures taken to assure product integrity (such as processes to detect counterfeit drugs). CMS also includes standards related to fraud and abuse prevention and

conflicts of interest, and solicits comments regarding what may or may not constitute a conflict of interest in the CAP and how such conflicts might be identified and mitigated.

ABSG supports CMS's implementation of strong standards in these areas. ABSG believes that CMS, physicians, and beneficiaries must have confidence that CAP vendors are capable of providing reliable, timely, and high-quality distribution or pharmacy services to beneficiaries. Moreover, we agree that Medicare contractors should adhere to high ethical standards and comply with all applicable fraud and abuse statutes and conflict-of-interest provisions. With regard to specific conflict-of-interest standards, ABSG believes that the final rule should address situations in which a physician or medical/nursing practice is managed by a company that is affiliated with a potential CAP vendor. In such cases, the physician may have no effective choice of a CAP vendor, and non-affiliated vendors may not have a meaningful opportunity to compete for the business of the physician practice. Thus, the final rule should include explicit conflict-of-interest standards to guard against preferential selection and treatment of potential CAP vendors that are affiliated with physician and medical/nursing practice management companies.

### **VIII. Bidding Entity Qualifications**

ABSG supports CMS's inclusion in the Proposed Rule of strong standards related to vendor qualifications, including management and operations standards, operation of a grievance process, experience, HIPAA compliance, licensure, and business integrity. We believe such criteria are necessary to ensure that only qualified entities are selected as CAP vendors.

### **IX. CAP Bidding Process - Evaluation and Selection**

#### **A. Prompt Payment**

ABSG recommends that CMS exclude prompt pay discounts from a CAP vendor's determination of "net acquisition cost" because such discounts reflect financing terms, rather than a reduction in the acquisition cost of the product. The Proposed Rule would require CAP vendors to fully disclose their reasonable, net acquisition costs for drugs included in the CAP contract. CMS lists examples of discounts that result in a reduction of actual cost to the vendor, including volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, refunds, and other price concessions. If CMS chooses to include prompt pay discounts in the definition of net acquisition costs, for consistency it also should increase the net acquisition cost by the external interest paid by a CAP vendor to acquire and carry inventory and receivables prior to receipt of CMS reimbursement and beneficiary co-payments. Further, the CAP Vendor's net acquisition cost should be increased by the amount of uncollectible beneficiary co-payments.

#### **B. Average Sales Price**

ABSG recommends that CMS exclude sales by manufacturers to CAP vendors from the calculation of ASP as a necessary step towards achieving meaningful cost savings and ensuring the success of the CAP. The Proposed Rule is silent regarding whether manufacturers must include prices negotiated with a CAP vendor in the calculation of average sales price ("ASP"). If CAP prices are included in the calculation of ASP, manufacturers will be discouraged from

offering significant discounts to CAP vendors, increasing costs to the Medicare program and beneficiaries.

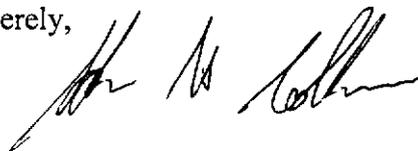
ABSG also recommends that prompt pay discounts should not be included in the calculation of ASP because they do not reflect any true price concessions. Instead, reductions in price related to timely payments would serve the purpose of compensating the CAP vendor for distribution services provided as part of the customary drug supply chain, including the costs of managing the delivery of products to the physician offices; establishing, monitoring, and collecting payments; assuming credit risks related to the physician practice's account; processing charges associated with the acceptance of credit card payments; risks related to product damage or spoilage; and other insurance and security expenses.

Because the CAP vendors will not receive any separate payment related to these necessary costs which are commonly reflected in prompt pay discounts, they should be excluded from the vendors' bids.

\* \* \* \*

ABSG appreciates the opportunity to present these comments to CMS. We hope our recommendations will be useful to CMS in developing and implementing the CAP. If you have any questions or need additional information, please do not hesitate to contact me at (972) 490-5551.

