

HB

70

STATE OF ALASKA
THE LEGISLATURE

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POUCH V. STATE CAPITOL
JUNEAU, ALASKA 99811
907-465-3800

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Mary Van Nimwegen

H. HESS - 1-25-87

#2

FISCAL NOTE

REQUEST:

Revision Date: _____
Title: An Act relating to pharmaceutical medical assistance for needy persons.
Sponsor: Rules Committee
Requestor: Governor

Agency Affected: Health & Social Services
BRU: Medical Assistance
Components: General Relief Medical and Medicaid Non-Facility

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 89	FY 90	FY 91	FY 92	FY 93	FY 94
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING		Ø	Ø	Ø	Ø	Ø

CAPITAL						
---------	--	--	--	--	--	--

REVENUE						
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FUNDING: (Thousands of Dollars)

GENERAL FUND						
FEDERAL FUNDS						
OTHER						
TOTAL						

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

ANALYSIS : (Attach a separate page if necessary)

* See Attached *

Prepared by: Kim Busch *Kim Busch*
Division: Director

Phone: 465-3355
Date: 11-3-88

Approved by Commissioner: [Signature]
Agency: DHSS

Date: 12-1-88

- Distribution (by preparer):
- Legislative Finance
 - Legislative Sponsor
 - Requestor
 - Office of Management and Budget
 - Impacted Agency(ies)

Summary

Before the last legislative session, pharmacy services for Medicaid eligible individuals were purchased from the General Relief Medical program because Alaska had not adopted the pharmacy option under the Medicaid program. During the last legislative session, CSSB 255, which was signed into law as Chapter 120, SLA 1988, added pharmacy services as a Medicaid option for the period October 1, 1988 - June 30, 1989. (SB 255 has a sunset clause which repeals Chapter 120 effective July, 1989.)

Unless this legislation is passed, a general fund appropriation of \$2,560 million will be needed in FY90 to continue to pay for pharmacy services for poor Alaskans. In essence, the state would be relinquishing \$2.56 million in federal match and pharmacy services for Medicaid eligible individuals would once again be purchased through the general relief medical program (GRM). Should general funds not be appropriated, significant reductions in pharmacy services would also likely occur.

Budgetary and Program Impact

All services which are purchased by the state under the Medicaid program receive a dollar-for-dollar federal match. All services purchased under the General Relief Medical program are entirely general funds.

The Department has submitted its FY90 budget assuming this legislation would pass, pharmacy services would remain as a Medicaid option and, \$2,560.2 in federal funds would be received as match. Consequently, this legislation has a zero fiscal note. If it passes, the total pharmacy cost of \$5.037 million is split between federal funds and general funds. The

proposed FY90 budget contains sufficient general funds to pay the state share, so pharmacy services would continue as currently provided.

If this legislation does not pass, federal matching funds for pharmacy services would be lost. Should this occur, an additional \$2,560.2 in general funds would be needed to replace the federal funds so that existing services could be maintained.

When pharmacy legislation (SB 255) passed in FY89, the department estimated \$2 million in savings because the total drug program cost about \$4 million. Services to new eligibles and utilization and price increases have since increased the total program cost to \$5 million. Consequently, returning to a totally general funded pharmacy program would cost \$1 million more in FY90 than it did in FY88, the last year in which pharmacy was entirely funded by several funds.

Throughout the interim, the department has worked diligently with pharmacists to fashion a Medicaid program which captures federal reimbursement while minimizing financial impact to pharmacists. A separate document describes the policy making process, the research conducted on pharmacy costs, and the reimbursement methodologies which resulted from that process.

If the legislature decides not to pass this legislation, the department requests that the full \$2.56 million in general funds be appropriated. This amount includes the inflation in pharmacy service costs which occurred from FY88 to FY90 in addition to the restoration of the general fund which had been supplanted by federal funds.

The following describes the sequence of modification to the FY90 budget that would be needed to continue present services should the legislation not pass:

1. Transfer \$2,476.9 State General Fund Match (SGFM) from the Medicaid Non-Facility component to the General Relief Medical component. (1,328.9 FY89 transfer for Chapter 120, 913.6 FY90 Budget Request transfer and 234.4 FY90 increments for price, utilization and eligibles.) If the program is not a Medicaid option, there are no federal funds to match with state general funds.
2. Decrement the Medicaid Non-Facility component for 2,560.2 federal funds. (1,412.3 FY89 Chapter 120, 913.6 FY90 Budget request and 234.3 FY90 increments for price, utilization and eligibles.) These federal match funds are not received if the pharmacy services are not provided through Medicaid.
3. Increment the General Relief Medical program for 2,560.2 state general funds to offset the federal decrements in #2 above.

The following chart depicts the development of the FY90 budget request and the above described modifications.

FY90 Budget Development

	<u>GRM</u>	<u>Medicaid Non-Facility</u>	<u>Total</u>
FY89 Authorization	913.6	2,741.2	3,654.8
C-4 Transfer	<u>(913.6)</u>	<u>913.6</u>	<u>0</u>
FY90 Adjusted Base	0	3,654.8	3,654.8
FY90 Increments:			
Federal Increment		913.6	913.6
Price		135.2	135.2
Eligibles		196.4	196.4
Utilization	<u> </u>	<u>137.1</u>	<u>137.1</u>
FY90 Budget Request	0	5,037.1	5,037.1

Required Modifications

Transfer SGFM	2,476.9	[1] (2,476.9)	0
Decrement Federal	-	[2] (2,560.2)	(2,560.2)
Increment SGF	[3] <u>2,560.2</u>	<u>-</u>	<u>2,560.2</u>
Totals	5,037.1	0	5,037.1

STEVE COWPER
GOVERNOR



STATE OF ALASKA
OFFICE OF THE GOVERNOR
JUNEAU

cc
1AB70
#3

January 9, 1989

The Honorable Sam Cotten
Speaker of the House
Alaska State Legislature
P.O. Box V
Juneau, AK 99811

Dear Representative Cotten:

Under the authority of art. III, sec. 18, of the Alaska Constitution, I am transmitting a bill relating to pharmaceutical medical assistance for needy persons in the medicaid program. The bill would add prescribed drugs as a covered medicaid service under that program. Chapter 120, SLA 1988 added prescribed drug services for fiscal year 1989 only. Passage of the attached bill will allow the state to continue to receive federal financial participation for these services.

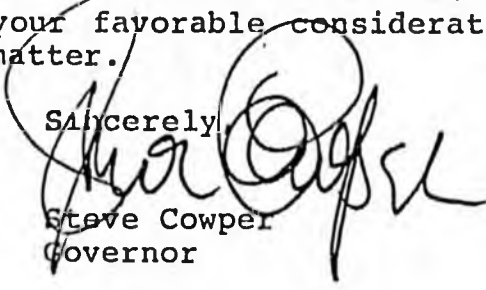
The bill has two main components: the authorization of prescribed drugs as a covered service under medicaid and the establishment of a priority for deletion of prescribed drugs if a funding shortfall occurs. Additionally, the bill adopts the federal medicaid standards of reimbursement for prescribed drugs, and the federal definition of prescribed drugs under the medicaid program.

