2007 Proposed OPPS Payment Rate for 61885 Adjusted by Wage Index (9/29/06 release)

Provider	Name	City	State	2005 volume	Wage Index	Proposed Payment Rate for (2007)	Wage Adjusted Payment
050197	SEQUOIA HOSPITAL	REDWOOD CITY	CA	*	1.5617	$ 10,829	$ 14,478
050454	UCSF MEDICAL CENTER	SAN FRANCISCO	CA	*	1.5445	$ 10,829	$ 14,367
050441	STANFORD HOSPITAL	STANFORD	CA	*	1.5324	$ 10,829	$ 14,288
310001	HACKENSACK UNIVERSITY MEDICAL CENTER	HACKENSACK	NJ	*	1.3344	$ 10,829	$ 13,002
330024	MOUNT SINAI HOSPITAL	NEW YORK	NY	*	1.3344	$ 10,829	$ 13,002
330072	OUR LADY OF MERCY MEDICAL CENTER	BRONX	NY	*	1.3344	$ 10,829	$ 13,002
330101	NEW YORK-PRESBYTERIAN HOSPITAL	NEW YORK	NY	*	1.3344	$ 10,829	$ 13,002
330214	NYU HOSPITALS CENTER	NEW YORK	NY	*	1.3344	$ 10,829	$ 13,002
310076	SAINT BARNABAS MEDICAL CENTER	LIVINGSTON	NJ	*	1.31235	$ 10,829	$ 12,858
310108	JFK MEDICAL CENTER	EDISON	NJ	*	1.31235	$ 10,829	$ 12,858
050108	SUTTER GENERAL HOSPITAL	SACRAMENTO	CA	*	1.2986	$ 10,829	$ 12,769
050590	METHODIST HOSPITAL	SACRAMENTO	CA	*	1.2986	$ 10,829	$ 12,769
070036	JOHN DEMPSEY HOSPITAL	FARMINGTON	CT	*	1.2536	$ 10,829	$ 12,477
070007	LAWRENCE & MEMORIAL HOSPITAL	NEW LONDON	CT	*	1.2031	$ 10,829	$ 12,148
220017	CARITAS CARNEY HOSPITAL INC	BOSTON	MA	*	1.1765	$ 10,829	$ 11,976
220071	MASSACHUSETTS GENERAL HOSPITAL	BOSTON	MA	*	1.1765	$ 10,829	$ 11,976
220116	TUFTS-NEW ENGLAND MEDICAL CENTER	BOSTON	MA	*	1.1765	$ 10,829	$ 11,976
050179	EMANUEL MEDICAL CENTER INC	TURLOCK	CA	*	1.1735	$ 10,829	$ 11,956
300003	MARY HITCHCOCK MEMORIAL HOSPITAL	LEBANON	NH	*	1.1732	$ 10,829	$ 11,954
050262	UCLA MEDICAL CENTER	LOS ANGELES	CA	*	1.1686	$ 10,829	$ 11,924
050438	HUNTINGTON MEMORIAL HOSPITAL	PASADENA	CA	*	1.1686	$ 10,829	$ 11,924
050485	LONG BEACH MEMORIAL MEDICAL CENTER	LONG BEACH	CA	*	1.1686	$ 10,829	$ 11,924
050625	CEDARS-SINAI MEDICAL CENTER	LOS ANGELES	CA	*	1.1686	$ 10,829	$ 11,924
030023	FLAGSTAFF MEDICAL CENTER	FLAGSTAFF	AZ	*	1.1538	$ 10,829	$ 11,828
050099	SAN ANTONIO COMMUNITY HOSPITAL	UPLAND	CA	*	1.1525	$ 10,829	$ 11,820
050327	LOMA LINDA UNIVERSITY MEDICAL CENTER	LOMA LINDA	CA	*	1.1525	$ 10,829	$ 11,820
050348	UNIV OF CALIFORNIA IRVINE MED CENTER	ORANGE	CA	*	1.1525	$ 10,829	$ 11,820
050082	ST JOHNS REGIONAL MEDICAL CENTER	OXNARD	CA	*	1.1439	$ 10,829	$ 11,764
310014	COOPER UNIVERSITY HOSPITAL	CAMDEN	NJ	*	1.1402	$ 10,829	$ 11,740
380014	GOOD SAMARITAN REGIONAL MEDICAL CTR	CORVALLIS	OR	*	1.1334	$ 10,829	$ 11,696
500001	NORTHWEST HOSPITAL	SEATTLE	WA	*	1.1261	$ 10,829	$ 11,648
500008	UNIVERSITY OF WASHINGTON MEDICAL CTR	SEATTLE	WA	*	1.1261	$ 10,829	$ 11,648
500014	PROVIDENCE EVERETT MEDICAL CENTER	EVERETT	WA	*	1.1261	$ 10,829	$ 11,648
500027	SWEDISH MEDICAL CENTER	SEATTLE	WA	*	1.1261	$ 10,829	$ 11,648
240010	ST MARYS HOSPITAL	ROCHESTER	MN	*	1.1239	$ 10,829	$ 11,634
380004	PROVIDENCE ST VINCENT MEDICAL CENTER	PORTLAND	OR	*	1.121	$ 10,829	$ 11,615
380007	LEGACY EMANUEL HOSPITAL	PORTLAND	OR	*	1.121	$ 10,829	$ 11,615
380009	OHSU HOSPITAL AND CLINICS	PORTLAND	OR	*	1.121	$ 10,829	$ 11,615
380017	LEGACY GOOD SAMARITAN HOSPITAL	PORTLAND	OR	*	1.121	$ 10,829	$ 11,615
050026	GROSSMONT HOSPITAL	LA MESA	CA	*	1.1202	$ 10,829	$ 11,610
050057	KAWEAH DELTA DISTRICT HOSPITAL	VISALIA	CA	*	1.1202	$ 10,829	$ 11,610

2005 vol	% of total
32	5%

Indicates a value of 10 or less

Provider	Name	City	State	2005 volume	Wage Index	Proposed Payment Rate for (2007)	Wage Adjusted Payment
050128	TRI-CITY MEDICAL CENTER	OCEANSIDE	CA	*	1.1202	$ 10,829	$ 11,610
050243	DESERT REGIONAL MEDICAL CENTER	PALM SPRINGS	CA	*	1.1202	$ 10,829	$ 11,610
050396	SANTA BARBARA COTTAGE HOSPITAL	SANTA BARBARA	CA	*	1.1202	$ 10,829	$ 11,610
290003	SUNRISE HOSPITAL & MEDICAL CENTER	LAS VEGAS	NV	*	1.1148	$ 10,829	$ 11,575
500129	TACOMA GENERAL ALLENMORE HOSPITAL	TACOMA	WA	*	1.1096	$ 10,829	$ 11,541
460021	DIXIE REGIONAL MEDICAL CENTER	ST GEORGE	UT	*	1.1006	$ 10,829	$ 11,482
390111	HOSPITAL OF UNIV OF PENNSYLVANIA	PHILADELPHIA	PA	*	1.0996	$ 10,829	$ 11,476
390174	THOMAS JEFFERSON UNIVERSITY HOSPITAL	PHILADELPHIA	PA	*	1.0996	$ 10,829	$ 11,476
500024	PROVIDENCE ST PETER HOSPITAL	OLYMPIA	WA	*	1.0985	$ 10,829	$ 11,469
490043	INOVA LOUDOUN HOSPITAL	LEESBURG	VA	*	1.0977	$ 10,829	$ 11,464
520098	UW HEALTH UW HOSPITALS AND CLINICS	MADISON	WI	*	1.0841	$ 10,829	$ 11,375
320002	ST VINCENT HOSPITAL	SANTA FE	NM	*	1.0808	$ 10,829	$ 11,354
140130	LAKE FOREST HOSPITAL	LAKE FOREST	IL	*	1.0798	$ 10,829	$ 11,347
140202	CONDELL MEDICAL CENTER	LIBERTYVILLE	IL	*	1.0798	$ 10,829	$ 11,347
230117	BORGESS MEDICAL CENTER	KALAMAZOO	MI	*	1.0797	$ 10,829	$ 11,347
240038	UNITED HOSPITALS INC	SAINT PAUL	MN	*	1.0782	$ 10,829	$ 11,337
240057	ABBOTT - NORTHWESTERN HOSPITAL INC	MINNEAPOLIS	MN	*	1.0782	$ 10,829	$ 11,337
380018	ROGUE VALLEY MEDICAL CENTER	MEDFORD	OR	*	1.0756	$ 10,829	$ 11,320
410007	RHODE ISLAND HOSPITAL	PROVIDENCE	RI	*	1.0744	$ 10,829	$ 11,312
060024	UNIVERSITY OF COLORADO HOSPITAL AUTHORITY	DENVER	CO	*	1.0719	$ 10,829	$ 11,296
060034	SWEDISH MEDICAL CENTER	ENGLEWOOD	CO	*	1.0719	$ 10,829	$ 11,296
230046	UNIVERSITY OF MICHIGAN HOSPITAL	ANN ARBOR	MI	*	1.0678	$ 10,829	$ 11,269
140010	EVANSTON NORTHWESTERN HEALTHCARE	EVANSTON	IL	*	1.067	$ 10,829	$ 11,264
140088	UNIVERSITY OF CHICAGO HOSPITALS	CHICAGO	IL	*	1.067	$ 10,829	$ 11,264
140191	INGALLS MEMORIAL HOSPITAL	HARVEY	IL	*	1.067	$ 10,829	$ 11,264
140252	NORTHWEST COMMUNITY HOSPITAL	ARLINGTON HEIGHTS	IL	*	1.067	$ 10,829	$ 11,264
140276	LOYOLA UNIVERSITY MEDICAL CENTER	MAYWOOD	IL	*	1.067	$ 10,829	$ 11,264
330224	BENEDICTINE HOSPITAL	KINGSTON	NY	*	1.066	$ 10,829	$ 11,258
150002	METHODIST HOSPITAL, INC,THE	GARY	IN	*	1.0564	$ 10,829	$ 11,195
150004	SAINT MARGARET MERCY HEALTHCARE CENTERS	HAMMOND	IN	*	1.0564	$ 10,829	$ 11,195
230104	HARPER UNIVERSITY HOSPITAL	DETROIT	MI	*	1.05015	$ 10,829	$ 11,155
230165	ST JOHN HOSPITAL & MEDICAL CTR	DETROIT	MI	*	1.05015	$ 10,829	$ 11,155
470003	FLETCHER ALLEN HOSPITAL OF VERMONT	BURLINGTON	VT	*	1.04825	$ 10,829	$ 11,142
230066	HACKLEY HOSPITAL	MUSKEGON	MI	*	1.0451	$ 10,829	$ 11,122
500044	DEACONESS MEDICAL CENTER	SPOKANE	WA	*	1.0422	$ 10,829	$ 11,103
230142	OAKWOOD ANNAPOLIS HOSPITAL	WAYNE	MI	*	1.04105	$ 10,829	$ 11,096
520138	AURORA ST LUKES MED CTR	MILWAUKEE	WI	*	1.0324	$ 10,829	$ 11,039
520177	FROEDTERT MEM LUTHERAN HSPTL	MILWAUKEE	WI	*	1.0324	$ 10,829	$ 11,039
240002	ST MARY'S/DULUTH CLINIC HEALTH SYSTEMS	DULUTH	MN	*	1.0285	$ 10,829	$ 11,014
520096	ALL SAINTS MED CTR ST MARYS CAMPUS	RACINE	WI	*	1.0209	$ 10,829	$ 10,965
230038	SPECTRUM HEALTH HOSPITALS	GRAND RAPIDS	MI	*	1.01755	$ 10,829	$ 10,943
230059	SAINT MARY'S HEALTH CARE	GRAND RAPIDS	MI	*	1.01755	$ 10,829	$ 10,943
230097	MUNSON MEDICAL CENTER	TRAVERSE CITY	MI	*	1.01755	$ 10,829	$ 10,943
030024	ST JOSEPH'S HOSPITAL AND MEDICAL CENTER	PHOENIX	AZ	*	1.0146	$ 10,829	$ 10,924