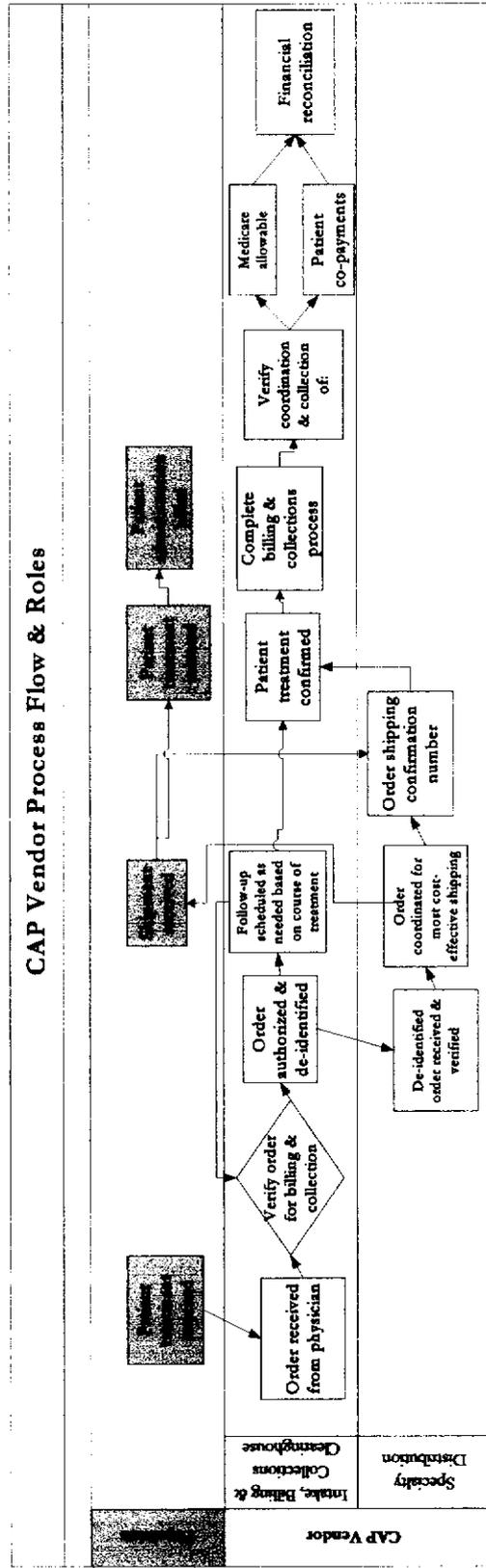
Sincerely,



Steve Collis  
President/General Manager  
AmerisourceBergen Specialty Group

cc: Rita Norton  
Vice President Government Affairs  
Peyton Howell  
President, Lash Group  
Dr. Jeffrey Scott  
President, International Physicians Network  
Bill Stickler  
President, Oncology Supply  
Mick Besse  
Vice President – General Manager, Besse Medical  
Neil Herson  
Vice President – General Manager, ASD Healthcare  
Joe Pugliese  
President, US Bioservices

# Exhibit A Distribution Model Flow Chart



## Exhibit B

Summary of Potential Models Described in ABSG Comments		
Distribution Model		Pharmacy Model
Service Model	Modified Risk Model	
<p>Cap Vendor is administering CAP as a service vendor (providing both billing clearinghouse and specialty distribution services). Potential advantage because CMS is the "purchaser".</p> <p>— Requires separation of clearinghouse and distribution services so that patient identity is separated from the product and product can be returned when appropriate.</p>	<p>This model is only feasible if the CAP vendor preserves all rights related to determining coverage prior to service and collection of payment information (including how copayment will be paid) prior to date of service and then collection of product administration.</p> <p>— Requires all the same separation of clearinghouse and distribution service</p>	<p><i>[This section is heavily obscured by a dark, grainy pattern, making the text illegible.]</i></p>

## Proposed CAP Model Summary of Key Recommendations

Recommendation	Rationale
<p><b>CMS implements CAP as a Distribution Model rather than a Pharmacy Model</b></p> <ul style="list-style-type: none"> <li>▪ Language is not clear in proposed rule and includes aspects of distribution and pharmacy services.</li> <li>▪ In order to accomplish implementation of Distribution Model, the final rule must specify that product is ordered based on patient need through the clearinghouse and is shipped to physician in a de-identified manner (order number) to address privacy concerns and to ensure that product is considered distributed product. Bid process must be clarified to address this issue.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only approach that is consistent with current processes and does not add additional/new costs associated with a pharmacy model such as:               <ol style="list-style-type: none"> <li>1. Inability to return product dispensed for an individual patient as part of a pharmacy program</li> <li>2. Clinical evaluation services</li> <li>3. Additional pharmacy specific costs</li> </ol> </li> <li>▪ Most cost effective approach</li> <li>▪ Utilizes existing specialty distribution resources rather than create necessity to new entities.</li> </ul>
<p><b>CMS implements CAP Distribution Final Rule as a "Service Model" approach</b></p> <ul style="list-style-type: none"> <li>▪ CAP vendor would serve as an administrator to CMS rather than being at risk for reimbursement from CMS and the patient.</li> <li>▪ At a minimum, CMS should allow this type of bid to be submitted.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Most cost effective and predictable approach.</li> <li>▪ If this model is not implemented, then the rule must limit risk exposure to the CAP Vendor.</li> </ul>
<p><b>CMS changes CAP Vendor claims processing timing and responsibility</b></p> <ul style="list-style-type: none"> <li>▪ In our preferred "Service Model" as well as a Modified Risk Model, it is essential that the CAP vendor have rights and authority to verify coverage and "collectability" before services are rendered.</li> </ul>	<ul style="list-style-type: none"> <li>▪ The CAP Vendor should bill CMS upon time of service consistent with standard practice.</li> <li>▪ The CAP Vendor must have rights to:               <ul style="list-style-type: none"> <li>○ verify coverage based on diagnosis prior to shipment;</li> <li>○ obtain information as to how the copayment will be paid in advance;</li> <li>○ bill upon time of service; and</li> <li>○ appeal claim denials regardless of status of physician claim.</li> </ul> </li> </ul>