With regard to the first of the two main components, the Department of Health and Social Services would continue to be required to cover prescribed drugs under the medicaid program after ch. 120, SLA 1988's temporary authorization expires. (Section 1 of the bill.) Before the temporary authorization (July 1, 1988), the department provided this service under the state-funded general relief medical program for medicaid recipients. While the change in program will not increase service to medicaid recipients, the bill will allow the State to continue to collect the federal funding that it collected under ch. 120, SLA 1988.

As to the second main component, sec. 2 of the bill would add prescribed drugs to the priority scheme in AS 47.07.035 that provides for elimination of services if a medicaid budget shortfall occurs. The bill would require that prescribed drugs be eliminated as a covered service under medicaid after personal care services in a recipient's home were eliminated, but before long-term care noninstitutional services were eliminated.

The Department of Health and Social Services (DHSS) views this bill as a critical step forward in continuing to maximize federal financial participation under the medicaid program. Without the federal financial participation that this bill would provide, a DHSS general fund budget shortfall of approximately \$2,500,000 will occur in FY 90 and prescribed drugs would be eliminated from medicaid coverage. Therefore, I urge your favorable consideration of, and prompt action on, this matter.

Sincerely,



Steve Cowper
Governor

STEVE COWPER, GOVERNOR

DEPT. OF HEALTH AND SOCIAL SERVICES

OFFICE OF THE COMMISSIONER

PO. BOX H
JUNEAU, ALASKA 99811-0601
PHONE: (907) 465-3030

(4)

Jim

January 13, 1989

The Honorable Johnny Ellis
Representative, Alaska State Legislature
P.O. Box V
Juneau, Alaska 99811

Dear Representative Ellis:

As you know, the Governor has introduced HB 70 which would extend the pharmaceutical program as a Medicaid option. If this bill does not pass this session, approximately \$2.5 million in additional general funds will be required to maintain the current pharmaceutical program for Medicaid and General Relief Medical recipients.

Consequently, I respectfully request that the HESS committee schedule hearings on this bill on the earliest convenient date.

Jay Livey of my staff will be contacting committee staff regarding this matter.

Thank you for your consideration.

Sincerely,

Jay Livey
for

Myra M. Munson
Commissioner

MM:JL:nb
pha.nlb/corr

TABLE OF MEDICAID PRIORITIES - AS 47.07.035

(5)

(Lowest to Highest)

Service	Recipients	FY89 Annual Amount
1. Chiropractic	600	381.2
2. Adult Dental	2,032	935.6
3. Emergency Hospital Services	-0-	-0-
4. Speech, Hearing & Language Disorders	298	159.4
5. Optometrists Services & Eyeglasses	4,543	905.0
6. Occupational Therapy	36	377.0
7. Prosthetic Devices	198	788.0
8. Medical Supplies & Equipment	330	
9. Clinic Services Includes Mental Health Clinics	1,384	3,497.8
10. Physical Therapy	224	152.2
11. Personal Care	96	797.2
12. Non-Institutional Long Term Care	-0-	-0-
13. Inpatient Psychiatric Services	69	3,552.4
14. Intermediate Care for the Mentally Retarded	116	6,983.6
15. Intermediate Care Services	400	17,108.6
16. Individuals Under 21 Not Eligible for AFDC	1,500	1,785.0
17. Skilled Nursing Services for Individuals under 21	14	786.3
18. Aged, Blind and Disabled Individuals	2,766	19,824.8
19. Individuals in a Hospital, Skilled or Intermediate Care Under 300% SSI level	49	2,800.2
20. Individuals Under 21 Under Supervision of the Department	500	595.0

13 Includes Alaska Psychiatric Institute

14 Includes Harborview Developmental Center

16-20 Are Eligibility Groups. The costs shown are included in the above optional services as well as the mandatory Medicaid services.

FY89 Annual Amount based on projection of 12/88.

Alaska's Medicaid Pharmacy Program
(Contact: Eric Hansen - 561-2171)

Goal Statement:

To facilitate the development and implementation of a Medicaid pharmacy program in Alaska by January 1, 1989 which maximizes federal matching funds with minimal financial impact to the pharmacy community; and with minimal adverse impact to the recipient community.

<u>Person</u>	<u>Action</u>	<u>Scheduled Completion Date</u>	<u>Date Completed</u>
All	1) Planning	July 15, '88	July 15
All	2) Steering Committee Nominations	July 20	August 12
E. Hansen	3) RFP's		
	a. Dispensing Fee Survey	July 20	July 22
	b. Pharmacist	August 4	August 5
E. Hansen	4) Proposal Evaluations		
	a. Dispensing Fee Survey	Sept. 1	Sept. 2
	b. Pharmacist	Sept. 10	Sept. 10
E. Hansen	5) Contracts in Place	Sept. 20	Oct. 11
K. Busch	6) Pricing Methodology Determined	Nov. 15	Dec. 10
Orkand	7) TVCC Work Order Submission	Nov. 16	Dec. 10
G. Landes	8) Emergency Regs Submission	Dec. 1	Jan. 16, '89
G. Landes	9) Medicaid Policy Manual Update	Dec. 20	
TVCC	10) Provider Manual Distribution	Dec. 20	Dec. 28
All	11) Program Implementation	Jan. 2, '89	Feb. 1, '89
E. Hansen	12) Contract Pharmacist for Program Administration	Feb. 20	
E. Hansen	13) Drug Cost Audit Required	March 1	
G. Landes	14) Draft State Plan Submitted	March 30	

Steering Committee Purpose:

- 1) Facilitate good communication and data sharing between the pharmacy community and the Department.
- 2) Provide representation for any and all contracting processes that are needed for the pharmacy program effort.
- 3) Produce a report on the program by April 1, 1989.

Steering Committee Membership:

Mark Percus, Kim Busch, Vance Sanders, Bill Larson, Dave Swanson,
For Subject: Eric Hansen, Elmer Lindstrom

(6)

Report of the
Pharmacy Program Steering Committee
January 16, 1989

Introduction:

This report is the product of the committee formed to guide the design, development and implementation of the Alaska Medicaid Pharmacy program, as mandated in the last legislative session.

Enclosed for background information are copies of the minutes of all the committee meetings; letters from the state to federal officials; the dispensing fee survey report; issues summary; contracts involved in the establishment of this program; and a copy of the Alaska State Plan and Regulations.

Mission:

The pharmacy committee was formed and tasked to:

Facilitate the development and implementation of a Medicaid pharmacy program in Alaska by January 1, 1989 which maximizes federal matching funds with minimal financial impact to the pharmacy community; and with minimal adverse impact to the recipient community.

Facilitate good communication and data sharing between the pharmacy community and Department.

Provide representation for any and all contracting processes that are needed for the pharmacy program effort.

Produce a report on the program by April 1, 1989.

Issues:

The primary focus of this effort has been to determine how pharmacies would be paid for dispensing drugs to Medicaid and General Relief Medical recipients.

The two components of a payment system are the dispensing fee (a fee which incorporates all overhead and profit); and the ingredient cost. Both of these components had to be determined as a result of independent accounting surveys of Alaska pharmacies.

The results of the dispensing fee survey show Alaska pharmacies having more than double the overhead of pharmacies nationwide (\$7.17 vs \$3.45). This the state agreed to support.

The actual formula is based on three significant variables: square footage, prescription volume, and percentage of Medicaid prescriptions. The average profit per prescription was found through the survey to be .73 cents. The state agreed to add this amount to the dispensing fee.