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Provider	Name	City	State	2005 volume	Wage Index	Proposed Payment Rate for (2007)	Wage Adjusted Payment
030083	PARADISE VALLEY HOSPITAL	PHOENIX	AZ	*	1.0146	$ 10,829	$ 10,924
030092	JOHN C LINCOLN DEER VALLEY HOSPITAL	PHOENIX	AZ	*	1.0146	$ 10,829	$ 10,924
030103	MAYO CLINIC HOSPITAL	PHOENIX	AZ	*	1.0146	$ 10,829	$ 10,924
230092	WA FOOTE HOSPITAL	JACKSON	MI	*	1.0106	$ 10,829	$ 10,898
450068	MEMORIAL HERMANN HOSPITAL	HOUSTON	TX	*	1.0094	$ 10,829	$ 10,890
450184	MEMORIAL HERMANN HEALTHCARE SYSTEM	HOUSTON	TX	*	1.0094	$ 10,829	$ 10,890
450193	ST LUKES EPISCOPAL HOSPITAL	HOUSTON	TX	*	1.0094	$ 10,829	$ 10,890
450211	MEMORIAL MEDICAL CENTER OF EAST TEXAS	LUFKIN	TX	*	1.0094	$ 10,829	$ 10,890
450222	CONROE REGIONAL MEDICAL CENTER	CONROE	TX	11	1.0094	$ 10,829	$ 10,890
450358	METHODIST HOSPITAL,THE	HOUSTON	TX	*	1.0094	$ 10,829	$ 10,890
450617	CLEAR LAKE REGIONAL MEDICAL CENTER	WEBSTER	TX	*	1.0094	$ 10,829	$ 10,890
390049	ST LUKES HOSPITAL OF BETHLEHEM	BETHLEHEM	PA	*	1.0093	$ 10,829	$ 10,889
390197	SACRED HEART HOSPITAL	ALLENTOWN	PA	*	1.0093	$ 10,829	$ 10,889
360006	RIVERSIDE METHODIST HOSPITAL	COLUMBUS	OH	*	1.0076	$ 10,829	$ 10,878
360017	GRANT MEDICAL CENTER	COLUMBUS	OH	*	1.0076	$ 10,829	$ 10,878
360152	DOCTORS HOSPITAL OHIO HEALTH	COLUMBUS	OH	11	1.0076	$ 10,829	$ 10,878
360218	LICKING MEMORIAL HOSPITAL	NEWARK	OH	*	1.0076	$ 10,829	$ 10,878
140239	ROCKFORD MEMORIAL HOSPITAL	ROCKFORD	IL	*	1.0048	$ 10,829	$ 10,860
490009	UNIVERSITY OF VIRGINIA HOSPITAL	CHARLOTTESVILLE	VA	*	1.0039	$ 10,829	$ 10,854
450462	PRESBYTERIAN HOSPITAL OF DALLAS	DALLAS	TX	*	0.9977	$ 10,829	$ 10,814
450647	MEDICAL CITY DALLAS HOSPITAL	DALLAS	TX	*	0.9977	$ 10,829	$ 10,814
450766	UT SOUTHWESTERN ZALE LIPSHY HOSPITAL	DALLAS	TX	*	0.9977	$ 10,829	$ 10,814
280020	SAINT ELIZABETH REGIONAL MEDICAL CENTER	LINCOLN	NE	*	0.9966	$ 10,829	$ 10,807
520037	ST JOSEPHS HSPTL	MARSHFIELD	WI	*	0.9947	$ 10,829	$ 10,794
390046	YORK HOSPITAL	YORK	PA	*	0.9942	$ 10,829	$ 10,791
200008	MERCY HOSPITAL	PORTLAND	ME	*	0.9862	$ 10,829	$ 10,739
440039	VANDERBILT UNIVERSITY HOSPITAL	NASHVILLE	TN	*	0.981	$ 10,829	$ 10,705
440082	ST THOMAS HOSPITAL	NASHVILLE	TN	*	0.981	$ 10,829	$ 10,705
440194	HENDERSONVILLE MEDICAL CENTER	HENDERSONVILLE	TN	*	0.981	$ 10,829	$ 10,705
110010	EMORY UNIVERSITY HOSPITAL	ATLANTA	GA	11	0.9793	$ 10,829	$ 10,694
110076	DEKALB MEDICAL CENTER	DECATUR	GA	*	0.9793	$ 10,829	$ 10,694
110165	SOUTHERN REGIONAL MEDICAL CENTER	RIVERDALE	GA	*	0.9793	$ 10,829	$ 10,694
110168	REDMOND REGIONAL MEDICAL CENTER	ROME	GA	*	0.9793	$ 10,829	$ 10,694
110219	SOUTH FULTON MEDICAL CENTER	EAST POINT	GA	*	0.9793	$ 10,829	$ 10,694
330241	UNIVERSITY HOSPITAL S U N Y HEALTH SCIENCE CENTER	SYRACUSE	NY	*	0.9776	$ 10,829	$ 10,683
340069	WAKEMED, RALEIGH CAMPUS	RALEIGH	NC	*	0.9775	$ 10,829	$ 10,683
340141	NEW HANOVER REGIONAL MEDICAL CENTER	WILMINGTON	NC	*	0.9771	$ 10,829	$ 10,680
150056	CLARIAN HEALTH PARTNERS, INCORPORATED	INDIANAPOLIS	IN	*	0.9769	$ 10,829	$ 10,679
150084	ST VINCENT HOSPITAL & HEALTH SERVICES	INDIANAPOLIS	IN	*	0.9769	$ 10,829	$ 10,679
100087	SARASOTA MEMORIAL HOSPITAL	SARASOTA	FL	*	0.9743	$ 10,829	$ 10,662
100213	BLAKE MEDICAL CENTER	BRADENTON	FL	*	0.9743	$ 10,829	$ 10,662
450137	BAYLOR ALL SAINTS MEDICAL CENTER AT FW	FORT WORTH	TX	*	0.9743	$ 10,829	$ 10,662
450324	TEXOMA MEDICAL CENTER	DENISON	TX	*	0.9743	$ 10,829	$ 10,662
450469	WILSON N JONES MEDICAL CENTER	SHERMAN	TX	*	0.9743	$ 10,829	$ 10,662

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Provider	Name	City	State	2005 volume	Wage Index	Proposed Payment Rate for (2007)	Wage Adjusted Payment
450855	HARLINGEN MEDICAL CENTER	HARLINGEN	TX	*	0.9731	$ 10,829	$ 10,654
490018	AUGUSTA MEDICAL CENTER	FISHERSVILLE	VA	*	0.9709	$ 10,829	$ 10,640
040021	SOUTHWEST REGIONAL MEDICAL CENTER	LITTLE ROCK	AR	*	0.9704	$ 10,829	$ 10,637
520035	AURORA SHEBOYGAN MEM MED CTR	SHEBOYGAN	WI	*	0.9684	$ 10,829	$ 10,624
340030	DUKE UNIVERSITY HOSPITAL	DURHAM	NC	*	0.9677	$ 10,829	$ 10,619
340061	UNIVERSITY OF NORTH CAROLINA HOSPITAL	CHAPEL HILL	NC	*	0.9677	$ 10,829	$ 10,619
150051	BLOOMINGTON HOSPITAL	BLOOMINGTON	IN	*	0.9619	$ 10,829	$ 10,581
150088	SAINT JOHN'S HEALTH SYSTEM	ANDERSON	IN	*	0.9619	$ 10,829	$ 10,581
520070	LUTHER HOSPITAL MAYO HEALTH SYSTEM	EAU CLAIRE	WI	*	0.9613	$ 10,829	$ 10,577
520045	THEDA CLARK MED CTR	NEENAH	WI	*	0.9607	$ 10,829	$ 10,573
520048	MERCY MED CTR	OSHKOSH	WI	*	0.9607	$ 10,829	$ 10,573
520193	AURORA BAYCARE MED CTR	GREEN BAY	WI	*	0.9607	$ 10,829	$ 10,573
160058	UNIVERSITY OF IOWA HOSPITAL & CLINICS	IOWA CITY	IA	*	0.9598	$ 10,829	$ 10,568
140091	CARLE FOUNDATION HOSPITAL	URBANA	IL	*	0.9582	$ 10,829	$ 10,557
100006	ORLANDO REGIONAL HEALTHCARE	ORLANDO	FL	*	0.9575	$ 10,829	$ 10,553
100007	FLORIDA HOSPITAL	ORLANDO	FL	*	0.9575	$ 10,829	$ 10,553
100045	FLORIDA HOSPITAL DELAND	DELAND	FL	*	0.9575	$ 10,829	$ 10,553
420078	GREENVILLE MEMORIAL HOSPITAL	GREENVILLE	SC	*	0.9566	$ 10,829	$ 10,547
320001	UNIVERSITY OF NEW MEXICO HOSPITAL	ALBUQUERQUE	NM	*	0.9564	$ 10,829	$ 10,546
440059	COOKEVILLE REGIONAL MEDICAL CENTER	COOKEVILLE	TN	*	0.955	$ 10,829	$ 10,536
100019	HOLMES REGIONAL MEDICAL CENTER	MELBOURNE	FL	*	0.9547	$ 10,829	$ 10,535
100177	CAPE CANAVERAL HOSPITAL	COCOA BEACH	FL	*	0.9547	$ 10,829	$ 10,535
100287	GOOD SAMARITAN MEDICAL CENTER	WEST PALM BEACH	FL	*	0.9535	$ 10,829	$ 10,527
420068	TRMC OF ORANGEBURG & CALHOUN	ORANGEBURG	SC	*	0.9531	$ 10,829	$ 10,524
360003	UNIVERSITY HOSPITAL, INC	CINCINNATI	OH	*	0.9522	$ 10,829	$ 10,518
360179	BETHESDA NORTH HOSPITAL	CINCINNATI	OH	*	0.9522	$ 10,829	$ 10,518
340126	WILSON MEDICAL CENTER	WILSON	NC	*	0.9492	$ 10,829	$ 10,499
460003	SALT LAKE REGIONAL MEDICAL CENTER	SALT LAKE CITY	UT	*	0.9476	$ 10,829	$ 10,488
460004	MCKAY-DEE HOSPITAL CENTER	OGDEN	UT	*	0.9476	$ 10,829	$ 10,488
460009	UNIVERSITY OF UTAH HOSPITAL	SALT LAKE CITY	UT	*	0.9476	$ 10,829	$ 10,488
460010	LDS HOSPITAL	SALT LAKE CITY	UT	*	0.9476	$ 10,829	$ 10,488
060022	MEMORIAL HOSPITAL	COLORADO SPRINGS	CO	*	0.9475	$ 10,829	$ 10,488
330005	KALEIDA HEALTH	BUFFALO	NY	*	0.9475	$ 10,829	$ 10,488
330102	KENMORE MERCY HOSPITAL	KENMORE	NY	*	0.9475	$ 10,829	$ 10,488
100012	LEE MEMORIAL HOSPITAL	FORT MYERS	FL	*	0.946	$ 10,829	$ 10,478
100220	SOUTHWEST FLORIDA REGIONAL MEDICAL CENTER	FORT MYERS	FL	*	0.946	$ 10,829	$ 10,478
360048	MEDICAL COLLEGE OF OHIO AT TOLEDO	TOLEDO	OH	*	0.9455	$ 10,829	$ 10,475
360112	ST VINCENT MERCY MEDICAL CENTER	TOLEDO	OH	*	0.9455	$ 10,829	$ 10,475
130007	ST ALPHONSUS REGIONAL MEDICAL CENTER	BOISE	ID	*	0.9445	$ 10,829	$ 10,468
230222	MIDMICHIGAN MEDICAL CENTER-MIDLAND	MIDLAND	MI	*	0.9439	$ 10,829	$ 10,464
100113	SHANDS HOSP AT THE UNIVERSITY OF FL	GAINESVILLE	FL	*	0.942	$ 10,829	$ 10,452
340013	RUTHERFORD HOSPITAL INC	RUTHERFORDTON	NC	*	0.9413	$ 10,829	$ 10,447
340053	PRESBYTERIAN HOSPITAL	CHARLOTTE	NC	*	0.9413	$ 10,829	$ 10,447
340113	CAROLINAS MEDICAL CENTER/BEHAV HEALTH	CHARLOTTE	NC	*	0.9413	$ 10,829	$ 10,447

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280013	THE NEBRASKA MEDICAL CENTER	OMAHA	NE	*	0.9399	$ 10,829	$ 10,438
360059	METRO HEALTH MEDICAL CENTER	CLEVELAND	OH	*	0.9396	$ 10,829	$ 10,436
360137	UNIVERSITY HOSPITALS OF CLEVELAND	CLEVELAND	OH	*	0.9396	$ 10,829	$ 10,436
360180	CLEVELAND CLINIC FOUNDATION - H18	CLEVELAND	OH	12	0.9396	$ 10,829	$ 10,436
030011	CARONDELET ST JOSEPHS HOSPITAL AND HEALTH CENTER	TUCSON	AZ	*	0.939	$ 10,829	$ 10,433
030064	UNIVERSITY MEDICAL CENTER	TUCSON	AZ	*	0.939	$ 10,829	$ 10,433
430090	SIOUX FALLS SURGICAL CENTER LLP	SIOUX FALLS	SD	*	0.9351	$ 10,829	$ 10,407
170040	UNIVERSITY OF KANSAS HOSPITAL	KANSAS CITY	KS	*	0.9345	$ 10,829	$ 10,403
260027	RESEARCH MEDICAL CENTER	KANSAS CITY	MO	*	0.9345	$ 10,829	$ 10,403
260048	TRUMAN MEDICAL CENTER HOSPITAL HILL	KANSAS CITY	MO	*	0.9345	$ 10,829	$ 10,403
260096	NORTH KANSAS CITY HOSPITAL	NORTH KANSAS CITY	MO	*	0.9345	$ 10,829	$ 10,403
260138	ST LUKES HOSPITAL OF KANSAS CITY	KANSAS CITY	MO	*	0.9345	$ 10,829	$ 10,403
340002	MISSION HOSPITALS, INC	ASHEVILLE	NC	*	0.93385	$ 10,829	$ 10,399
450056	SETON MEDICAL CENTER	AUSTIN	TX	*	0.9328	$ 10,829	$ 10,392
450809	NORTH AUSTIN MEDICAL CENTER	AUSTIN	TX	*	0.9328	$ 10,829	$ 10,392
130002	MAGIC VALLEY REGIONAL MEDICAL CENTER	TWIN FALLS	ID	*	0.9313	$ 10,829	$ 10,382
440048	BAPTIST MEMORIAL HOSPITAL	MEMPHIS	TN	*	0.9307	$ 10,829	$ 10,379
440049	METHODIST HEALTHCARE MEMPHIS HOSPITALS	MEMPHIS	TN	*	0.9307	$ 10,829	$ 10,379
150017	LUTHERAN HOSPITAL OF INDIANA	FORT WAYNE	IN	*	0.9283	$ 10,829	$ 10,363
150021	PARKVIEW HOSPITAL	FORT WAYNE	IN	*	0.9283	$ 10,829	$ 10,363
100001	SHANDS JACKSONVILLE	JACKSONVILLE	FL	*	0.9281	$ 10,829	$ 10,362
100127	MORTON PLANT HOSPITAL	CLEARWATER	FL	*	0.9265	$ 10,829	$ 10,351
100128	TAMPA GENERAL HOSPITAL	TAMPA	FL	*	0.9265	$ 10,829	$ 10,351
340014	FORSYTH MEMORIAL HOSPITAL	WINSTON-SALEM	NC	*	0.9246	$ 10,829	$ 10,339
340047	NORTH CAROLINA BAPTIST HOSPITAL	WINSTON-SALEM	NC	*	0.9246	$ 10,829	$ 10,339
340148	MEDICAL PARK HOSPITAL	WINSTON-SALEM	NC	*	0.9246	$ 10,829	$ 10,339
450002	PROVIDENCE MEMORIAL HOSPITAL	EL PASO	TX	*	0.9238	$ 10,829	$ 10,334
340131	CRAVEN REGIONAL MEDICAL CENTER	NEW BERN	NC	*	0.9223	$ 10,829	$ 10,324
230070	COVENANT MEDICAL CENTERS, INC	SAGINAW	MI	*	0.9211	$ 10,829	$ 10,316
420007	SPARTANBURG REGIONAL MEDICAL CENTER	SPARTANBURG	SC	*	0.9208	$ 10,829	$ 10,314
420004	MEDICAL UNIVERSITY HOSPITAL	CHARLESTON	SC	*	0.9197	$ 10,829	$ 10,307
320085	MOUNTAIN VIEW REGIONAL MEDICAL CENTER	LAS CRUCES	NM	*	0.9187	$ 10,829	$ 10,301
160083	MERCY MEDICAL CENTER-DES MOINES	DES MOINES	IA	*	0.917	$ 10,829	$ 10,290
180088	NORTON HOSPITALS, INC	LOUISVILLE	KY	*	0.9155	$ 10,829	$ 10,280
390001	COMMUNITY MEDICAL CENTER	SCRANTON	PA	*	0.91455	$ 10,829	$ 10,274
530012	WYOMING MEDICAL CENTER	CASPER	WY	*	0.9145	$ 10,829	$ 10,273
110036	MEMORIAL HEALTH UNIV MED CEN,INC	SAVANNAH	GA	*	0.9139	$ 10,829	$ 10,269
140067	SAINT FRANCIS MEDICAL CENTER	PEORIA	IL	*	0.9126	$ 10,829	$ 10,261
330030	NEWARK-WAYNE COMMUNITY HOSPITAL	NEWARK	NY	*	0.9103	$ 10,829	$ 10,246
060012	CENTURA HEALTH-ST MARY CORWIN MEDICAL CENTER	PUEBLO	CO	*	0.9091	$ 10,829	$ 10,238
060020	PARKVIEW MEDICAL CENTER INC	PUEBLO	CO	*	0.9091	$ 10,829	$ 10,238
360070	MERCY MEDICAL CENTER	CANTON	OH	*	0.9076	$ 10,829	$ 10,228
110007	PHOEBE PUTNEY MEMORIAL HOSPITAL	ALBANY	GA	*	0.9056	$ 10,829	$ 10,215
040004	WASHINGTON REGIONAL MED CTR AT NO HILLS	FAYETTEVILLE	AR	*	0.9027	$ 10,829	$ 10,197