# Congress of the United States

House of Representatives

109th Congress

Committee on Small Business

2361 Rayburn House Office Building

Washington, DC 20515-0315

APR 22 2005

April 21, 2005

Via Hand Delivery

The Honorable Mark McClellan, M.D.

Administrator

Centers for Medicare and Medicaid Services

200 Independence Avenue, S.W., Room 314-G

Washington, DC 20201

**RE: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, 70 Fed. Reg. 10,746 (March 4, 2005); CMS-1325-P; Comments on the Regulatory Impact Analysis**

Dear Administrator McClellan:

On March 4, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule to implement § 303(d) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) mandating the use of a competitive bidding for drugs that are covered under Medicare Part B. 42 U.S.C. § 1395w-3b. Specifically, the proposed rule requires that physicians utilizing the drugs covered under Part B obtain them from vendors selected through a competitive bidding process or directly from the manufacturer and receive reimbursement based on the average sales price of the pharmaceuticals. CMS correctly found that the proposed rule is significant under Executive Order 12,866 (E.O.). Given its determination, CMS then prepared a detailed economic analysis of the proposal as mandated by the E.O. Despite the economic analysis incorporated into the regulatory impact analysis, CMS never made a finding required by the Regulatory Flexibility Act, 5 U.S.C. §§ 601-12 (RFA). More significantly, CMS failed to assess the proposal's impact on those small businesses that might want to participate as vendors under this competitive acquisition program (CAP). CMS should extend the comment period and republish the proposed rule with a proper finding under the RFA. The republished proposal must contain an analysis of the impact on potential small business vendors.

**I. Necessary Findings under the RFA are a Prerequisite to Ensuring Adequate Small Business Outreach**

As CMS notes, the RFA requires the agency to prepare an initial regulatory flexibility analysis (IRFA) unless it certifies that the proposal will not have a significant economic impact on a substantial number of small entities. The regulatory impact analysis prepared pursuant to the mandates of the E.O. correctly states the law. An accurate rendition of the law is no substitute for the compliance. CMS provides no conclusion required by the RFA; that is a certification of no impact or a finding that the rule will have a significant economic impact on a substantial number of small entities.

While at first blush the omission seems irrelevant given the depth of analysis otherwise provided by CMS, the failure actually undermines another critical component of the RFA – outreach to the small business community. Section 609(a) of the RFA, 5 U.S.C. § 609(a), provides in pertinent part:

When any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule shall assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the reasonable use of techniques....

The point of this requirement does not provide some special benefit to small businesses. Rather, it stems from the fundamental tenet that notice and comment rulemaking enables regulated businesses to educate the agency on the proposed rule. *E.g.*, *Phillips Petroleum v. Johnson*, 22 F.3d 616, 620 (5th Cir. 1994), *cert. denied*, 514 U.S. 1092 (1995); *Spartan Radiocasting v. FCC*, 617 F.2d 314, 321 (4th Cir. 1980); *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 632 & n.51 (D.C. Cir. 1973); *Texaco Inc. v. FPC*, 412 F.2d 740, 744 (3d Cir. 1969). The RFA's mandate to certify or prepare an IRFA directly follows from the Administrative Procedure Act's (APA) mandate that an agency educate itself on the proposed rule. Since the vast majority of businesses regulated by a federal agency are small, logical decisionmaking strongly militates in favor of obtaining input from the largest segment of businesses that will be affected by the proposal. Absent this information, an agency may not be able to craft a rule that achieves its statutory objectives because small businesses may not have the technical capacity to meet the strictures of the rule. In addition, compliance with the rule may be sufficiently costly that it forces small businesses to close or undermines other regulatory objectives of the agency. This failure then undermines the rationality of the rule.