Ingredient costs vary widely by pharmacy, but the state's approach is to pay as close to actual cost as is possible to determine from the results of the drug cost survey.

It has consistently been the intent of all parties to this effort to maximize reimbursement to the pharmacy, within the constraints of federal requirements for accountability and reasonableness.

From the outset, all those involved recognized that Alaska's situation was very unique. Not only have we the highest costs in the country, but we have been paying full "asked price" for all prescriptions. The federal position is that government will not pay retail price. So the conflict is apparent and irreconcilable.

However, it is the consensus of this committee that the most favorable terms possible have been developed for the pharmacy program. Particular concern for the smaller pharmacies is alleviated as the formula that arose from the survey data increases payments as size and volume decrease.

The pharmacist members of the committee however, are of the opinion that federal regulators are too restrictive, and that state court action against the federal government would result in a more favorable program.

Also, three states are challenging the federal policies in this area in court. It is the recommendation of this committee that all decisions of this nature be monitored and that state policy be modified, if possible, in the future to more closely reflect the preferred options of variable fees and payment of list catalog price (average wholesale price or "AWP").

Cost/Benefit Analysis:

The total pre-time cost for the contracts to design, develop and implement the Medicaid pharmacy program was \$164,500. Savings through receipt of federal matching funds for the fiscal year ending June 30, 1989 is projected at \$1,000,000 with \$2,500,000 projected to be saved each year thereafter before inflation.

Development Process:

The Committee as a whole has operated in an open, inclusive way with the full participation and cooperation of all parties. Further, it was agreed that all representatives were conscientious in pursuing favorable program terms.

(7)

ALASKA LEGAL SERVICES CORPORATION

419 SIXTH STREET, SUITE 322

JUNEAU, ALASKA 99801

TELEPHONE (907) 586-6425

January 23, 1989

State of Alaska
House HESS Committee

Re: H.B. 70

Dear Committee members:

This letter is about H.B. 70, which will be the subject of a Committee hearing on Wednesday, January 25, 1989. Kim Busch of the Division of Medical Assistance has asked me to convey my views on this bill to the Committee. Unfortunately, I will be out of town and unable to attend the hearing. Please accept this letter as my formal testimony.

I am an attorney for Alaska Legal Services Corporation in its Juneau office. A large part of my practice consists of public benefits work, including medicaid and general relief medical ("GRM") cases. I am also a consumer advocate representative on the Medical Care Advisory Committee and a consumer advocate member of the Pharmacy Program Steering Committee.

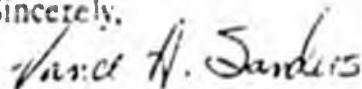
The Pharmacy Program Steering Committee was initiated by the Division of Medical Assistance to provide a forum for interested persons to propose or comment on proposals for implementing Alaska's Medicaid Pharmacy program. As you know, last year the legislature passed a law that moved funding for Alaska's pharmacy program from the G.R.M. (100% state dollars) to the medicaid program (equal state and federal funding). The Steering Committee's task was to bring together the expertise of pharmacists, policy makers, and consumers to formulate the best possible medicaid pharmacy program for Alaska's future pharmacy needs.

I believe the Steering Committee has done just that. In so doing, we held regular meetings which were open to the public. We had a high level of participation, including affected members of urban and rural pharmacies. Throughout this process, the Division of Medical Assistance sought and received valuable input. Once a decision was made on the workings of the program, the Department defended it with the federal bureaucracy.

As the consumer representative on the committee, I implore you to think long and hard before allowing the law authorizing the medicaid pharmacy program to sunset. In FY 90 alone, the state will realize a savings of 2.5 million dollars because of this program. Please do not retrench from a well-conceived and fiscally sound program.

On behalf of all indigent recipients of medical care in Alaska, I thank you for your time and effort on this important issue.