Indicates a value of 10 or less

Provider	Name	City	State	2005 volume	Wage Index	Proposed Payment Rate for (2007)	Wage Adjusted Payment
170122	VIA CHRISTI REGIONAL MEDICAL CENTER	WICHITA	KS	*	0.9016	$ 10,829	$ 10,190
170123	WESLEY MEDICAL CENTER	WICHITA	KS	*	0.9016	$ 10,829	$ 10,190
260032	BARNES JEWISH HOSPITAL	SAINT LOUIS	MO	*	0.8998	$ 10,829	$ 10,178
260105	ST LOUIS UNIVERSITY HOSPITAL	SAINT LOUIS	MO	*	0.8998	$ 10,829	$ 10,178
260179	ST LUKES HOSPITAL	CHESTERFIELD	MO	*	0.8998	$ 10,829	$ 10,178
490032	VIRGINIA COMMONWEALTH UNIVERSITY HEALTH SYSTEM	RICHMOND	VA	*	0.8997	$ 10,829	$ 10,177
340116	FRYE REGIONAL MEDICAL CENTER	HICKORY	NC	*	0.8991	$ 10,829	$ 10,173
250042	NW MISSISSIPPI REGIONAL MED CENTER	CLARKSDALE	MS	*	0.8984	$ 10,829	$ 10,169
440002	JACKSON-MADISON COUNTY GENERAL HOSPITAL	JACKSON	TN	*	0.8984	$ 10,829	$ 10,169
430077	RAPID CITY REGIONAL HOSPITAL	RAPID CITY	SD	*	0.8973	$ 10,829	$ 10,162
010039	HUNTSVILLE HOSPITAL	HUNTSVILLE	AL	*	0.8967	$ 10,829	$ 10,158
180067	UNIVERSITY OF KENTUCKY HOSPITAL	LEXINGTON	KY	*	0.8965	$ 10,829	$ 10,156
330011	OUR LADY OF LOURDES MEMORIAL HOSPITAL, INC	BINGHAMTON	NY	*	0.8963	$ 10,829	$ 10,155
450083	EAST TEXAS MEDICAL CENTER	TYLER	TX	*	0.8963	$ 10,829	$ 10,155
270004	DEACONESS BILLINGS CLINIC	BILLINGS	MT	*	0.8956	$ 10,829	$ 10,151
140148	MEMORIAL MEDICAL CENTER	SPRINGFIELD	IL	*	0.8951	$ 10,829	$ 10,147
440091	MEMORIAL HEALTHCARE SYSTEM, INC	CHATTANOOGA	TN	*	0.8948	$ 10,829	$ 10,145
440104	ERLANGER MEDICAL CENTER	CHATTANOOGA	TN	*	0.8948	$ 10,829	$ 10,145
450058	BAPTIST HEALTH SYSTEM	SAN ANTONIO	TX	*	0.8945	$ 10,829	$ 10,143
450213	UNIVERSITY HEALTH SYSTEM	SAN ANTONIO	TX	*	0.8945	$ 10,829	$ 10,143
450388	METHODIST HOSPITAL	SAN ANTONIO	TX	*	0.8945	$ 10,829	$ 10,143
360009	LIMA MEMORIAL HEALTH SYSTEM	LIMA	OH	*	0.8925	$ 10,829	$ 10,130
450834	PHYSICIANS CENTRE,THE	BRYAN	TX	*	0.8903	$ 10,829	$ 10,116
150082	DEACONESS HOSPITAL	EVANSVILLE	IN	*	0.8898	$ 10,829	$ 10,113
150100	ST MARY'S MEDICAL CENTER - EVANSVILLE	EVANSVILLE	IN	*	0.8898	$ 10,829	$ 10,113
010033	UNIVERSITY OF ALABAMA HOSPITAL	BIRMINGHAM	AL	*	0.8889	$ 10,829	$ 10,107
140164	MEMORIAL HOSPITAL OF CARBONDALE	CARBONDALE	IL	*	0.8889	$ 10,829	$ 10,107
260017	PHELPS COUNTY REGIONAL MEDICAL CENTER	ROLLA	MO	*	0.8889	$ 10,829	$ 10,107
330013	ALBANY MEDICAL CENTER HOSPITAL	ALBANY	NY	*	0.8849	$ 10,829	$ 10,081
330057	ST PETER'S HOSPITAL	ALBANY	NY	*	0.8849	$ 10,829	$ 10,081
190111	WILLIS KNIGHTON MEDICAL CENTER	SHREVEPORT	LA	*	0.8848	$ 10,829	$ 10,080
370028	INTEGRIS BAPTIST MEDICAL CENTER	OKLAHOMA CITY	OK	*	0.8807	$ 10,829	$ 10,054
370093	O U MEDICAL CENTER	OKLAHOMA CITY	OK	*	0.8807	$ 10,829	$ 10,054
370148	EDMOND MEDICAL CENTER	EDMOND	OK	*	0.8807	$ 10,829	$ 10,054
370192	NORTHWEST SURGICAL HOSPITAL	OKLAHOMA CITY	OK	*	0.8807	$ 10,829	$ 10,054
370203	PHYSICIANS HOSPITAL OF OKALHOMA	OKLAHOMA CITY	OK	*	0.8807	$ 10,829	$ 10,054
360064	ST ELIZABETH HEALTH CENTER	YOUNGSTOWN	OH	*	0.8799	$ 10,829	$ 10,049
260137	FREEMAN HEALTH SYSTEM - FREEMAN WEST	JOPLIN	MO	*	0.8794	$ 10,829	$ 10,045
450825	CORNERSTONE REGIONAL HOSPITAL	EDINBURG	TX	*	0.8794	$ 10,829	$ 10,045
100212	OCALA REGIONAL MEDICAL CENTER	OCALA	FL	*	0.8793	$ 10,829	$ 10,045
270014	ST PATRICK HOSPITAL AND HEALTH SCIENCES CENTER	MISSOULA	MT	*	0.8783	$ 10,829	$ 10,038
150109	LAFAYETTE HOME HOSPITAL	LAFAYETTE	IN	*	0.8777	$ 10,829	$ 10,034
170012	SALINA REGIONAL HEALTH CENTER	SALINA	KS	*	0.8776	$ 10,829	$ 10,034
490007	SENTARA NORFOLK GENL HOSP	NORFOLK	VA	*	0.8774	$ 10,829	$ 10,032

**** Indicates a value of 10 or less***

Provider	Name	City	State	2005 volume	Wage Index	Proposed Payment Rate for (2007)	Wage Adjusted Payment
450034	CHRISTUS ST ELIZABETH HOSPITAL	BEAUMONT	TX	*	0.871	$ 10,829	$ 9,991
490042	CARILION NEW RIVER VALLEY MEDICAL CENTER	CHRISTIANSBURG	VA	*	0.87	$ 10,829	$ 9,984
490024	CARILION MEDICAL CENTER	ROANOKE	VA	*	0.8651	$ 10,829	$ 9,952
190046	TOURO INFIRMARY	NEW ORLEANS	LA	*	0.8649	$ 10,829	$ 9,951
110095	TIFT REGIONAL MEDICAL CENTER	TIFTON	GA	*	0.8632	$ 10,829	$ 9,940
170120	LABETTE COUNTY MEDICAL CENTER	PARSONS	KS	*	0.8626	$ 10,829	$ 9,936
390110	CONEMAUGH VALLEY MEMORIAL HOSPITAL	JOHNSTOWN	PA	*	0.8574	$ 10,829	$ 9,902
260040	COX MEDICAL CENTER	SPRINGFIELD	MO	*	0.857	$ 10,829	$ 9,900
260065	ST JOHN'S REGIONAL HEALTH CENTER	SPRINGFIELD	MO	*	0.857	$ 10,829	$ 9,900
390050	ALLEGHENY GENERAL HOSPITAL	PITTSBURGH	PA	*	0.8568	$ 10,829	$ 9,898
390164	UPMC PRESBYTERIAN SHADYSIDE	PITTSBURGH	PA	*	0.8568	$ 10,829	$ 9,898
510001	WEST VIRGINIA UNIVERSITY HOSPITALS	MORGANTOWN	WV	*	0.8568	$ 10,829	$ 9,898
390062	NASON HOSPITAL	ROARING SPRING	PA	*	0.8538	$ 10,829	$ 9,879
450040	COVENANT MEDICAL CENTER	LUBBOCK	TX	*	0.8536	$ 10,829	$ 9,878
450686	UNIVERSITY MEDICAL CENTER	LUBBOCK	TX	*	0.8536	$ 10,829	$ 9,878
370097	SOUTHWESTERN MEDICAL CENTER	LAWTON	OK	*	0.8485	$ 10,829	$ 9,844
250078	FORREST GENERAL HOSPITAL	HATTIESBURG	MS	*	0.8461	$ 10,829	$ 9,829
260068	BOONE HOSPITAL CENTER	COLUMBIA	MO	*	0.8456	$ 10,829	$ 9,826
330103	OLEAN GENERAL HOSPITAL	OLEAN	NY	*	0.843	$ 10,829	$ 9,809
260094	SKAGGS COMMUNITY HEALTH CENTER	BRANSON	MO	*	0.8412	$ 10,829	$ 9,797
190002	LAFAYETTE GENERAL MEDICAL CENTER	LAFAYETTE	LA	*	0.8408	$ 10,829	$ 9,794
040118	NEA MEDICAL CENTER	JONESBORO	AR	*	0.8345	$ 10,829	$ 9,754
370025	MUSKOGEE REGIONAL MEDICAL CENTER	MUSKOGEE	OK	*	0.831	$ 10,829	$ 9,731
370114	ST JOHN MEDICAL CENTER, INC	TULSA	OK	*	0.831	$ 10,829	$ 9,731
440034	METHODIST MEDICAL CENTER OF OAK RIDGE	OAK RIDGE	TN	*	0.8227	$ 10,829	$ 9,677
440067	LAKEWAY REGIONAL HOSPITAL	MORRISTOWN	TN	*	0.8227	$ 10,829	$ 9,677
440017	WELLMONT HOLSTON VALLEY MEDICAL CENTER	KINGSPORT	TN	*	0.8215	$ 10,829	$ 9,669
250072	CENTRAL MISSISSIPPI MEDICAL CENTER	JACKSON	MS	*	0.8214	$ 10,829	$ 9,668
250104	JEFF ANDERSON REGIONAL MED CENTER	MERIDIAN	MS	*	0.8214	$ 10,829	$ 9,668
440144	HARTON REGIONAL MEDICAL CENTER	TULLAHOMA	TN	*	0.8122	$ 10,829	$ 9,609
010040	GADSDEN REGIONAL MEDICAL CENTER	GADSDEN	AL	*	0.806	$ 10,829	$ 9,568
350002	ST ALEXIUS MEDICAL CENTER	BISMARCK	ND	*	0.78675	$ 10,829	$ 9,443
350015	MEDCENTER ONE	BISMARCK	ND	*	0.78675	$ 10,829	$ 9,443
040062	ST EDWARD MERCY MEDICAL CENTER	FORT SMITH	AR	*	0.785	$ 10,829	$ 9,432
010152	UNIV OF SOUTH AL KNOLLWOOD HOSPITAL	MOBILE	AL	*	0.7847	$ 10,829	$ 9,430
053303	CHILDRENS HOSPITAL - SAN DIEGO	SAN DIEGO	CA	*	not available	$ 10,829	
363303	CHILDRENS HOSPITAL MEDICAL CENTER	AKRON	OH	*	not available	$ 10,829	
TOTAL	**298 Providers**			**649**			

**** Indicates a value of 10 or less***

Pharmaceutical "Charge Compression" under the Medicare Outpatient Prospective Payment System

Mary Jo Braid, Kevin F. Forbes, and Donald W. Moran

Analysis of the actual acquisition costs of a sample of pharmaceuticals demonstrates that payment rates for pharmaceutical therapies under the Medicare hospital outpatient prospective payment system (OPPS) are systematically biased against fully reimbursing high cost pharmaceutical therapies. Under the Centers for Medicare and Medicaid Services' (CMS') methodology, which assumes a constant markup, a bias in the cost estimate occurs when hospitals apply below average markups in establishing their charges for pharmaceutical products with above average costs. We developed a model of the relationship between product costs and charge markups. The logarithmic model shows that an increase in the acquisition cost per episode can be expected to lead to a reduction in the charge markup multiple. When markups for pharmaceuticals decline as acquisition cost increases, a rate-setting methodology that assumes a constant markup results in reimbursement for higher cost products that can be far below acquisition cost. The incentives in the payment system could affect site of care choices and beneficiary access.
Key words: *Medicare reimbursement, hospital outpatient prospective payment system, pharmaceutical, charge compression.*

SINCE the implementation of the outpatient prospective payment system (OPPS) in August 2000, hospital charge-setting practices have emerged as a critical issue in understanding the effects of the new payment system. Payment rates under this system are based on estimates of cost calculated by multiplying the hospital charge by a departmental average cost-to-charge ratio. It has been suggested that this system contains a material downward bias in cost estimates relative to actual hospital acquisition costs for high-cost pharmaceuticals because hospitals apply below average markups in establishing their posted charges for pharmaceutical products with above average costs. This hypothesis, which the Centers for Medicare and Medicaid Services (CMS) has labeled "charge compression," would, if confirmed, result in under reimbursement of pharmacy services relative to other services in the outpatient setting. It would also affect the incentives hospital decision makers face in deciding between therapeutic alternatives and also in determining appropriate sites of care for various therapies.