The critical flaw in the CMS proposal is its failure to identify whether the proposal will have a significant impact on a substantial number of small entities. Without this identification,

small businesses remain unaware that the proposal may have potential consequences for their operations. To be sure, an agency's certification at the proposed rule stage may be incorrect and thus dissuade small entities from commenting. Nevertheless, certification represents the best estimate from the agency that small entities need not be overly concerned about the proposal. In contradistinction, preparation of an IRFA constitutes a definitive declaration from the agency that small businesses must pay special heed to the proposal and file comments in order to educate the agency as it crafts a final rule.

Absent such a declaration, the analytical burden suddenly shifts from the agency to the regulated small business community to determine whether the proposal affects them. CMS's failure is akin to the Bureau of Reclamation setting out a notice that it plans to build a new dam along the Colorado River but leaves the determination of whether the construction creates significant environmental impacts to the communities along the affected part of the river in contravention of § 102(2)(c) of the National Environmental Policy Act (NEPA), 42 U.S.C. § 4332(2)(C). It is beyond cavil that the Bureau of Reclamation's failure to make a definitive statement about the environmental consequences does not satisfy the precept of logical agency decisionmaking. Given the parallels between the RFA and NEPA, *Associated Fisheries of Maine v. Daley*, 127 F.3d 104, 114 (1st Cir. 1997), CMS, at a minimum, must notify the small business community of the potential impact of the rule through a certification or designation of its regulatory impact analysis as its IRFA (an action permissible under the RFA, 5 U.S.C. § 605(a), to the extent that the impact analysis covers all the elements set forth in § 603 for inclusion in an IRFA). Its failure to do so constitutes a violation of the RFA and potentially subjects the regulation to challenge pursuant to § 611 of that Act. CMS can remove potential legal problems by republishing the proposed rule with a certification statement or IRFA.

## **II. CMS Failed to Examine the Impact of the Proposal on an Important Sector of the Small Business Community – Potential Vendors to Physicians**

The following statement represents the extent of CMS's analysis of the impact on potential vendors to physicians (exclusive of drug manufacturers):

[t]his proposed rule would have an impact on entities, either existing or formed specifically for this purpose, that are involved in the dispensing of drugs. This impact would be dependent on the categories of drugs and geographic areas that are determined to fall under the CAP and on their ability to successfully compete and receive approval as a vendor under the competitive acquisition program.

70 Fed. Reg. at 10,768.

The critical element in this analysis relates to the ability of the small businesses to receive approval as vendors and then compete for customers. CMS does not analyze the contracts in an

effort to ascertain whether its proposed terms and conditions foreclose opportunities for small businesses to participate as vendors. Nor does CMS assess whether other terms and conditions would be less burdensome on small businesses while still creating an adequate competitive acquisition program. For example, CMS might consolidate requirements across geographic areas that are so large that small vendors do not have the distribution resources needed to fall within the range of technical competence demanded for a responsive bid.<sup>1</sup> If small businesses are unable to file responsive bids due to contractual requirements crafted by CMS, the adverse consequences on the ability of small businesses to compete in the CAP needs no further expatiation.

An adequate IRFA requires CMS to assess the impact on small businesses and examine less burdensome alternatives. In the context of this rulemaking, the RFA requires CMS to develop alternative contractual terms and conditions, such as prohibitions on consolidation of vendor requirements, that do not prevent small businesses from successfully competing under the competitive acquisition program.

### **III. Failure to Comply with the RFA may result in Implementation Delays due to Judicial Challenges to the Final Rule**

Section 611 of the RFA authorizes judicial review of agency compliance with the Act. To enforce compliance, courts may remand the rule to the agency and defer enforcement against small businesses until the agency complies with the requirements of the RFA. 5 U.S.C. § 611(a)(4). Thus, the failure to comply with the RFA may delay implementation of the CAP or force CMS to craft another set of rules for contracting with small business vendors.