Sincerely,



Vance A. Sanders
Attorney at Law

09 Aug 88

State	Fiscal Year 1988				Fiscal Year 1987				Number of Prescriptions Processed*			
	Dispensing Fee	Copayment	Ingredient Reimbursement Basis	Formulary Status	State MAC	State MAC'd drugs	Vendor Drug Payments	Avg Ingrad- ient Cost Per Claim		Average Price*		
Alabama	\$3.25	.50-3.00	MAC+9.2% AMP	Yes No	C B	Yes No	12 0	\$31,081,371 N/A	\$0.00 No History	\$12.05 21.00	3,210,767 100,000	
Alaska	7.00		--- Alaska's Capitation Plan ---									
Arizona			AMP	Yes	C	Yes	25	\$41,719,545	\$12.97	\$16.32	2,077,274	
Arkansas	\$4.01		EAC	Yes	C	Yes	155	\$369,810,319	\$10.38	\$14.41	27,605,245	
California	\$4.05	\$1.00 (1)	EAC (9)	Yes	C	Yes	200	\$22,444,056	\$15.30	\$10.50		
Colorado	\$3.20	\$1.00	AMP/EAC	Yes	C	No		\$32,603,536	\$11.07	\$14.53	2,696,141	
Connecticut	\$3.55 (2)		AMP	No	B	No		\$4,406,023	\$10.66	\$14.31	197,741	
Delaware	\$3.65		AAC	No	B	No		\$11,120,062		\$14.73	756,647	
Dist of Columbia	\$4.25	\$0.50	AMP (8)	No	B	Yes	(11)	\$116,229,853				
Florida	\$4.23		MAC+7%	No	B	No		\$111,007,153		\$16.59	7,519,597	
Georgia	\$4.26		AMP	Yes	C	Yes	85	\$9,863,075			555,144	
Hawaii	\$3.22		AMP/EAC	Yes	C	No		\$2,920,350	\$9.13	\$12.63	191,791	
Idaho	2.50-3.50		AMP/EAC	No	B	No		\$137,797,393				
Illinois	\$3.47		AMP-7.5%	Yes	C	Yes	(4)	\$75,389,630	\$15.41	\$10.41	4,252,774	
Indiana	\$3.00		AMP-3%	No	B	No		\$33,777,984	\$10.15	\$13.57	2,508,720	
Iowa	\$3.20 (2)	\$1.00	AMP (8)	No	B	Yes	35	\$20,223,950	\$9.67	\$13.46	1,642,180	
Kansas	2.46-4.67	\$1.00	AMP/EAC	Yes	C	Yes	(4)	\$36,446,526	\$6.58	\$9.83	4,084,774	
Kentucky	\$3.25		EAC (8)	Yes	C	Yes	229	\$86,566,603	\$10.66		6,109,545	
Louisiana	\$3.51		EAC	No	B	Yes	733	\$21,086,107	\$11.91	\$15.26	1,316,180	
Maine	\$3.55	\$0.50	EAC (8)	No	B	Yes	32	\$45,330,006		\$16.13	3,250,190	
Maryland	\$3.20	\$0.50 (1)	EAC	No	B	Yes	153	\$89,829,373				
Massachusetts	\$3.22		AMP/EAC	No	A	Yes	(4)	\$129,397,205	\$9.43	\$12.57	10,294,129	
Michigan	\$3.45	\$0.50	AAC (8)	Yes	C	Yes	(4)	\$47,430,102				
Minnesota	\$4.00		AMP-10%	Yes	C	Yes	120	\$47,005,541	\$11.79	\$15.12	3,074,857	
Mississippi	\$3.31	\$1.00	EAC	Yes	C	Yes	(4)	\$46,775,000		\$11.30		
Missouri	\$3.00	.50-2.00	AMP/EAC	Yes	C	Yes	(4)	\$7,837,330				
Montana	2.00-3.75	\$1.00	EAC (8)	No	A	No		\$10,284,744	\$10.20	\$13.20	1,267,284	
Nebraska	4.30-5.12 (2)		EAC (6, 8)	No	B	Yes	395	\$4,751,057		\$10.94	252,304	
Nevada	\$3.95		AMP-10%	No	B	No		\$7,296,685	\$9.42	\$12.32	592,417	
New Hampshire	2.85-3.00	.50-1.00	EAC/AMP	No	B	No		\$104,568,805	\$11.15	\$14.86	8,284,261	
New Jersey	3.63-3.97		EAC (8)	No	B	Yes	132	\$14,689,445	\$13.04	\$15.51	950,400	
New Mexico	\$3.65		AMP/EAC	No	B	Yes	(4)	\$385,312,110	\$10.82	\$13.42		
New York	\$2.60		EAC	Yes	C	No		\$65,511,242	\$13.30	\$16.87	3,004,020	
North Carolina	\$3.05 (1)	\$0.50	AMP/EAC	No	A	No		\$7,516,587	\$10.78	\$14.53	530,620	
North Dakota	\$3.75		AMP/EAC	No	B	No		\$150,570,202	\$9.45	\$12.57	12,302,041	
Ohio	\$3.12		EAC/AMP	Yes	C	Yes	317	\$31,075,000	\$14.60	\$10.09	1,312,660	
Oklahoma	\$3.55 Max		AMP	Yes	C	Yes	(4)	\$21,140,425	\$10.64	\$14.07	1,025,312	
Oregon	3.45-3.75		EAC/AMP	No	A	Yes	300	\$143,387,994	\$11.30	\$14.05	12,120,407	
Pennsylvania	\$2.75	\$0.50	EAC/AMP	No	B	Yes	126	\$14,426,849		\$13.97	1,055,085	
Rhode Island	\$3.40		EAC/AMP	No	B	Yes	28	\$32,385,353	\$12.98	\$16.28	1,089,276	
South Carolina	\$3.30	\$1.00	EAC (8)	No	B	Yes	7	\$5,767,588	\$10.78	\$15.03	354,080	
South Dakota	\$4.25	\$1.00	EAC (8)	No	B	Yes	40	\$80,961,451	\$9.71	\$13.19	6,304,177	
Tennessee	\$4.21		AMP-7%	Yes	C	Yes	150	\$123,297,069	\$11.69	\$15.87	7,597,796	
Texas	1.51		EAC (6, 8)	No	B	Yes	145	\$9,933,605		\$12.39	815,122	
Utah	\$3.40		EAC (8)	No	B	Yes	46	\$8,082,238		\$14.45	550,324	
Vermont	\$2.75	\$1.00	AMP/EAC	No	B	Yes	352	\$55,496,164	\$10.73	\$13.13	4,225,285	
Virginia	\$3.40	.50-1.00	EAC	No	B	Yes	82	\$43,891,312	\$9.15	\$12.55	4,128,011	
Washington	3.05-3.85		8% AMP	Yes	C	Yes	282	\$19,739,981	\$11.91	\$12.66	831,149	
West Virginia	\$2.75	.50-1.00	AMP	Yes	C	No		\$66,232,967	\$8.40	\$12.39	2,847,030	
Wisconsin	\$3.20	\$0.50	AMP/EAC	No	B	Yes	291					
Wyoming			--- No Vendor Drug Program ---						average	\$11.02	\$14.39	* Approx number

PERCENTAGE OF MEDICAID CASES BY RACE AND REGION
for month of 6/88

<u>REGION</u>	<u>Alaska Native</u>	<u>American Indian</u>	<u>Hispanic</u>	<u>Black</u>	<u>White</u>	<u>Asian</u>	<u>Pacific Island.</u>	<u>Other/ Unknown</u>
Anchorage	23.0	1.0	3.3	12.8	53.0	4.6	1.3	.8
Kotzebue	98.9	.2	-	-	.8	-	-	-
Nome	97.0	.2	.2	-	1.5	.2	-	.8
Northern	41.7	1.0	1.8	5.9	47.7	1.2	.3	.3
Southcentral	28.2	.7	1.0	.5	66.9	.4	.9	1.6
Southeast	46.0	1.3	.9	1.1	46.8	1.5	.7	1.6
Southwest	98.3	.1	-	-	1.1	-	.1	-
Total	44.2	.8	1.8	5.9	47.5	2.1	.8	.8

Pharmacy Expenditure Analysis

	Actuals						Projected	
	FY 83	FY 84	FY 85	FY 86	FY 87	FY 88	FY 89 (12/88)	FY 90 (12/89)
Total	1,358.0	1,806.2	2,453.8	2,769.3	2,847.0	3,883.6	3,518.2	4,134.1
GR	196.3	169.5	204.0	268.3	83.5	103.2	85.4	142.4
Medicaid	1,159.7	1,636.7	2,249.8	2,472.0	2,763.5	3,780.4	3,532.8	3,991.7
5%	579.9	819.4	1,124.4	1,244.0	1,381.0	1,890.2	1,766.4	1,995.9
% Change Total		33.15%	35.65%	12.5%	3.14%	36.41%	-6.83%	14.26%
% Change Medicaid		41.30%	37.23%	10.81%	10.89%	32.80%	-6.55%	12.55%
% Change GR		-14.52%	20.35%	31.52%	-65.62%	23.59%	-17.25%	66.74%

FY85 - FY86

Total Cost to the State 14,085.1
 Cost to State had program
 been Medicaid funded 7,041.6