The charge compression hypothesis theorizes that when hospitals allocate the costs of operating the pharmacy department in setting prices in their chargemasters, they do not use a constant percentage allocation method that would result in charges with uniform markups over product acquisition cost. This theory is consistent with information gleaned from discussions with hospital reimbursement consultants and other experts in

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Mary Jo Braid, MPH, *is a Principal with The Moran Company, a health policy consulting firm located in Rosslyn, VA.*

Kevin F. Forbes, PhD, *is an Associate Professor and Chair of the Department of Business and Economics at The Catholic University of America in Washington, DC.*

Donald W. Moran *is the President of The Moran Company located in Rosslyn, VA.*

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the field regarding the way hospitals set their charges. The information provided by these sources, while anecdotal, suggests that many or most hospitals allocate costs, at least in part, on the basis of a standardized, flat dollar per order charge. In addition, these very high cost items may have low markups on a percentage basis. If charges were, in fact, being set this way, the charge compression hypothesis would be confirmed because such a practice would result in very high charge markups for the lowest-cost pharmacy items (*e.g.*, aspirin), while at the same time generating very low percentage markups for the highest-cost items (*e.g.*, expensive biotechnology products). We tested the charge compression hypothesis empirically.

Background

In August of 2000, with the implementation of the OPPS, Medicare began reimbursing most outpatient hospital services based on ambulatory payment classifications (APCs). Prior to that time, hospital outpatient departments were paid based on allowable cost as reported on hospital cost reports. CMS sets APC payment rates prospectively by using claims data and hospital cost reports. Payment rates for 2003 were set using claims data for dates of service between April 1, 2001, and March 31, 2002, and the most recently submitted cost reports presented by the hospital available at the time the rates were set.

APCs are groupings of procedure codes with similar clinical characteristics and costs. There are 569 APCs in 2003. When a hospital bills for a procedure, it is paid the rate for the APC to which that procedure maps. In general, this payment is intended to cover the entire facility cost of the procedure, including all incidental supplies. Hospitals can be paid an additional amount, however, for selected drugs and devices. Due to historical limits on payments to hospital outpatient departments, in aggregate CMS reimburses less than the actual hospital costs as represented in hospital cost reports.

In establishing the OPPS, Congress required CMS to pay for new medical technologies on a passthrough basis for no less than two years and no more than three years.[1] When prospective APC payments started in August of 2000, most pharmaceuticals and medical devices were paid on this basis. Hospitals were paid 95 percent of average wholesale price (AWP) for passthrough drugs and biologicals. Beginning in 2003, when the passthrough status for many products expired, CMS decided to continue to pay separately for drugs and biologicals that it estimated cost more than $150 per administration. The payment for pharmaceutical therapies that were below the $150 threshold were packaged with the primary procedure payment across a number of APCs. In 2003, there were 160 drugs and biologicals that were separately paid under their own APC because they met this threshold. At the time the final rule was published, there were also 17 drugs that still qualified for passthrough payments at 95 percent of AWP.

Since CMS does not collect actual acquisition cost data for drugs and biologicals under the Medicare program, the payment rates for separately reimbursed drugs that do not qualify for passthrough status are based on an estimate of hospital cost using billed charges from the claims data and cost report data. This is the same mechanism used to set payments for all APCs in the OPPS.

To establish payment for a separately reimbursed drug or biological, the

cost-to-charge ratio for each hospital's pharmacy department is calculated from its cost report. Then, for each claims line, CMS multiplies the billed charge by that hospital's pharmacy department cost-to-charge ratio. CMS then calculates the estimated per unit cost by dividing this number by the total billed units. CMS then calculates the median cost per unit across all OPPS hospitals, weighted by the number of units billed for each drug. The payment weight is calculated by dividing this median cost by the median cost of APC 601, which serves as the reference APC for the purpose of weight calculations. CMS then calculates a conversion factor, which is a dollar amount that the weight is multiplied by to reach the payment rate. The conversation factor is calculated to assure that the budget neutrality requirements of the program are met.

Study Data

Using Medicare OPPS claims data, we conducted an empirical test of hospital charge-setting practices across all hospitals in the United States.[2] We used the OPPS claims data file that contained claims with dates of service from April 1, 2001, through March 31, 2002. This is the file CMS used to set the final payment APC weights for 2003.

Since, during this period, hospitals were eligible to receive transitional passthrough payments for designated pharmaceutical products, the dataset contains over 13 million claims lines coded for specific pharmaceutical products using the Health Care Financing Administration (HCFA) common procedure coding system (HCPCS) classifications, permitting us to identify the use of individual pharmaceutical products.[3] Since each claims line contains posted charge and billed units information, these data permit us to directly observe how specific hospitals establish unit charges for specific products.

We pulled the claims lines for pharmaceuticals from the claims file and calculated the estimated cost per unit. We then trimmed records that were three standard deviations from the geometric mean based on the estimated cost per unit, as CMS does in its rate-setting methodology. With the remaining records, we calculated the median charge per unit for each pharmaceutical.

To evaluate hospital charge-setting practices, it is necessary to compare the available charge information for specific products with data on product-specific hospital acquisition costs. For this part of the analysis, we obtained product-specific acquisition cost data from the pharmacy departments of two large hospitals, the larger of which was a member of one of the largest national group purchasing organizations (GPO) and hence acquired its drugs at the national contract price. The pricing information we were able to obtain from these datasets, while not strictly representative of all possible prices paid by hospitals, should be representative of the competitively determined market price paid by a significant number of hospitals nationwide. We used the pricing information for this hospital, therefore, as our default dataset, substituting pricing information from the second hospital only when analysis of the first hospital's data relative to the Medicare OPPS payment rate in 2001 (95 percent of AWP) made clear that that hospital's data reflected unit pricing anomalies relative to the unit volume concepts embodied in the HCPCS classification system.

We received acquisition cost data on 152 separate drugs. In this analysis, we trimmed

13 outlier observations based on markups that were less than one or more than three standard deviations from the mean. This left us with acquisition cost data for 139 drugs, 80 of which were separately payable in 2003.

The acquisition costs that we received for the two hospitals are the costs recorded in the financial systems of each hospital's pharmacy based on data current in early 2002. Since pharmaceutical manufacturers change their prices on different schedules and with different frequencies, the recorded prices for many of these products would have been applicable in 2001, while others may have been updated in 2002. Based on our experience in working with pharmaceutical pricing information, price timing issues might cause us to slightly over estimate the prices prevailing in 2001, which corresponds with the first three quarters of the CMS public use file.

From our prior work with proprietary pricing information, we have observed that the variance in actual acquisition costs net of contract discounts for specific products across hospitals is not large (perhaps plus or minus 5 percent), and that the national GPO contract price should fall to the low end of the actual price distribution. We believe, therefore, that the charge markups over acquisition cost we estimate in this analysis are probably slightly overstated relative to a true national average, but accurately reflect the relationship between costs and charges across products.

We used the hospital ownership type reported by the hospitals on the Medicare cost report found on the healthcare cost report information system (HCRIS). We collapsed the reported ownership type to three categories: (1) for profit; (2) not-for profit; and government.

Study Design

We hypothesized that the markup for a drug (*i.e.*, the ratio of the amount charged by a hospital relative to its acquisition cost) is a function of its acquisition cost. This is represented by the equation:

$$MARKUP_i = f(\text{Acquisition Cost}_i)$$

where:

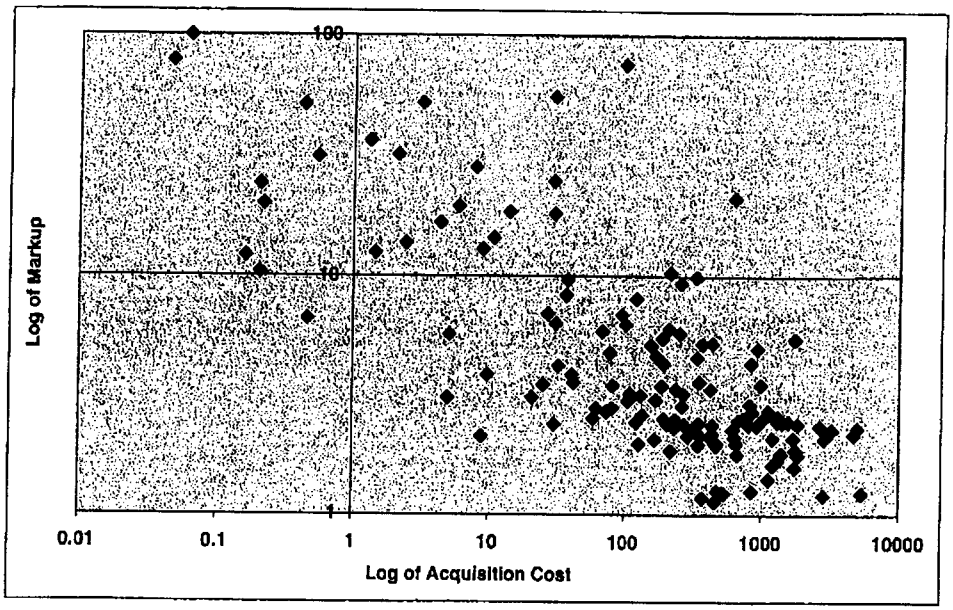
$MARKUP_i$	is the ratio of median charge per administration relative to the acquisition cost per administration; and
$\text{Acquisition Cost}_i$	is the acquisition cost per administration.

We tested this hypothesis using the drug as the unit of analysis. We calculated the median charge per unit recorded in the OPPS claims data. Also from the OPPS claims data, we calculated the average units per claims line. The median charge per unit multiplied by the average units per claims line results in the median charge per administration. The acquisition cost per administration was obtained using the unit acquisition cost obtained from the hospitals and multiplying this by the average units per line obtained from the OPPS claims data.

Results

The relationship between acquisition cost and markup is logarithmic. Moreover, charge compression exists in the sense that the markup declines as acquisition cost increases. Figure 1 shows the log of the markup plotted against the log of the acquisition cost for the 139 drugs in the study. The figure suggests that the markup tends to decline

Figure 1. Acquisition Cost and Markups



nonlinearly as acquisition cost increases given that both axis in the diagram are scaled in logarithms. A possible explanation of this inverse relationship is that the markup is partly determined by a fixed per order cost that gets allocated over a larger dollar amount as acquisition cost increases.

A model specification that incorporates this finding is the double logarithmic formulation:

$$\ln(\text{MARKUP}_i) = c + b \ln(\text{Acquisition Cost}_i)$$

where c and b are parameters to be estimated in the analysis.

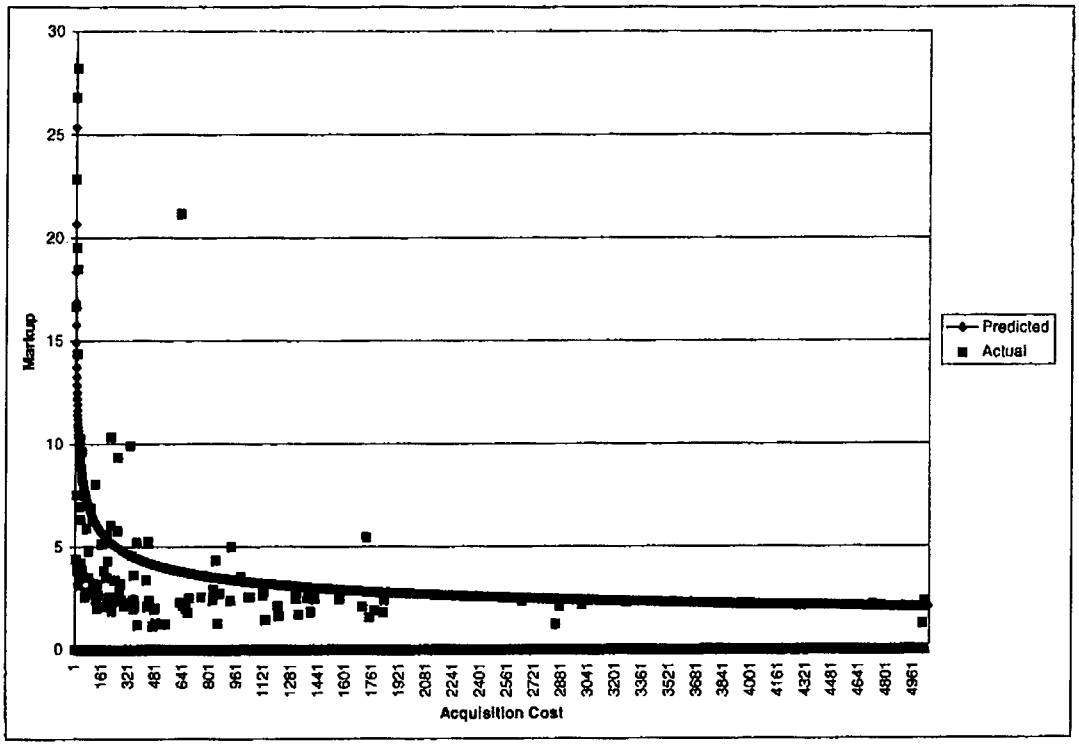
This model was estimated for 139 drugs. The results are presented in Figure 2.