CMS published the proposed CAP regulations pursuant to the mandatory notice and comment rulemaking requirements set forth in § 1871(b) of the Medicare Act. 42 U.S.C. § 1395hh(b). Once notice and comment rulemaking is required by either the APA or some other statute, 5 U.S.C. § 603(a), the agency must comply with the analytical requirements of the RFA. See *United States Telecommunications Ass'n v. FCC*, 400 F.3d 329 (D.C. Cir. 2005); *Associated Fisheries of Maine v. Daley*, 127 F.3d 104 (1st Cir. 1997); *Southern Offshore Fishing Ass'n v. Daley*, 995 F. Supp. 1411 (M.D. Fla. 1998). And specifically, the failure to perform an adequate initial analysis can undermine the validity of any final analysis. See *Southern Offshore Fishing Ass'n*, 995 F. Supp. at 1436.

CMS cannot cite the prohibitions on judicial review of certain aspects of the CAP to avoid judicial review pursuant to the RFA. It cannot be argued that the statutory restrictions on judicial review in § 303(d) of the MMA implicitly repeal § 611 of the RFA. The Supreme Court

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<sup>1</sup> This situation is exacerbated by the Secretary's authority to exempt the CAP from any of the requirements of the Federal Acquisition Rules (FAR). The FAR incorporates provisions designed to protect small businesses from contract consolidation and imposes other obligations on federal agencies to ensure that small businesses receive a fair opportunity to compete for contracts. The Secretary could exempt the CAP from all of those provisions.

has repeatedly stated that repeals of earlier enacted statutes by later-enacted statutes through implication are strongly disfavored unless there is an irreconcilable conflict between the two statutes or the latter statute covers the whole of the earlier statute and is a substitute for the earlier one. *Branch v. Smith*, 538 U.S. 254, 272 (2003), citing *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936). No irreconcilable conflict exists because Congress did not provide a blanket exemption to judicial review of the CAP – only certain aspects of it. In establishing the CAP, Congress prohibited judicial review of the following: 1) amount of payments made for drugs; 2) the award of contracts; 3) establishment of competitive acquisition areas; 4) the implementation of the phase-in mandated under the CAP; 5) selection of categories of drugs subject to competitive bidding under Part B; and 6) bidding structure and number of contractors selected. 42 U.S.C. § 1395w-3b(g). For example, Congress did not prohibit judicial review if CMS failed to comply with the notice and comment requirements of § 1871(b) of the Medicare Act. Nor can it be said that the provisions concerning judicial review covers the whole of the earlier statute. Section 303(d) of the MMA makes no mention of the procedural requirements that CMS must follow in drafting rules to implement the CAP. Absent a clear expression of Congressional intent, § 303(d) of the MMA does not repeal the judicial review provisions of the RFA.

#### **IV. Conclusion**

CMS can easily avoid potential legal pitfalls elucidated in this letter by republishing the proposal with a corrected regulatory flexibility analysis. The analysis must include an assessment of the potential impact of contract terms on the capability of small businesses to compete as vendors. In turn, such an analysis will generate ideas from potential vendors about changes that might further improve the competitive acquisition program. The ultimate winner will be the taxpayer because a well-designed CAP should save money. Should your staff have any comments about this letter, please contact the Committee's regulatory counsel, Barry Pineles at 202-225-3983.

Sincerely,

A handwritten signature in black ink that reads "Donald A. Manzullo MC". The signature is written in a cursive, slightly slanted style.

Donald A. Manzullo  
Chairman

April 18, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1325-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

APR 21 2005

**Re: Competitive Acquisition Program (CAP) for Medicare Part B**

To whom it may concern:

The New York City affiliate of the National Alliance for the Mentally Ill, (NAMI-NYC Metro) is one of the largest affiliates of NAMI, a national mental health education, advocacy and support organization for mental health consumers and their family members.

Our consumer members require access to a broad range of psychiatric medications to remain in recovery and out of the hospital. Psychiatric medications, unlike medications for other chronic illness such as heart disease and diabetes, are not interchangeable. Some psychiatric medications that are effective for mental health consumers with a particular diagnosis are completely ineffective for others with the same diagnosis.

To ensure that a broad range of psychiatric medications are available, we recommend that the following issues be considered before the commencement of the CAP program.

- Include all psychiatric medications to treat disorders in the DSM-IV (revised) from the start of the program. Specifically, ensure availability to “long-acting” or injectable antipsychotic medications, which help some of our members reduce the number of in-hospital days required.
- If the CAP program is phased-in, include all psychiatric medications in the first phase of the program.
- If separate categories for medications are developed, designate one solely for psychiatric drugs.
- Develop adequate reimbursement procedures to discourage vendors from discontinuing medications, including those that address uncollectible co-pays.

On behalf of our members, we thank you for taking these recommendations into consideration.

Sincerely,



Evelyn Roberts, Ph.D.  
Executive Director