FY89 - FY90

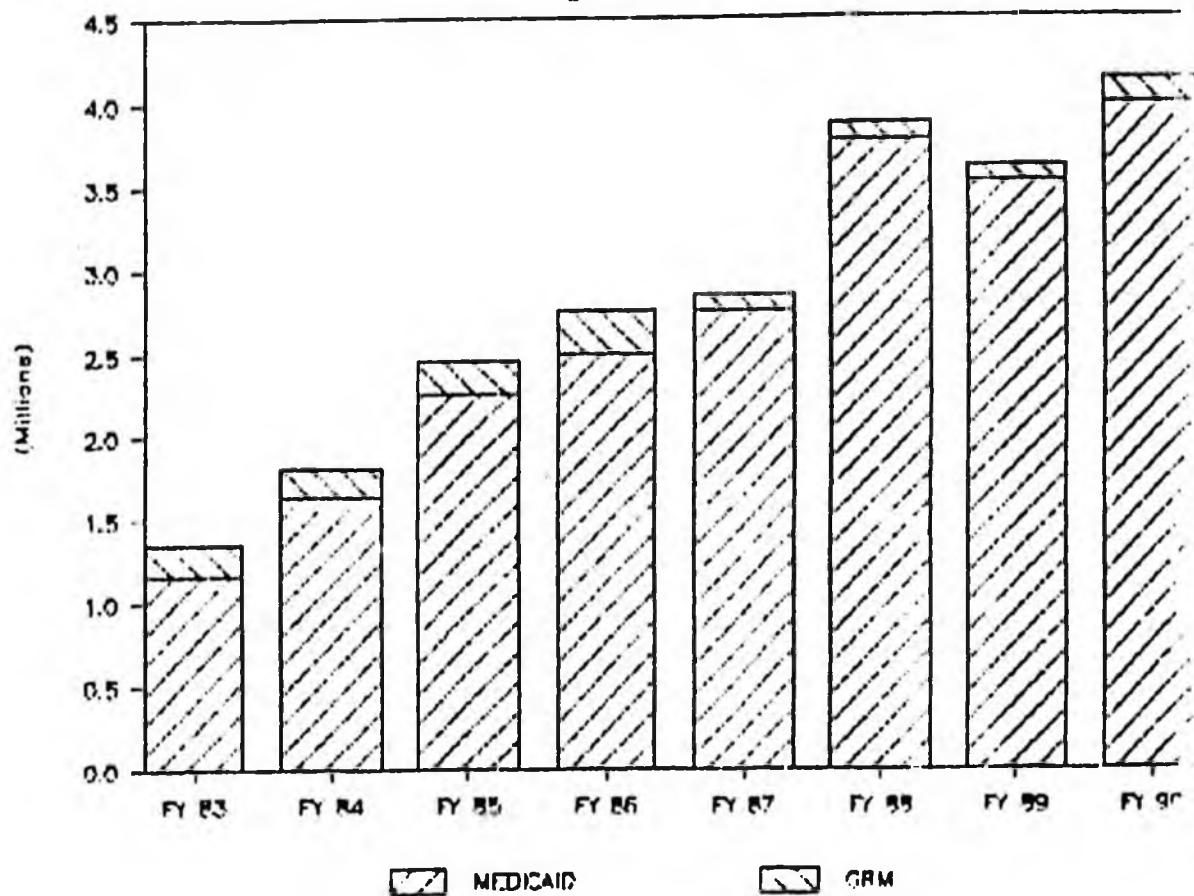
Potential Savings
 if program moved to Medicaid 3,762.3

- .FY 87
- .GR program redefinition
 - .Implement Pharmacy Cost Containment Per Year
 - .8% Copayments
 - In FY 84 107,000 prescriptions were covered. A \$1 copayment resulted in an annual savings of: 177.0
 - .Over the Counter
 - Elimination of over the counter purchases with exception of insulin resulted in a savings of: 61.0
 - .30 day Supply or hand
 - No way to directly measure in the claims payment system. Estimated at: 50.0
 - .Generic Substitution where possible
 - No way to directly measure in the claims payment system. Estimated at: 27.0
- =====
- 415.0

.FY 89 and FY 90 Projections based on 12/88 projection.

PHARMACY EXPENDITURES

25-Jan-89



AFDC	STDS.									
	7/1/81	7/1/82	1/1/83	1/1/84	1/1/85	1/1/86	7/1/86	1/1/87	1/1/88	1/1/89
A1 2	508	516	597	617	638	657	657	665	692	719
3	577	616	674	696	719	740	740	740	776	806
4	634	651	751	775	800	823	823	833	866	899
5	697	750	828	854	881	906	906	917	953	989
6	760	818	905	933	962	989	989	1001	1040	1079
7	823	886	986	1012	1043	1072	1072	1085	1127	1169
EA ADD	63	68	77	79	81	83	83	84	87	90

ANI 1	222	238	238	246	254	261	261	264	275	286
2	445	476	476	492	508	522	522	528	550	572
3	506	544	553	571	589	605	605	612	637	662
4	571	612	630	650	670	688	688	696	724	752
5	634	680	707	729	751	771	771	780	811	842
6	697	748	784	808	832	854	854	864	898	932
7	760	816	861	887	913	937	937	948	985	1022
EA ADD	63	68	77	79	81	83	83	84	87	90

SINGLE ADULT/ PREGNANT WOMAN* 11/1/83	286	308	*359 *382	*391	404	416	416	421	437	453
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**ADDITIONAL INCREMENT FOR INCAP. SPOUSE				**145	**150	**154	**154	**156	**162	**168
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APA	WASKY SUIT									
INDIV. -35	426	426	546	566	586	605	624	632	659	685
+35	526	526								
COUPLE -35	638	638	802	830	859	887	925	937	976	1015
+35	773	773								
M.H.P. NEEDS:	35	70	70	70	70	70	70	70	70	75 75
-INDIV. B			451	466	482	497	516	523	545	567
-B ELIG. COUPLE			660	683	707	730	768	778	811	843
-A COUPLE, 1 INELIGIBLE			660	683	707	730	749	759	791	823
-B COUPLE, 1 INELIGIBLE			518	536	555	573	592	600	625	650
-NURSING HOME 300% CASES				942	975	1008	1020	1020	1062	1104

SSI STANDARDS:										
-INDIV. "A" LVC. ARR.				314	325	336	336	340	354	368
-INDIV. "B" LVC. ARR.				209.34	216.67	224	224	226.67	236	245.3
-COUPLE "A"				472	488	504	504	510	532	553
-COUPLE "B"				314.67	325.34	336	336	340	354.67	368.6
-SSI - LONG TERM N.H.									25 30 30	

APA-SSI RESOURCE LIMITS:										
- INDIVIDUAL				1500	1600	1700	1700	1800	1900	2000
- COUPLE				2250	2400	2550	2550	2700	2850	3000

100% of Federal Poverty Level -c										2/12/85
Alaska Monthly Standard -c										1
										2
										3
										4
										5
										6
										7
										8

AFDC = Aid to Families with Dependent Children
 A1 = AFDC Adult Included
 ANI = AFDC Adult Not Included
 APA = Adult Public Assistance (Old Age Assistance, Aid to the Disabled, Aid to the Blind)
 M.H.P. = Nursing Home Person Needs Allowance
 B = Eligible individual or couple who live in another's household

ANCHORAGE CONSUMER PRICE INDEX
ALL URBAN CONSUMERS

<u>Period</u>	<u>Medical Care</u>	<u>Medical Care Services</u>
FY83 to FY84	4.77%	4.71%
FY84 to FY85	5.02%	4.83%
FY85 to FY86	7.47%	7.76%
FY86 to FY87	14.52%	15.65%
FY87 to FY88	6.8%	7.46%

Percentages displayed represent the percent change from one fiscal year compared to the next fiscal year.

Medical Care - Included in this category is prescription drugs, non-prescription drugs, internal and respiratory over-the-counter drugs, non-prescription medical equipment and supplies.

Medical Care Services - Physician services, dental and eye care services, other medical professional services, hospital and related services, other inpatient costs, and outpatient services.