As Figure 2 illustrates, the constant term (c) was estimated to equal 2.885 while the coefficient on ln (Acquisition Cost) was −0.295. This finding of a negative coefficient on ln (Acquisition Cost) is consistent with the hypothesis of charge compression. Specifically, given the t-statistic of 12.26 (in absolute value), the null hypothesis that the markup is independent of the acquisition cost can be rejected at less than the one percent level. In terms of overall explanatory power, the model has an R^2 of 0.558. Perhaps more interesting is how much of the actual markup (as separate from the logarithmic form) is explained by the model. The R^2 of the markup is a more modest 0.476. These

Figure 2. Model Estimates

	Estimated Coefficient	T-Statistic
C	2.885	19.38
Ln (Acquisition Cost)	−0.295	12.26
Number of Observations	139	
R-Squared in Terms of Ln (Markup)	0.558	
R-Squared in Terms of Markup	0.476	

Figure 3. Pharmaceutical Acquisition Cost and Markup: Actual vs. Predicted



are respectable levels of explanatory power given that the data are cross-sectional in nature.

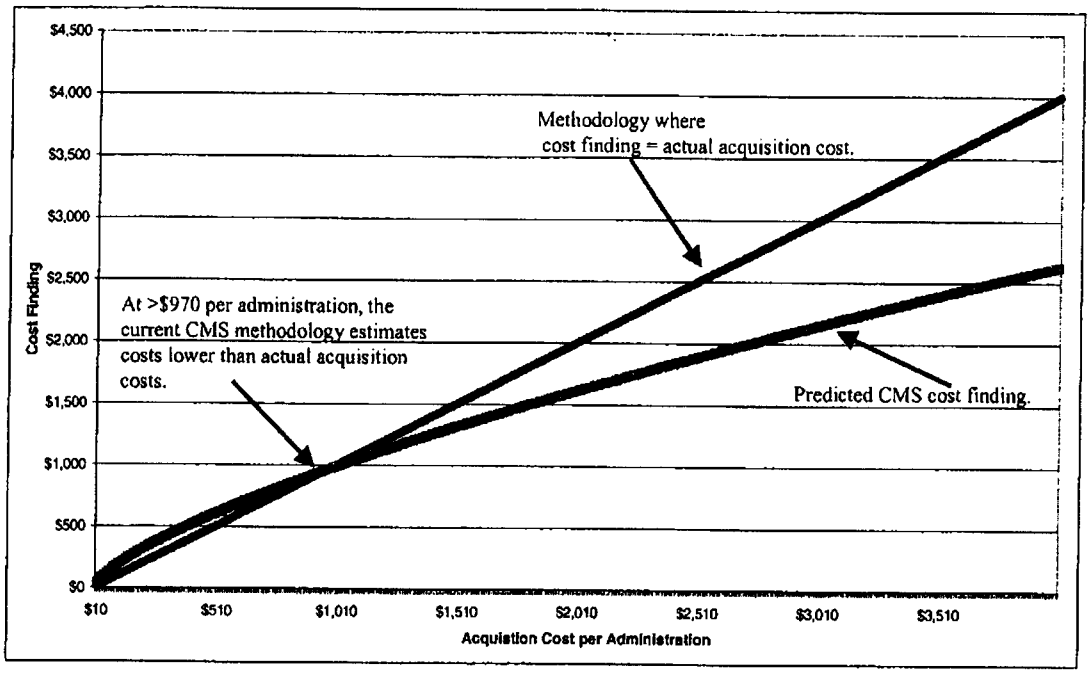
This model predicts an inverse relationship between the cost of the product and the expected percentage charge markup. Figure 3 presents the model predicted values and the actual observed values.

Due to the double log functional form in the model, the coefficient on the independent variable can be interpreted as an elasticity. In this case, the estimated coefficient on ln (Acquisition Cost) indicates that the markup declines approximately 2.95 percent for every 10 percent increase in acquisition costs. The model predicts that the least costly products (those under $20 per episode) will have markups in excess of 1,000 percent. For instance, the model predicts that a product with an acquisition cost of $5 will have a markup of 1,577 percent. The model also predicts that the markup percentage falls as acquisition cost rises. The markup is predicted to be less than 3.00 for products with acquisition costs per administration greater than approximately $1,400.

Modeling the Effect on CMS Cost Estimates

Given that the national average hospital pharmacy department cost-to-charge ratio is approximately 0.30, a pharmaceutical product would need a charge multiple of 3.33 in order for the current CMS methodology

Figure 4. Acquisition Cost and Predicted Cost Finding



to produce a cost estimate equal to actual product acquisition cost. The charge multiple would have to be even greater to account for the labor and overhead associated with running the pharmacy.

The effect of using a constant cost-to-charge ratio to estimate cost, as the current CMS methodology does, is illustrated in Figure 4. We first plot a methodology in which the actual acquisition cost per administration would equal the estimated cost finding. Of course, this does not include pharmacy overhead costs. We then plot the CMS predicted cost finding as a function of the acquisition cost using this model. For this graph, we use the national average cost-to-charge ratio of 0.30.

With the national average hospital pharmacy department cost-to-charge ratio of approximately 0.30, the model predicts that the CMS cost finding will exceed acquisition cost when acquisition cost per administration is $970 or less. For example, a product with an acquisition cost of $100 dollars has a predicted cost finding of $195. The results also indicate that the CMS cost finding will be less than the acquisition cost when the acquisition cost exceeds $970. For example, a product with an acquisition cost of $1,500 has a predicted cost finding of approximately $1,320 given the average hospital pharmacy department cost-to-charge ratio of approximately 0.30. This deficiency between the predicted cost finding and the acquisition cost increases as the acquisition cost goes up. For example, while the predicted deficiency is approximately $180 for a product with acquisition cost of $1,500, it increases to approximately $850 for a product with an acquisition cost of $3,000.

Effect of Hospital Characteristics

Further, we investigated whether the pattern of charging behavior is affected by whether the hospital is for profit as compared to either not-for-profit, or government operated. To address this issue, consider the following estimating equation:

$$\ln(\text{MARKUP}_{k,i,}) = c_k + b_k \ln(\text{Acquisition Cost}_{ki})$$

where k = for profit, not-for-profit, and government run hospitals.

The equation was estimated using Zellner's Seemingly Unrelated Regression technique. This method takes into account that the error term in one equation may be related to the error term in the other two equations. This is an especially useful technique given that if the model over predicts the markup for a particular drug in the for profit sector, there is a good chance that it may over predict for the other two ownership types. The results are also corrected for the presence of heteroscedasticity.

The estimation results are presented in Figure 5. Consistent with the results reported in Figure 2, note that the coefficients on ln (Acquisition Cost) are negative in all three cases. It is also worth observing that the magnitude of the coefficients on ln (Acquisition Cost) is larger in absolute value than when the analysis was conducted at the more aggregate level. This is not entirely surprising, given the inherent biases that result from aggregation. Also note that both the constant term and the coefficient on ln (Acquisition Cost) are larger in absolute value for the profit seeking hospitals, as compared to both the nonprofit and government run hospitals. This suggests that while charge compression is evident for all three types of ownership, it is a more robust phenomenon in the for profit sector. This conjecture was tested using a Wald test. This test enables one to test whether the observed differences in the estimated coefficients are the result of random chance. The results of this analysis indicate that the coefficients in the nonprofit equation are not statistically different from those in the government equation. The results also indicate that the observed differences in the coefficients for the for profit hospitals and those of the other two sectors are statistically significant at the 5 percent significant level.

In terms of explanatory power, the for profit equation is able to account for 51 percent of the variation in the logarithm of the markup (but only 42.7 percent of the variation in markup itself), while the R-squares

Figure 5. Parameter Estimates for Ln (Markup) Equation by Type of Hospital Ownership

	For Profit Hospitals	Not-for-Profit Hospitals	Government Operated Hospitals
C	3.46*	2.93*	3.15*
Ln (Acquisition Cost)	−0.381*	−0.322*	−0.359*
R-Squared in Terms of Ln (Markup)	0.511	0.47	0.39
R-Squared in Terms of the Markup	0.427	0.153	0.297
N	138	138	138

*Statistically significant at 1 percent.

for the other two equations are significantly lower. This is not entirely surprising given that the econometric specification presumes that decision makers only take economic considerations into account when setting charges.

Bias in Payment Rates

The results presented previously suggest that the charge compression phenomenon is real, measurable, and has a clearly material downward effect on Medicare's accounting-based estimate of the cost for pharmaceutical products in the outpatient hospital setting. CMS uses the cost estimate to set payment rates. Here, we examine to what extent reimbursement rates are also affected.

In the absence of any bias in reimbursement, the ratio of reimbursement payment to acquisition cost would be a constant one.[4] Moreover, there would not be any systematic relationship between the reimbursement rate and acquisition costs. To test whether bias is present, consider the following regression model that relates the natural logarithm of the reimbursement rate with the natural logarithm of acquisition costs:

$$\ln(\text{Reimbursement Rate}) = a + b \ln(\text{Acquisition Cost})$$

where Reimbursement Rate = 2003 Medicare payment rate/acquisition cost.

The model was estimated using data for the 80 drugs that are separately reimbursed under Medicare OPPS in 2003. The results are reported in Figure 6.

As shown in Figure 6, in terms of overall explanatory power, the model has a R^2 of 0.216. The R^2 is a somewhat more respectable 0.33 if measured in terms of the reimbursement rate as opposed to its natural logarithm of the reimbursement rate. In any event, the model's overall explanatory power is relatively modest, but not hopelessly so given that the data are cross-sectional in nature. It is possible that this model, which uses reimbursement rates, is slightly less predictive compared to the model that looked at CMS's estimated costs. This is because of the effect of the policy implemented by CMS in the final rule, which dampens the effect of changes in payment rates that resulted from using only the cost finding. Under the dampening policy, CMS limited the reduction in median costs for APCs whose median costs would otherwise have fallen by more than 15 percent in 2003, compared to 2002. However, only one-half of the difference over the 15 percent threshold was returned and these limited increases were further mitigated by application of budget neutrality requirements. Even with the dampening policy, the bias in reimbursement rates is still evident and statistically significant.

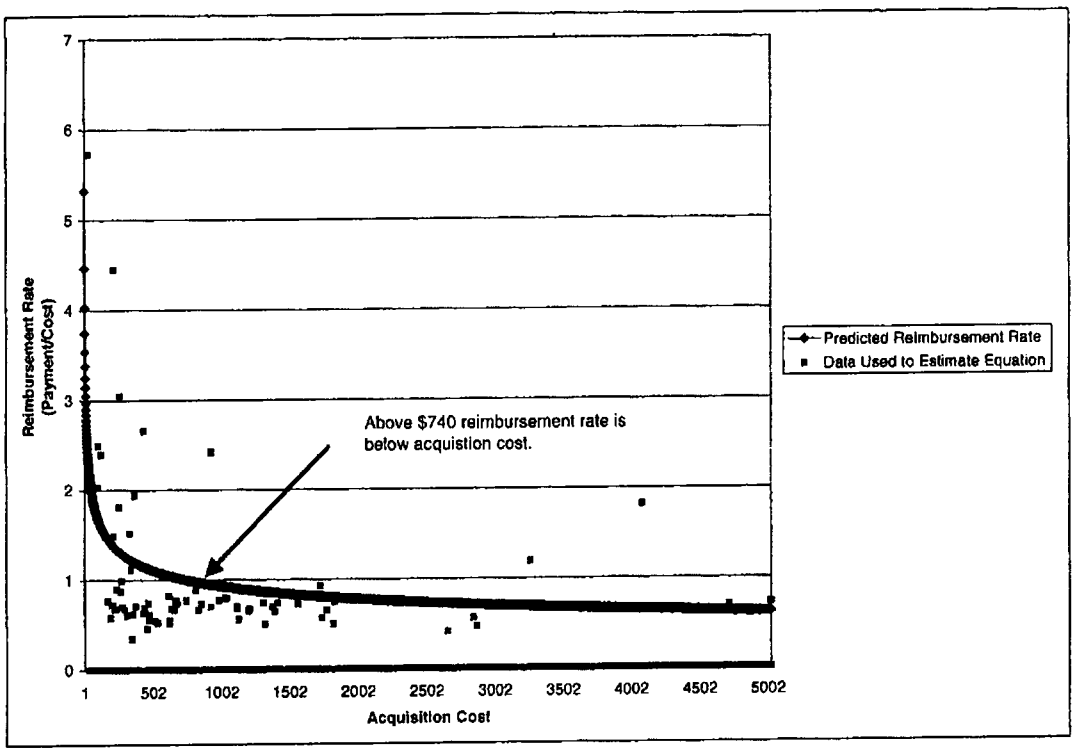
Figure 6. Estimated Parameters for Reimbursement Equation

	Estimated Coefficient	T-Statistic
C	1.4618	3.12*
Ln (Acquisition Cost)	−0.2531	3.61*
Number of Observations	80	
R-Squared in Terms of Ln (Markup)	0.216	
R-Squared in Terms of Markup	0.33	

*Statistically significant at the 1 percent level.