UNDUPLICATED NUMBER OF MEDICAID RECIPIENTS BY PROGRAM
for June 1988

<u>Assistance Program</u>	<u>Unduplicated Recipients</u>
Old Age Assistance	
Cash	1,939
No Cash	283
Aid to the Blind	
Cash	55
No Cash	0
Aid to the Disabled	
Cash	2,679
No Cash	81
AFDC Children	
Cash	14,064
No Cash	4,692
AFDC Adults	
Cash	6,436
No Cash	563
Program Total	
Cash	25,173
No Cash	5,619
	<hr/>
Total Recipients	30,792

PERCENTAGE OF MEDICAID RECIPIENTS BY AGE
for month of 6/88

<u>AGES</u>	<u>PERCENTAGE of RECIPIENTS</u>
Under 1	4%
1 - 5	21%
6 - 14	23%
15 - 20	9%
21 - 44	28%
45 - 64	6%
65 - 74	5%
75 - 84	3%
85 +	1%

NUMBER OF MEDICAID CASES BY REGION
for month of 6/88

	<u>AFDC</u>	<u>APA</u>	<u>Medicaid Only</u>
Anchorage	2972	1720	1020
Kotzebue	222	175	37
Nome	231	252	55
Northern	1276	919	421
Southcentral	1438	910	581
Southeast	778	601	378
Southwest	691	909	435
	<hr/>	<hr/>	<hr/>
Total	7608	5486	2927

AFDC = Aid to Families with Dependent Children

APA = Adult Public Assistance

Medicaid only = Medicaid benefits with no cash related cash assistance

PERCENTAGE OF MEDICAID CASES BY RACE AND REGION
for month of 6/88

<u>REGION</u>	<u>Alaska Native</u>	<u>American Indian</u>	<u>Hispanic</u>	<u>Black</u>	<u>White</u>	<u>Asian</u>	<u>Pacific Island.</u>	<u>Other/ Unknown</u>
Anchorage	23.0	1.0	3.3	12.8	53.0	4.6	1.3	.8
Kotzebue	98.9	.2	-	-	.8	-	-	-
Nome	97.0	.2	.2	-	1.5	.2	-	.8
Northern	41.7	1.0	1.8	5.9	47.7	1.2	.3	.3
Southcentral	28.2	.7	1.0	.5	66.9	.4	.9	1.6
Southeast	46.0	1.3	.9	1.1	46.8	1.5	.7	1.6
Southwest	98.3	.1	-	-	1.1	-	.1	-
Total	44.2	.8	1.8	5.9	43.5	2.1	.8	.8

nursing facility, and that are—
 (i) Provided by a registered nurse or a licensed practical nurse;
 (ii) Under the direction of the recipient's physician; and
 (iii) Provided to a recipient in his own home or in a hospital or skilled nursing facility.

W Clinic services.

"Clinic services" means preventive, diagnostic, therapeutic, rehabilitative, and other medical services that—
 (1) Are provided to outpatients;
 (2) Are provided by a facility that is part of a hospital but is organized separately to provide medical care to outpatients; and
 (3) Except in the case of nurse-midwives, as specified in § 440.165, are supervised by or under the direction of a physician or dentist.

21050, May 17, 1982)

X Dental services.

"Dental services" means diagnostic, preventive, or corrective procedures provided by or under the supervision of a dentist in the practice of his profession, including treatment

of the teeth and associated structures of the oral cavity; and
 (2) Disease, injury, or impairment that may affect the oral or general health of the recipient.

"Dentist" means an individual licensed to practice dentistry or dental hygiene.

45224, Sept. 29, 1978, as amended at 24888, Apr. 11, 1980)

10 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

"Physical therapy" means services prescribed by a physician and provided to a recipient under the direction of a qualified physical therapist. It includes any necessary supplies and equipment.

"Qualified physical therapist" means an individual who is—
 (1) A graduate of a program of physical therapy approved by both the Council on Medical Education of the American Medical Association and the

American Physical Therapy Association or its equivalent; and

(2) Where applicable, licensed by the State.

(b) *Occupational therapy.* (1) "Occupational therapy" means services prescribed by a physician and provided to a recipient by or under the direction of a qualified occupational therapist. It includes any necessary supplies and equipment.

(2) A "qualified occupational therapist" is an individual who is—

(i) Registered by the American Occupational Therapy Association; or

(ii) A graduate of a program in occupational therapy approved by the Council on Medical Education of the American Medical Association and engaged in the supplemental clinical experience required before registration by the American Occupational Therapy Association.

(c) *Services for individuals with speech, hearing, and language disorders.* (1) "Services for individuals with speech, hearing, and language disorders" means diagnostic, screening, preventive, or corrective services provided by or under the direction of a speech pathologist or audiologist, for which a patient is referred by a physician. It includes any necessary supplies and equipment.

(2) A "speech pathologist or audiologist" is an individual who—

(i) Has a certificate of clinical competence from the American Speech and Hearing Association;

(ii) Has completed the equivalent educational requirements and work experience necessary for the certificate; or

(iii) Has completed the academic program and is acquiring supervised work experience to qualify for the certificate.

143 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980)

§ 440.120 Prescribed drugs, dentures, prosthetic devices, and eyeglasses.

(a) "Prescribed drugs" means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are—

(1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;

(2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

(3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.

(b) "Dentures" are artificial structures made by or under the direction of a dentist to replace a full or partial set of teeth.

(c) "Prosthetic devices" means replacement, corrective, or supportive devices prescribed by a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law to—

(1) Artificially replace a missing portion of the body;

(2) Prevent or correct physical deformity or malfunction; or

(3) Support a weak or deformed portion of the body.

(d) "Eyeglasses" means lenses, including frames, and other aids to vision prescribed by a physician skilled in diseases of the eye or an optometrist.

§ 440.130 Diagnostic, screening, preventive, and rehabilitative services.

(a) "Diagnostic services," except as otherwise provided under this subpart, includes any medical procedures or supplies recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, to enable him to identify the existence, nature, or extent of illness, injury, or other health deviation in a recipient.

(b) "Screening services" means the use of standardized tests given under medical direction in the mass examination of a designated population to detect the existence of one or more particular diseases or health deviations or to identify for more definitive studies individuals suspected of having certain diseases.

(c) "Preventive services" means services provided by a physician or other

licensed practitioner of the healing arts within the scope of his practice under State law to

(1) Prevent disease, disability, and other health conditions or their progression;

(2) Prolong life; and

(3) Promote physical and mental health and efficiency.

(d) "Rehabilitative services," except as otherwise provided under this subpart, includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level.

§ 440.140 Inpatient hospital services, skilled nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for mental diseases.

(a) *Inpatient hospital services.* (1) "Inpatient hospital services for individuals age 65 or older in institutions for mental diseases" means services provided under the direction of a physician for the care and treatment of recipients in an institution for mental diseases that meets the requirements specified in § 482.60(b), (c), and (d) of this chapter and—

(i) Meets the requirements for utilization review in § 482.50(a), (b), (c), and (e) of this chapter; or

(ii) Has been granted a waiver of those utilization review requirements under section 190.3(a)(4) and Subpart H of Part 456 of this subchapter.

(2) "Institution for mental diseases" means an institution that is primarily engaged in providing diagnosis, treatment, or care of individuals with mental diseases, including medical care, nursing care, and related services.

(b) *Skilled nursing facility services.* "Skilled nursing facility services for individuals age 65 or older in institutions for mental diseases" means skilled nursing facility services as defined in § 440.40 that are provided in institutions for mental diseases, as defined in paragraph (a) of this section.

(2) Meet the State plan and payment requirements described in this subpart, as applicable.

(b) *Application of the rule.* The payment methodology used by a State to set payment rates for routine SNF or ICF services must apply to all swing-bed hospitals in the State.

152 FR 28148, July 28, 1987

EFFECTIVE DATE NOTE: At 52 FR 28148, July 28, 1987, § 447.280 was revised, effective October 20, 1987. For the convenience of the user, the superseded text is set forth as follows.

§ 447.280 Hospital providers of SNF and ICF services (swing-bed hospitals).

(a) If the State plan provides for SNF services furnished by a swing-bed hospital, as specified in § 440.40(a) of this chapter, the methods and standards used to determine payment rates must provide for payment for the routine SNF services at the average rate per patient day paid to SNFs for routine services furnished during the previous calendar year.

(b) If the State plan provides for ICF services furnished by a swing-bed hospital, as specified in § 440.150(f) of this chapter, the methods and standards used to determine payment rates must provide for payment for the routine ICF services at the average rate per patient day paid to ICFs, other than ICFs for the mentally retarded, for routine services furnished during the previous calendar year.

Subpart D—Payment Methods for Other Institutional and Noninstitutional Services

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted. Redesignated at 46 FR 47973, Sept. 30, 1981.

§ 447.300 Basis and purpose.

In this subpart, §§ 447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.342 of this subpart implements section 1902(a)(43) of the Act, which permits the State plan to provide for payment to a physician for laboratory services which the physician did not personally perform or supervise. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health

clinic services in accordance with regulations prescribed by the Secretary.

146 FR 48580, Oct. 1, 1981

§ 447.301 Definitions.

For the purposes of this subpart—
“Brand name” means any registered trade name commonly used to identify a drug.

“Estimated acquisition cost” means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

“Multiple source drug” means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

152 FR 28687, July 31, 1987

EFFECTIVE DATE NOTE: At 52 FR 28657, July 31, 1987, § 447.301 was added, effective October 29, 1987.

§ 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.
146 FR 48580, Oct. 1, 1981

§ 447.303 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is available in expenditures for payments for services that do not exceed the upper limits.

NOTE: The Secretary may waive any limitation on reimbursement imposed by Subpart D of this part for experiments conducted under section 402 of Pub. L. 90-428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92-603, and under section 222(a) of Pub. L. 92-603.
146 FR 48580, Oct. 1, 1981, 49 FR 54744, Nov. 4, 1984

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital services and clinic services: Upper limits of payment.

(a) *General rule.* FFP is not available for any payment that exceeds the amount that would be payable to providers under comparable circumstances under Medicare.

(b) *Application of the rule.* Payments by an agency for outpatient hospital services may not exceed the total payments received by all providers from beneficiaries and carriers or intermediaries for providing comparable services under comparable circumstances under Medicare.

152 FR 28148, July 28, 1987

EFFECTIVE DATE NOTE: At 52 FR 28148, July 28, 1987, § 447.321 was revised, effective October 20, 1987. For the convenience of the user, the superseded text is set forth as follows.

§ 447.321 Outpatient hospital services and clinic services: Upper limits of payment.

The agency may not pay more than the combined payments the provider gets from the beneficiaries and carriers or intermediaries for providing comparable services under comparable circumstances under Medicare.

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

DRUGS

§ 447.331 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed the amount that would result from the application of the specific limits established in accordance with § 447.332 if a specific limit has not been estab-

lished for other drugs. Paragraph (b) applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.332 must not exceed in the aggregate, payment for that the agency has determined by applying the lower of the:

(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.332 does not apply if a physician certifies in his or her own handwriting that it is in the best medical interest of a particular recipient.

(2) The agency may decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like “brand necessary” is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

152 FR 28657, July 31, 1987

EFFECTIVE DATE NOTE: At 52 FR 28657, July 31, 1987, § 447.331 was revised, effective October 29, 1987. For the convenience of the user, the superseded text is set forth as follows.

§ 447.331 Drugs: Upper limits of payment.

(a) The agency may not pay more than the lesser of the provider's usual and customary charges plus a reasonable dispensing fee or the general public's usual and customary charges.

(b) Cost must be determined in accordance with § 447.332.

(c) The dispensing fee must be established by the agency under § 447.332.

143 FR 45253, Sept. 29, 1978, as amended by 45 FR 24889, April 1, 1980

§ 447.332 Upper limits for multiple source drugs.

(a) Establishment and issuance of a listing. (1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.

(b) Specific upper limits. The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

[52 FR 28658, July 31, 1987]

EFFECTIVE DATE NOTE: At 52 FR 28658, July 31, 1987, § 447.332 was revised, effective October 29, 1987. For the convenience of the user, the superseded text is set forth as follows:

§ 447.332 Cost of drugs

(a) Multiple source drug. A "multiple source drug" means a drug marketed or sold by two or more manufacturers or labelers of a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name. Except as specified in paragraph (b), the cost of each multiple source drug designated by the Pharmaceutical Reimbursement Board (46 CFR Part 10) and published in the *Federal Register* must be the lower of

(1) The maximum allowable cost (MAC) established by the Board and published in the *Federal Register*, or

(2) The estimated acquisition cost as described in paragraph (c) of this section.

(b) Exception. Certification of brand name drugs. (1) The cost of a multiple source drug is not limited to the MAC if a physician certifies in his own handwriting that, in his medical judgment, a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

(c) All other drugs. (1) The agency must set the cost of all other prescribed drugs at the estimated acquisition cost.

(2) "Estimated acquisition cost" means the agency's best estimate of what price providers generally are paying for a drug.

(3) The basis for the estimate must be the package size providers buy most frequently.

NOTE: To help Medicaid agencies with these estimates, HHS makes available information, on a current basis, on the acquisition cost of the most frequently prescribed drugs.

§ 447.333 State plan requirements, findings and assurances.

(a) State plan. The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) Findings and assurances. Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances

(1) Findings. The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.332(a) of this subpart, are in accordance with the upper limits specified in § 447.332(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart.

(2) Assurances. The agency must make assurances satisfactory to HCFA that the requirements set forth in § 447.331 and 447.332 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) Recordkeeping. The agency must maintain and make available to HCFA, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent information to support its findings and assurances.

[52 FR 28658, July 31, 1987]

EFFECTIVE DATE NOTE: At 52 FR 28658, July 31, 1987, § 447.333 was revised, effective October 29, 1987. For the convenience of the user, the superseded text is set forth as follows:

§ 447.333 Dispensing fee.

(a) The agency may set the dispensing fee by taking into account the results of surveys of the costs of pharmacy operation. The agency must periodically survey pharmacy operations including

- (1) Operational data;
(2) Professional services data;
(3) Overhead data; and
(4) Profit data.

(b) The dispensing fee may vary according to -

- (1) Size and location of pharmacy;
(2) Whether the drug is a legend item (for which Federal law requires a prescription) or nonlegend item; and
(3) Whether the drug is dispensed by a physician or an outpatient department of an institution.

(c) The dispensing fee may also vary for drugs furnished recipients in institutions by a pharmacy using a unit dose system. In those cases -

- (1) The dispensing fee is added to the ingredient cost of the drug actually used; and
(2) The fee is either -
(i) An amount added to the cost of each unit dose; or

§ 447.331 Upper limits for multiple source drugs.

(a) Establishment and issuance of a listing. (1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.

(b) Specific upper limits. The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

[52 FR 28658, July 31, 1987]

EFFECTIVE DATE NOTE: At 52 FR 28658, July 31, 1987, § 447.331 was revised, effective October 29, 1987. For the convenience of the user, the superseded text is set forth as follows:

§ 447.331 Upper limits for multiple source drugs.

(a) Establishment and issuance of a listing. (1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.

(b) Specific upper limits. The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by HCFA that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

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[52 FR 28658, July 31, 1987]

Report
On the Cost of Dispensing
Pharmaceutical Prescriptions
In the State of Alaska

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December 1988

The big lie about generic drugs

As patents on some best-selling prescription drugs run out, the makers have turned on a propaganda war against their generic competitors.