The coefficient on ln (Acquisition Cost) was −0.2531 and the associated t statistic indicates that the coefficient is highly statistically significant. This finding of a negative and highly statistically significant coefficient on ln (Acquisition Cost) is consistent with

Figure 7. Acquisition Cost and Reimbursement Rate



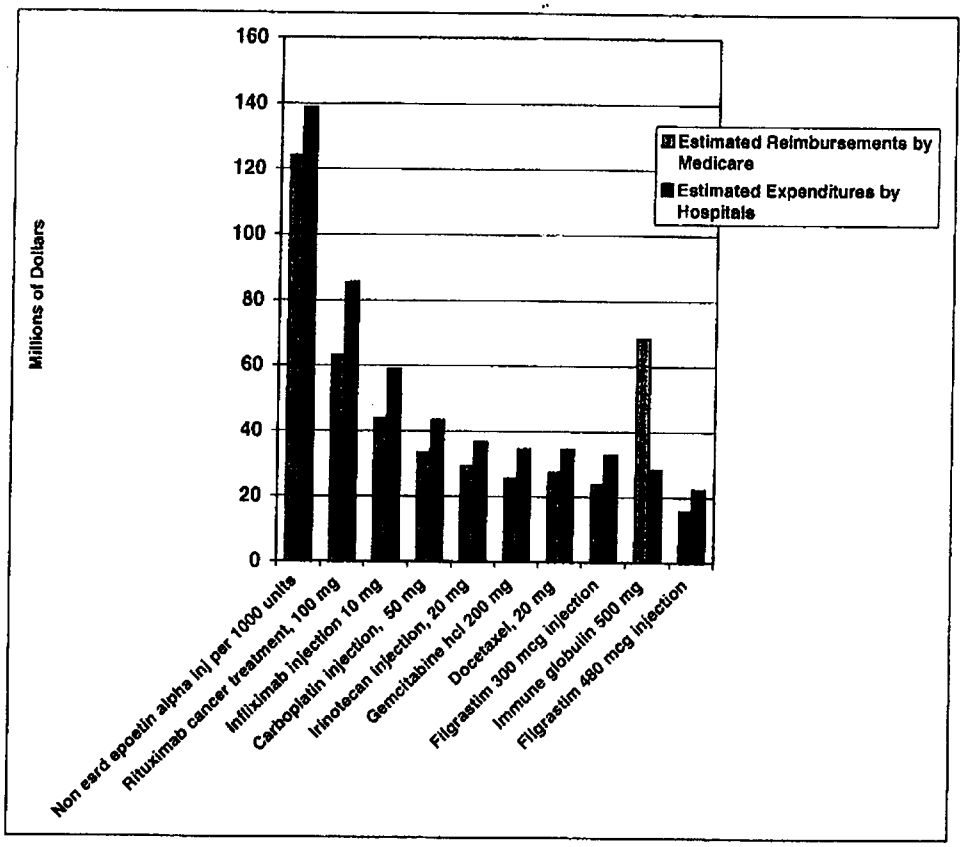
the hypothesis that charge compression, in conjunction with CMS' methodology for reimbursing hospitals, biases the payment system away from full reimbursement for high cost drugs. Specifically, the results indicate that a 10 percent increase in acquisition cost reduces the reimbursement rate by about 2.5 percent.

Figure 7 depicts the estimated relationship between acquisition cost and the reimbursement rate. Observe that the reimbursement rate is systematically below unity once the acquisition cost per administration exceeds approximately $740.

To illustrate the reimbursement effects at the drug level, we identified the top 10 drugs in our sample based on total expenditures using 2001 and 2002 volumes and 2003 payment rates. Figure 8 shows the aggregate reimbursement compared to acquisition expenditures for these drugs. Nine of ten of them are reimbursed at less than acquisition cost.

As is predicted in the model, there are some drugs that are reimbursed at a rate greater than acquisition cost in addition to those reimbursed at less than acquisition cost. We used our sample of 80 separately reimbursed drugs and compared the reimbursement rate to the acquisition cost. Using this comparison, we divided them into those that were reimbursed more than and

Figure 8. Medicare Reimbursements and Acquisition Expenditures by Hospitals for Top 10 Pharmaceuticals



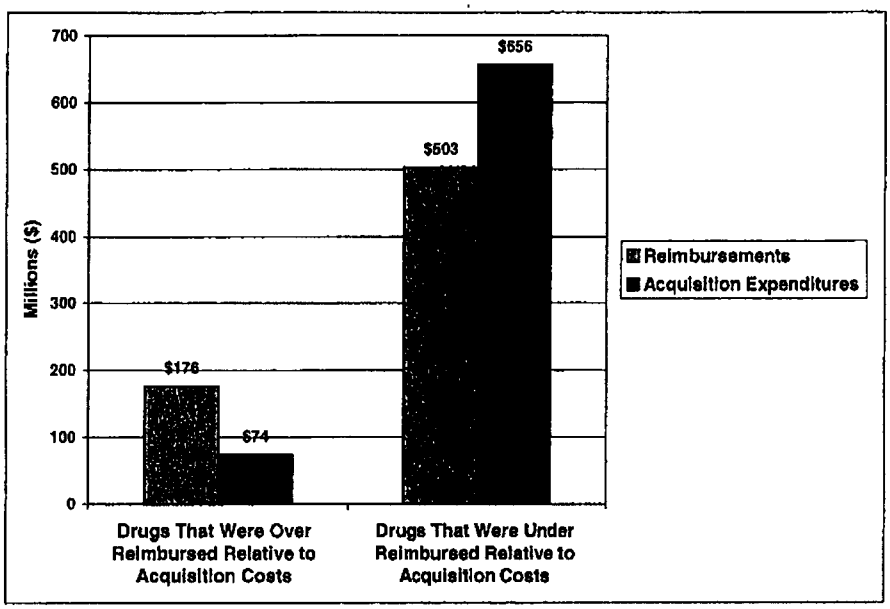
less than acquisition cost. Figure 9 shows the aggregate over and under reimbursement, based on 2001 and 2002 volumes.

These numbers are likely to understate the under reimbursement in 2003 since the acquisition costs we used are based on data from early in 2002. While those drugs reimbursed more than acquisition cost have an aggregate excess reimbursement of $102 million, drugs reimbursed less than acquisition costs have a short fall of $153 million. These numbers are only for 80 of the 160 drugs separately payable in 2003 for which we had actual acquisition cost data.

Policy Implications

We find, in these results, convincing evidence that the hypothesized charge compression phenomenon is real. We found that the relationship between acquisition cost and markup is logarithmic and that the charge markup declines as acquisition cost per administration increases. When the model is estimated taking into account hospital

Figure 9. Medicare Reimbursements and Hospitals Acquisition Expenditures for Both Over and Under Reimbursed Drugs



ownership type, the same relationship between markup and acquisition cost is shown for each category of ownership. This relationship has an effect on the payment rates that CMS sets. Higher cost pharmaceutical therapies are systematically reimbursed below acquisition cost (*i.e.*, the payment system is biased against full reimbursement for higher cost therapies). Reimbursement compared to acquisition cost for the top 10 pharmaceuticals by total expenditures indicates that 9 of the 10 are significantly under reimbursed.

The biased reimbursement has an effect on the incentives hospitals face when making decisions on services to offer and organization of outpatient health care delivery. Access to care for selected therapies could be diminished under this system.

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1. The OPPS was established under the Balanced Budget Act of 1997 (BBA). The passthrough program was required by the Balanced Budget Refinement Act (BBRA). The relevant statutory provisions can be found in § 1833(t) of the Social Security Act. The passthrough program is described in paragraph (6).
2. The OPPS data file contained claims from 4,522 hospitals. Claims from hospitals in Maryland and hospitals with outlier cost-to-charge ratios were removed from the database prior to its release.
3. While the HCPCS coding system for drugs is based on the generic name, rather than the brand name, the vast majority of drug products eligible for separate reimbursement under the

OPPS in 2001 and 2002 had no actual generic equivalents.

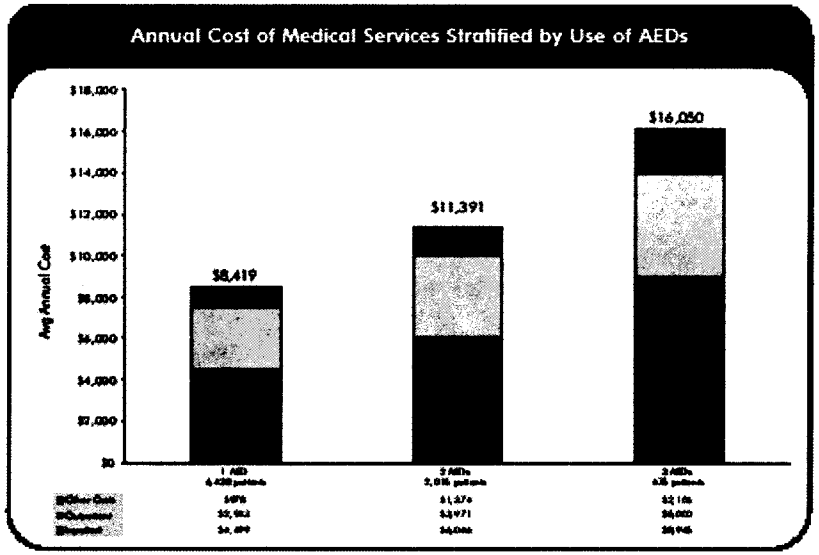
4. Overall, the OPPS methodology is designed, due to the effect of statutory budget neutrality requirements, to reimburse hospitals at approximately 82 percent of total costs. In theory, therefore, one could expect the ratio of reimbursement to acquisition costs to be 0.82, except that non-product acquisition costs would not be covered. In a prior study, The Moran Company replicated the methodology employed by Myers & Stauffer in a 1999 study for the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services (CMS)) and found that non-product costs typically total at least 33 percent of product acquisition costs.

Economic Considerations for Epilepsy Treatment and VNS Therapy™

Table of Contents

Griffiths et al Study
Financial Burden of Epilepsy

Treatment costs for patients receiving three or more antiepileptic drugs (AEDs) are almost twice those of patients receiving only one AED.



Griffiths RI, Schrammel PN, Morris GL, Wilis SH, Lasseter DM, Strauss MJ. *Payer costs of patients diagnosed with epilepsy.* Epilepsia. 1999;40:356.

Cost of Epilepsy

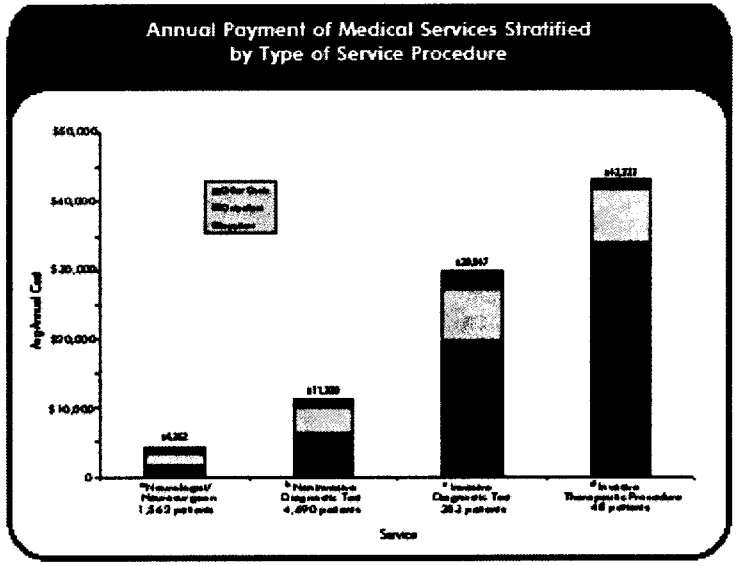
- Epilepsy is the second most common neurological condition affecting up to two percent of the population (Boon, 2002).
- The U.S. annual financial burden of epilepsy has risen from $3.6 billion (1975) to $12.5 billion (1995). (Begley, 2000).
- Indirect costs total ≈ $10.8 billion in lost productivity (including missed work days, decreased number of hours worked, and unemployment). (Begley, 2000).

Treatment options for refractory epilepsy patients include:

- Antiepileptic Drugs (AEDs)
- VNS Therapy
- Epilepsy Surgery

Griffiths et al Study
Annual Costs of Epilepsy Therapies

Costs for patients receiving the most intensive level of service were almost ten times those of the most easily managed patients (Griffiths, 1999).

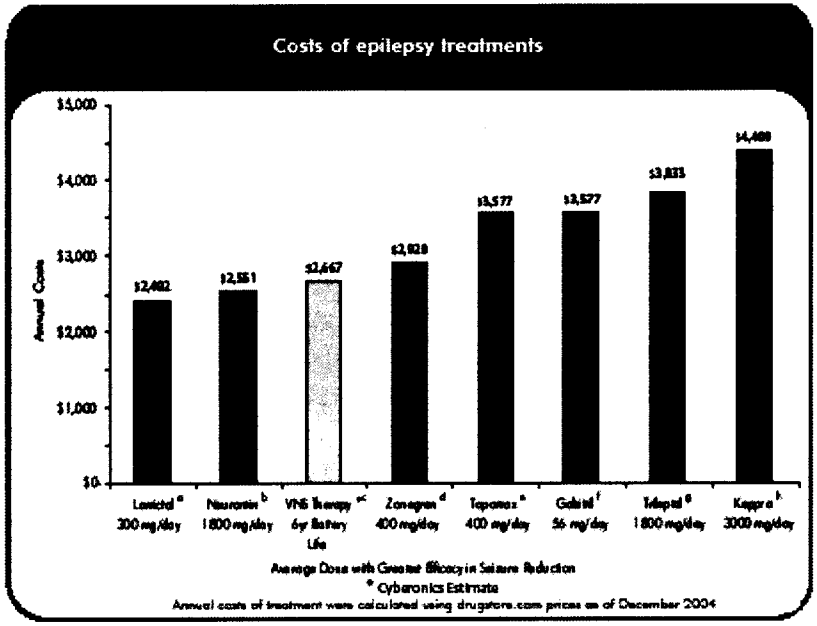


Griffiths RL, Sonnenmeier RN, Morris GL, Wylie EM, Lobainer DM, Strauss MJ. Payer costs of patients diagnosed with epilepsy. Epilepsia. 1999;40:354

a Neurologist or neurosurgeon visits but no invasive procedures or noninvasive diagnostic tests
b Electroencephalography or radiologic examination, but no invasive procedure
c Spinal tap, implantation of depth and/or subdural electrodes or Wada activation test for hemispheric function, but had no invasive therapeutic procedure
d Craniotomy for lobectomy or hemispherectomy

Cochrane Collaboration® Comparison Adjunctive Epilepsy Treatments

VNS Therapy costs compare favorably to newer AEDs which have been developed as an "add-on" treatment for drug-resistant partial epilepsy.



VNS Therapy Costs

- **$16,000 estimated initial costs includes:
  - Device Cost
  - Device Lead
- Average VNS Therapy cost is $2,667 per year*
  - ***Based on median battery life of six years (Model 102 Pulse Generator)

Coverage and Reimbursement by:

- Medicare
- Medicaid
- Most private and commercial payers

**Device cost only
*** April 2005

a Jette NJ, Marson AG, Hutton JL. Topiramate add-on for drug-resistant partial epilepsy. Cochrane Database Syst Rev. 2002; CD001417.

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c Source: Cybernics

d Chaseewitul R, Marson AG. Zonisamide add-on for drug-resistant partial epilepsy. Cochrane Database Syst Rev. 2002; CD001416.

Boon et al Study
Epilepsy-Related Direct Medical Costs

VNS Therapy compares favorably to other therapeutic options in terms of reduced monthly seizure frequency and costs.

VNS Therapy

The VNS Therapy System was FDA approved in 1997 for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with medically refractory partial onset seizures. Approximately *30,000 patients have been implanted in the U.S. The procedure is performed mainly in an outpatient setting under general anesthesia.

Direct Medical Costs of Refractory Epilepsy

Treatment with VNS Therapy resulted in a major decrease in Epilepsy-Related Direct Medical Costs.

VNS Therapy was associated with a 50% reduction in Epilepsy-Related Direct Medical Costs.

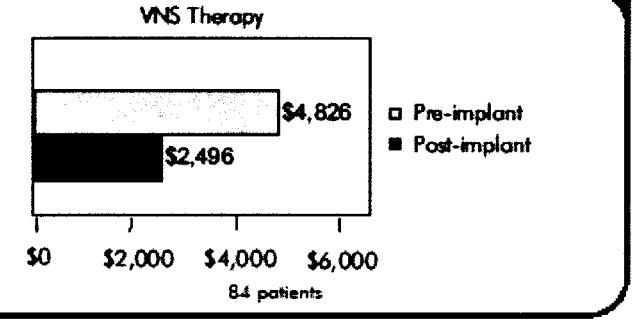
* As of April 2005

Seizure and cost reduction of epilepsy

Treatment	Seizure Frequency		US dollars		
	Baseline	% Reduction	Baseline	% Reduction	Savings
AEDs	12/mo	25%	$2,525	4%	$104
Surgery	6/mo	83%	$1,465	19%	$279
VNS Therapy	21/mo	66%	$4,826	48%	$2,330

84 patients

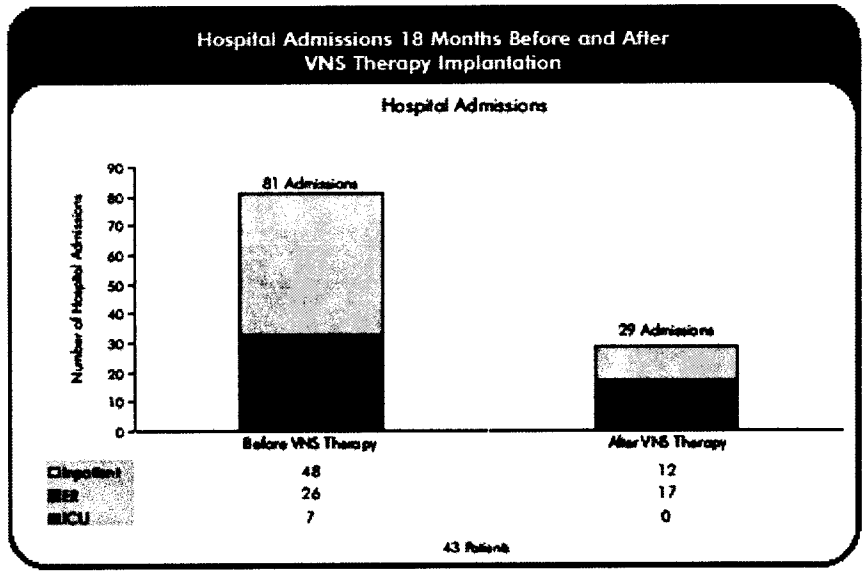
Pre and post VNS Therapy implant cost reduction



Boon P, D'Have M, Van Walleghem P, et al. Direct cost of refractory epilepsy incurred by three different treatment modalities: a prospective assessment. Epilepsia. 2002;43:96-102.

Ben-Menachem et al Study
VNS Therapy Impact on Health Care Utilization and Cost

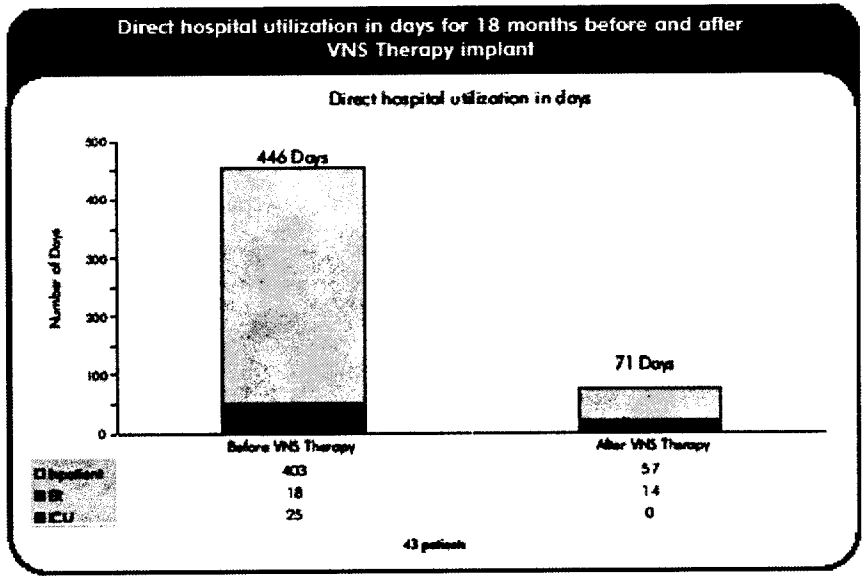
Ben-Menachem et al reported a 64% decrease in post-VNS Therapy admissions compared to pre-VNS Therapy admissions. Estimated annual savings with VNS Therapy were $3,000 per patient.



Interpreted from Ben-Menachem E, Hellstrom K, Varoqueaux O. Analysis of direct hospital cost before and 18 months after treatment with vagus nerve stimulation therapy in 43 patients. Neurology. 2002;59:344-347.

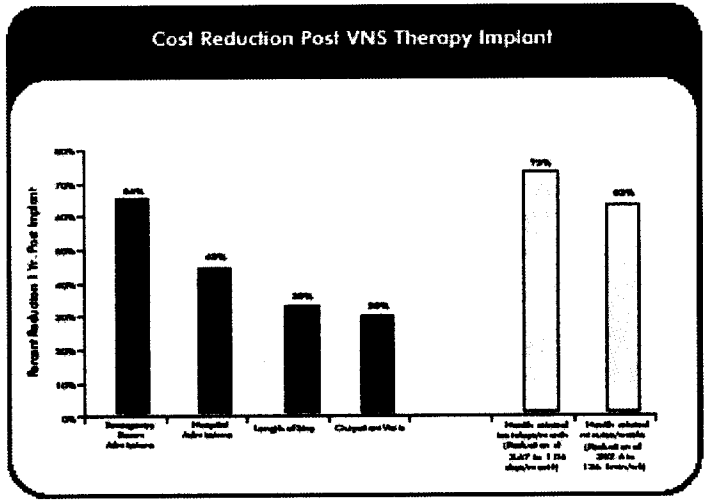
Ben-Menachem et al Study
VNS Therapy Impact on Health Care Utilization and Cost

Ben-Menachem et al reported an 84% reduction in total hospital utilization (inpatient stays, emergency room visits, and intensive care unit stays)



Interpreted from Ben-Menachem E, Hellstrom K, Verstappen D. Analyses of direct hospital cost before and 18 months after treatment with vagus nerve stimulation therapy in 43 patients. Neurology. 2002;59:544-547.

Bernstein et al, American Epilepsy Society Abstract
Impact on Direct and Indirect Utilization Costs



(Interpreted from Bernstein AL, Barkan H, Hess T. American Epilepsy Society Abstract. Epilepsia. 2003; 44 suppl. 9:32 (Abst. 2.425.))

Rationale

This study analyzed the effect of VNS Therapy on direct costs, indirect costs, and utilization of medical services in a large, staff model health maintenance organization.

Methodology

- Analysis of 140 patients treated with VNS Therapy
- Patient data analyzed one year pre VNS Therapy vs. one year post VNS Therapy
- Analysis performed on all medical utilization costs

Results

After one year of VNS Therapy, statistically significant reduction in utilization of:

• Outpatient visits	p<0.001
• Emergency room admissions	p<0.001
• Hospital admissions	p=0.021
• Length of stay	p=0.330, NS

Conclusion

- Statistically significant improvements were noted in both direct and indirect costs of care including marked decreases in emergency room visits and the number of hospital admissions.
- Improvements with indirect costs were reflected in decreases in both time missed from work and time spent on health problems.
- The significant reductions support the cost effectiveness of VNS Therapy as a treatment for refractory epilepsy.

Summary
VNS Therapy Cost-Effectiveness

Compared to other treatment options, VNS Therapy provides a cost-effective treatment option for patients with refractory epilepsy

VNS Therapy findings in Griffiths et al, American Study, 9,090 patients
Annual cost of refractory epilepsy ranges from $4,362 to $43,333. Treatment costs ($16,050) for patients receiving three AEDs are nearly twice those of patients receiving only one AED.

VNS Therapy findings in Boon et al, Belgian Study, 84 patients
- Reduced annual Epilepsy-Related Direct Medical Costs 50% with VNS Therapy

VNS Therapy findings in Ben-Menachem et al., Swedish Study, 43 patients at 18 months
- Reduced ER visits by 35%
- Reduced hospital admissions by 64%
- Reduced days in the hospital by 84%
- Reduced annual costs by $3,000

VNS Therapy Findings in Bernstein et al, American Epilepsy Society Abstract, 140 patients. 12 months pre-implant vs. 12 months post-implant
- Reduced ER visits by 64%
- Reduced hospital admissions by 43%
- Reduced outpatient visits by 29% (quarterly turn)
- Reduced length of hospital stay by 32%

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Cyberonics®

100 Cyberonics Boulevard
Houston, Texas 77058 USA
Tel: 800.332.1375 • Fax: 281.218.9332

Cyberonics Europe, S.A./N.V.
Belgicastraat 9
1930 Zaventem • Belgium
Tel: +32 2 720 95 93 • Fax: +32 2 720 60 53

www.VNSTherapy.com

Reimbursement Department
Tel: 888.506.8082
Fax: 888.577.7205
Email: Reimbursement.Dept@cyberonics.com

ECET05-11-1000

Economic Burden of Medicare Beneficiaries with Treatment-Resistant Depression (TRD)

The Moran Company recently conducted a detailed analysis of Medicare claims for the year 2004.[1] The goal of this analysis was to determine the annual costs for Medicare beneficiaries receiving treatment for one of several depression diagnoses codes (ICD-9 diagnosis codes: 296.2x, 296.3x, and 296.5x) and the annual costs of patients with TRD with a previous depression-related hospitalization or previous ECT treatment (i.e., TRDEH). The analysis also compared the under 65 Medicare beneficiaries to the over 65 Medicare beneficiaries and noted no real differences in total annual health care costs or services utilized.

In the 2004 Medicare claims database, there were approximately 42 million total Medicare beneficiaries and 1.1 million Medicare beneficiaries who received at least one health care service with a primary diagnosis of MDD. An algorithm was applied to find those patients with a pattern of care that exemplified severe treatment resistance. Patients were believed to have TRDEH if they received four or more episodes of care with a primary diagnosis of depression and were hospitalized for their depression (4 MDD DX + IP) or received ECT (MDD + ECT) or were hospitalized and received ECT (MDD + ECT + IP) within a 1-year period.

As shown in the table below, of the 1.1 million Medicare beneficiaries with a primary diagnosis of MDD, approximately 103,000 (0.26% of total Medicare beneficiaries) fit into one of the TRDEH categories in 2004. This group of patients for whom VNS Therapy is a proposed covered benefit cost Medicare approximately $3.3 billion in 2004 Before Part D medication costs. Of the total annual health care costs in 2004 (before Part D medication expenses), inpatient services ranged from 48% to 51% of the total, physician/professional services accounted for between 23% and 26%, and outpatient hospital services accounted for between 10% and 14% of the total costs.

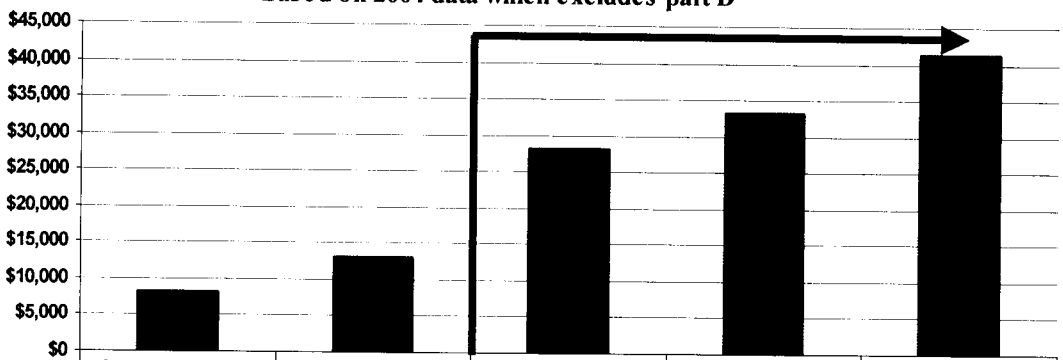
Annual Cost based on 2004 5% SAF Medicare files						
	Total # of Medicare Beneficiaries	< 65 years old	≥ 65 years old	Total $s	<65 $s	>65 $s
MDD (Primary)	1,120,000	520,000	600,000	$17,000	$13,000	$20,000
4 MDD DX + IP	80,000	46,000	34,000	$31,000	$28,000	$35,000
MDD + ECT	13,000	5,000	8,000	$33,000	$33,000	$34,000
MDD + ECT + IP	10,000	4,000	6,000	$40,000	$41,000	$39,000

MDD = major depressive disorder, DX=diagnosis, IP = inpatient hospital services, ECT = electroconvulsive therapy

In terms of age, slightly more than 50% of the Medicare patients with TRDEH are under 65 years of age. Most of these Medicare beneficiaries under age 65 are likely disabled because of their MDD and its ineffective treatments, particularly considering that

depression is the number one cause of disability in the United States and causes nearly two times the number of disability-adjusted life-years as ischemic heart disease (8.0 versus 4.5).[2] As shown in the graph below, TRDEH patients under age 65 cost Medicare four to five times the average annual costs of all Medicare beneficiaries under age 65 and the costs of care for these patients escalate rapidly with hospitalizations and ECT.

Under 65 Years of Age: Direct Medicare Beneficiary Cost Comparison
Based on 2004 data which excludes part D



	Average under 65 cost	MDD Primary	4 TRD DX & IP Admission	TRD + ECT	TRD + ECT + IP
Per Beneficiary	$8,100	$13,000	$28,000	$33,000	$41,000
Beneficiaries (<65 yo)	5,000,000	520,000	46,000	5,000	4,000
Cost	$40,400,000,000	$6,760,000,000	$1,288,000,000	$165,000,000	$164,000,000

Similar to refractory epilepsy, Medicare has enormous exposure and opportunities for savings in TRDEH because of the high percentage of patients with TRDEH who are under age 65. The average age of the Medicare beneficiaries prescribed VNS Therapy to date is 53. At $3.3 billion of expenditures per year, Medicare's exposure for coverage only of ineffective traditional antidepressants for premature Medicare beneficiaries with TRDEH likely exceeds $40 billion ($3.3 billion times 12 years of premature benefits).

Clearly, patients with TRD who have reached the stage of illness requiring treatment with ECT or hospitalization have an overwhelming medical need for FDA-approved treatments that provide accumulating and durable, long-term safety and effectiveness. Only VNS Therapy is safe, effective, FDA approved, and has fully informative labeling for use in TRD, including this well-defined subset of TRD beneficiaries that make up the TRDEH population.

---

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[2] Ustun TB, Ayuso-Mateos JL, Chatterji S, Mathers C, Murray CJ. Global burden of depressive disorders in the year 2000. *Br J Psychiatry* 2004;184:386-392.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1997

William H. Duffell, Jr., Ph.D.
Vice President, Clinical & Regulatory Affairs
Cyberonics, Inc.
17448 Highway 3, Suite 100
Webster, Texas 77598-4135

Re: P970003
NeuroCybernetic Prosthesis (NCP®) System
Filed: January 27, 1997
Amended: April 18, May 15, and July 16, 1997

Dear Dr. Duffell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the NeuroCybernetic Prosthesis (NCP®) System which includes the Model 100 NCP Generator, the Model 200 NCP Programming Wand, the Model 250 NCP Programming Software, the Model 300 Series NCP Vagus Nerve Stimulation Lead, the Model 400 Tunneling Tool, and NCP System Accessories, subject to the conditions described below and in the "Conditions of Approval" (enclosed). This device is indicated for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures, which are refractory to anti-epileptic medications. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the general conditions of approval (enclosed), you must conduct the studies outlined in the amendment dated July 16, 1997, ("Description of the Postapproval Studies - P970003"). The information to be collected for five years will include:

1. continued reporting on a cohort of E05 patients;
2. characterization of the long-term morbidity and mortality; and
3. development of an approach to identifying responders and non-responders.

If appropriate, the results of the long-term data must be reflected in the labeling (via a supplement) when the post-approval study is completed.

Expiration dating for the generator and the lead has been established and approved at one and two years, respectively. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and

effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities, the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanently implantable device.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list examples of permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)). Pursuant to 21 CFR § 821.20(d), FDA will be adding the Vagus Nerve Stimulator/ NeuroCybernetic Prosthesis (NCP®) System to these lists by publishing a notice in the FEDERAL REGISTER announcing that FDA believes that this device is subject to tracking under section 519(e)(1). This notice will also solicit public comments on FDA's determination.

If you have questions concerning this approval order, please contact Ann H. Costello, Ph.D., D.M.D., at (301) 443-8517.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2005

Ms. Annette Zinn, M.P.H., J.D., RAC
Director and Senior Counsel, Regulatory Affairs
Cyberonics, Inc.
100 Cyberonics Boulevard
Houston, TX 77058

Re: P970003/S50
VNS Therapy System
Filed: October 27, 2003
Amended: December 4 and 19, 2003; February 17, March 18 and 29, April 5 and 8, July 7 and 8, September 8 and 23, 2004; and March 11, and June 28, 2005
Procode: MUZ

Dear Ms. Zinn:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the VNS Therapy System. This device is indicated for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments. The PMA supplement is approved. You may begin commercial distribution of the device as modified in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements outlined in the enclosure, you must conduct the following postapproval studies to further characterize the optimal stimulation dosing and patient selection criteria for the VNS Therapy System for treatment-resistant depression (TRD). The first study is a prospective, multicenter, randomized, double-blind comparison of different output currents in 450 new subjects with TRD. You have agreed to assess the effectiveness responses to differing outputs 16 weeks after the end of a 4-6 week titration period during which concomitant therapies will not be changed. You have also agreed to follow these subjects for at least one year following implantation to further characterize duration of response as well as safety parameters at

these higher doses. The second study is a prospective, observation registry study of 1000 implanted subjects with TRD with follow-up extending to 5 years after implantation. This study is designed to evaluate long-term patient outcomes as well as predictors of response to therapy. Post approval study progress reports and results will be submitted as a report to the PMA at 6 month intervals. As appropriate, CDRH may request panel review of the postapproval study data. When necessary, the results will be incorporated into the labeling, via a supplement.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling affected by this supplement in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact me at (301) 827-7975.

Sincerely yours,

Daniel Schultz, M.D.
Director
Center for Devices and
Radiological Health
Food and Drug Administration

Enclosure

Medicare
Coverage Issues
Manual

Department of Health and Human Services

Health Care Financing Administration

Transmittal No. 114 **Date** April 1999

CHANGE REQUEST 470

REVISED MATERIAL	REVISED PAGES	REPLACED PAGES
Table of Contents	2 pp.	2 pp.
Secs. 60-21 - 60-22	1 p.	1 p.

NEW IMPLEMENTING INSTRUCTIONS--EFFECTIVE DATE: For services furnished on or after July 1, 1999

Section 60-22, Vagus Nerve Stimulation for the Treatment of Seizures, states that clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed. This policy is in accordance with the FDA-labelled usage for the device.

The neurostimulator pulse generator is implanted subcutaneously below the left clavicle and the lead is attached to the vagus nerve in the neck. The procedure is performed in the hospital and usually requires an overnight stay. The implant procedure is usually coded by the surgeon using CPT codes 64573 (electrode placement) and 61885 (neurostimulator placement).

In addition, a physician, usually a neurologist, typically tests the device and leads and sets the initial programming parameters, both in the operating room and in the office setting during the days/weeks following the implant. The services are coded with the following CPT codes: 95970 (no reprogramming), 95974 (with intraoperative or subsequent programming, first hour), and/or 95975 (additional 30 minutes after first hour - billed as add-on to 95974). These analysis and programming codes also may be billed periodically to test and reprogram the device.

The ICD-9-CM for implantation of a neurostimulator into the vagus nerve is 04.92. The diagnosis codes for intractable epilepsy are 345.41 and 345.51. Infrequently contractors might see the diagnosis code for convulsions, 780.39, used to identify potentially eligible patients.

There are not any corresponding claims processing instructions at this time. Contractors should not make any systems changes in order to implement this policy.

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

COVERAGE ISSUES

Prosthetic Devices

Braces - Trusses - Artificial Limbs and Eyes

Patient Education Programs

Nursing Services

60-21 INTRAPULMONARY PERCUSSIVE VENTILATOR (IPV) - NOT COVERED

IPV is a mechanized form of chest physical therapy. Instead of a therapist clapping or slapping the patient's chest wall, the IPV delivers mini-bursts (more than 200 per minute) of respiratory gasses to the lungs via a mouthpiece. Its intended purpose is to mobilize endobronchial secretions and diffuse patchy atelectasis. The patient controls variables such as inspiratory time, peak pressure and delivery rates.

Studies do not demonstrate any advantage of IPV over that achieved with good pulmonary care in the hospital environment and there are no studies in the home setting. There are no data to support the effectiveness of the device. Therefore, IPV in the home setting is not covered.

60-22 VAGUS NERVE STIMULATION FOR TREATMENT OF SEIZURES

In the past 10 years, there have been significant advances in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, 25-50 percent of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs.

The vagus nerve is a mixed nerve carrying both somatic and visceral afferent and efferent signals. The majority of vagal nerve fibers are visceral afferents with wide distribution. The basic premise of vagus nerve stimulation in the treatment of epilepsy is that vagal visceral afferents have a diffuse central nervous system projection and the activation of these pathways has a widespread effect upon neuronal excitability. Besides activation of well-defined reflexes, vagal stimulation produces evoked potentials recorded from the cerebral cortex, the hippocampus, the thalamus, and the cerebellum.

The vagus nerve stimulation system is comprised of an implantable pulse generator and lead and an external programming system used to change stimulation settings. Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. Vagus nerve stimulation is not covered for patients with other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.

A partial onset seizure has a focal onset in one area of the brain and may or may not involve a loss of motor control or alteration of consciousness. Partial onset seizures may be simple, complex, or complex partial seizures, secondarily generalized.

VNS VAGUS NERVE STIMULATION

COMMON CODING OPTIONS FOR VNS THERAPY (VAGUS NERVE STIMULATION)

ICD-9-CM (DSM-IV)—DIAGNOSIS CODES

Depression

296.2x*	Major depressive disorder, single episode
296.3x*	Major depressive disorder, recurrent episode
296.5x*	Bipolar I disorder, most recent episode (or current) depressed

*x = appropriate level, please specify:
0 = unspecified
2 = moderate
3 = severe, without mention of psychotic behavior
5 = in partial or unspecified remission

Epilepsy

345.41	Partial epilepsy with impairment of consciousness
345.51	Partial epilepsy without impairment of consciousness
780.39	Other convulsions

ICD-9-CM PROCEDURE CODES—IMPLANTATION, REPLACEMENT, OR REMOVAL

04.92	Implantation or replacement of peripheral neurostimulator lead(s)
86.94	Insertion or replacement of single array neurostimulator pulse generator
04.93	Removal of peripheral neurostimulator lead(s)
86.05	Incision with removal of foreign body or device from skin and subcutaneous tissue; removal of neurostimulator pulse generator (single array, dual array)

REVENUE CODES

278	Medical device and implants
360	General classification O.R. services

PHYSICIAN AND OUTPATIENT FACILITY CPT-4 CODES

Implant

64573	Incision for implantation of neurostimulator electrodes; cranial nerve
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

Revision or Removal

64585	Revision or removal of peripheral neurostimulator electrodes
61888	Revision or removal of cranial neurostimulator pulse generator or receiver

ANALYSIS-PROGRAMMING—ALL SETTINGS

95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95974	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
95975	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

VNS VAGUS NERVE STIMULATION

DIAGNOSIS RELATED GROUPS (HOSPITAL INPATIENT ONLY)

007	Peripheral & cranial nerve & other nerve system procedure with complications
008	Peripheral & cranial nerve & other nerve system procedure without complications

MEDICARE OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Hospital Outpatient Category C—Codes

C1767	Generator, Neurostimulator
C1778	Lead, Neurostimulator

Ambulatory Payment Classification (Hospital Outpatient)

Group		CPT-4 Code
APC 0039	Level I Implantation of Neurostimulator	61885
APC 0225	Level I Implantation of Neurostimulator Electrodes	64573
APC 0692	Electronic Analysis of Neurostimulator Pulse Generators	95974, 95975
APC 0218	Level II Nerve and Muscle Tests	95970

Cyberonics has compiled this coding information for your convenience. It is the provider's responsibility to file claims with appropriate ICD-9, CPT-4, HCPCS revenue, and/or APC codes along with charges for the services provided. Please contact your local payer if you have questions regarding appropriate coding guidelines.

Cyberonics offers a VNS Therapy Reimbursement Department at
1-888-508-8082
or e-mail VNSTherapycallcenter@cyberonics.com

Cyberonics®
CYBERONICS, INC.
100 Cyberonics Boulevard, Houston, Texas 77058 USA
Tel: 1-888-508-8082
Fax: 1-888-577-7205
www.VNSTherapy.com

DECC05-21-4000

VNS THERAPY
VAGUS NERVE STIMULATION

Ambulatory Payment Classification (APCs) for Vagus Nerve Stimulation Updated January 1, 2006 Medicare Outpatient Prospective Payment System (OPPS) Update VNS Therapy Implant

- Improved APC payment rates to better reflect device & procedure costs
- C Codes remain required for reimbursement and data collection purposes

	APC	New Rate
(61885) Insertion or replacement of cranial neurostimulator	**0039**	**$11,603**
(64573) Incision for implantation of cranial neurostimulator electrodes	**0225**	**$14,928**
(95974 & 95975) Neurostimulator analysis-programming	**0692**	**$118**

The Status Indicators for these APCs are designated as (S) a "Significant Procedure." Therefore; there is no multiple surgical procedure discount applied.

Important points for Hospitals to remember:

- Correct Coding - CMS reimburses hospitals at the APC payment rate assigned to a specific CPT code. Use of correct codes ensures appropriate payment.
- CMS believes coding of devices is vital to enhancing the device - dependent APC claims data. Again, hospitals will be required to include device category codes on claims when such devices are used in conjunction with procedures billed and paid for under the OPPS.
- Specifically, C1767 Generator, neurostimulator **will be required** for payment of APC 0039. C1778 Lead, neurostimulator **will be required** for payment of APC 0225. Hospitals will need to review the chargemaster for supplies used during VNS Therapy implant surgery to ensure the HCPCS codes for these devices are present. Charges for the procedure and device will need to be assigned to the appropriate CPT or HCPCS code.
- Complete and accurate coding is necessary for appropriate reimbursement and critical for future APC payment rates. Paying particular attention to this detail now may be extremely beneficial to future payments. Please feel free to share this document with others at the hospital that may find this information beneficial.

For more information, please call the **Cyberonics VNS Therapy Reimbursement Hotline at 1-888-508-8082** to be connected to your local Regional Alliance Manager.

Additional information can also be accessed through CMS. CMS has posted APC materials, including all addendums and its Medicare Manuals on the Internet. The CMS homepage can be found at http://www.cms.gov. You should also contact your Medicare Fiscal Intermediary to clarify questions and/or concerns regarding billing and coding.