The goal: To make sure you keep paying top dollar.

In 1983, a group of New York legislators tried to save consumers money by changing the prescription forms used by the state's doctors. Under their proposal, patients would receive a generic drug from pharmacists unless the doctor wrote "dispense as written" when prescribing a brand-name drug. Prescription drugs marketed under their generic names often are half the price of the same drug sold under a brand name—the name given it by the company that held the original patent.

Three of America's largest drug companies—American Home Products, Bristol-Myers, and Hoffmann-LaRoche—sent key legislators a "Memorandum in Opposition." It featured aerial photos of two modern "major pharmaceutical manufacturers" played against a ground-level shot of "a New York City generic manufacturer." The latter photo focused on a garbage-strewn vacant lot. "We would appreciate your contrasting their facilities," the memo said, "and question whether you believe [they] can uniformly produce identical drug products."

That was the opening salvo in the latest round of a long war waged by the makers of brand-name drugs against the generic-drug firms that compete with them. The brand-name companies dominate the \$25-billion annual market in prescription drugs. They barrage legislators, doctors, pharmacists, and consumers with an unrelenting message: Generic drugs are low in quality and may harm you.

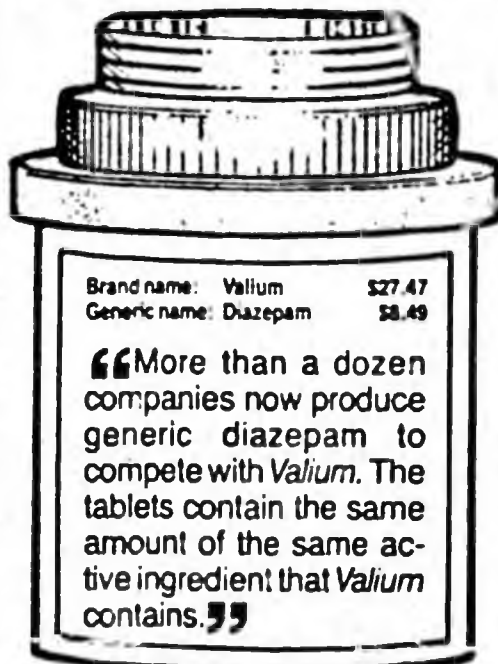
Few distortions in the history of commercial propaganda have cost consumers more money than that one.

Who makes what?

The 59 firms that make brand-name drugs are called "innovator" drug companies. Each of them devotes millions of dollars a year to developing new drugs and ushering them through a long testing and approval process. When an innovator's drug is finally approved, the company gives it a brand name like *Valium* or *Inderal* and then spends millions more promoting it. As a reward for its investment,

the innovator earns a patent that protects the drug from competition, usually for at least a decade.

When the patent expires, any pharmaceutical company can apply for Federal approval to produce its own version of that drug and market it under the drug's "generic" name—diazepam rather than *Vali-*



um, for example, or propranolol rather than *Inderal*.

Most generic drugs are manufactured not by fly-by-night factories operating next to garbage dumps but by the very same companies that develop brand-name drugs. Indeed, the 59 brand-name drug companies manufacture about 80 percent of all generic drugs as well. Some 300 smaller pharmaceutical companies scramble for the rest of the generic market.

More than a dozen companies now produce generic diazepam to compete with *Valium*, which is made by Hoffmann-LaRoche. These manufacturers include not only generic companies but also two of the largest innovator firms, American Cyanamid and Warner-Lambert. The tablets differ from *Valium* in color and shape,

and in the inactive "excipients" used to formulate all tablets. But they contain the same amount of the same active ingredient that *Valium* contains.

For the innovator companies, however, the big profit is in their brand-name products, not their generic sidelines. And the main price competition for those high-profit brands comes not from other innovator companies but from the smaller generic firms, which commonly charge the lowest prices.

Thus brand-name firms "would have you believe that only they make that magic formula," says a senior official at the U.S. Food and Drug Administration. "But they don't. And frankly, what's required is not all that complicated."

Quality: The crucial issue

FDA inspectors visit all drug-manufacturing facilities to insure they meet standards for equipment, workplace cleanliness, and drug quality, purity, and strength. "In most instances," says the FDA, "the generic firms have modern, state-of-the-art equipment and plants that compare favorably to or even surpass those of innovator companies."

But the real proof of generic quality resides in the pills themselves: Do they work as well as their brand-name counterparts? Independent experts we've consulted say the answer is yes. They cite FDA's approval standards as the reason.

Currently, generic-drug approval differs from new-drug approval in one major way: The maker of a generic drug no longer has to carry out clinical studies to establish safety and efficacy for drugs introduced since 1962. Such studies, says the FDA, merely redemonstrate what's already known from the original manufacturer's studies. Instead, a generic manufacturer must prove to the FDA that it has formulated the product correctly, using the same amount of the identical active ingredient in the brand-name version.

If the generic is made well, it will be absorbed into the bloodstream as rapidly and completely as the brand-name product it matches. The FDA test required for dem-

onstrating that is called a bioequivalence study, a far more sophisticated procedure than the tests the agency used in earlier years for pre-1962 drugs. The generic manufacturer carries out this study on 20 to 24 healthy men. Typically, the men are first given a single dose of the generic product. Technicians take blood samples at timed intervals and then determine the amount of drug in each blood sample. These values are plotted over time, producing a "bioavailability curve" that describes the absorption of the drug into the bloodstream.

Later the same procedure is repeated on the same subjects, this time using the brand-name product. If the generic drug's bioavailability curve closely matches that of the brand-name drug, the FDA will approve the product. A drug that's bioequivalent to another should have the same therapeutic effect.

Bioequivalence tests enable generic companies to market their products relatively quickly and inexpensively. Rankled by that competition, the brand-name companies publicly attack the validity of the tests. Yet brand-name firms rely on bioequivalence testing themselves. Many of them reformulate their own products from time to time, adding a new coating or changing the inactive ingredients. Not surprisingly, they don't want to spend millions of dollars on clinical studies to show that the newly formulated pill also works.

Instead, they do what generic firms do—carry out a bioequivalence test comparing the new formulation with the old. They then submit their data to the FDA for approval. Bristol-Myers has gotten 105 of its formulations approved this way; American Home Products, 86; Hoffmann-LaRoche, 13.

When evaluating bioequivalence, the FDA looks at two things: how much of the drug is absorbed into the bloodstream and how fast. The generic must match the brand-name drug closely, but it needn't be identical. That's because two formulations of the same drug can vary slightly in their absorption and still work equally well in the body. Most pharmacological experts agree that differences of less than 20 percent are not clinically significant for most drugs. If a generic drug differs by more than 20 percent in either the speed or amount of absorption, the FDA won't approve it.

This allowable difference is called the "plus-or-minus 20 percent rule." The brand-name companies insist that the variability allowed for generics is much too great. They've distorted the carefully established rule into a scary hypothetical situation that goes like this:

A patient takes Generic X, whose bioavailability tested out as 120 percent of the

brand-name's. That patient's prescription is then refilled with another version of the drug, Generic Y, whose bioavailability is 80 percent of the brand-name's. The change from 120 percent to 80 percent means a 33 percent decrease in bioavailability—and, it's claimed, drug therapy that may no longer be effective. Brand-name companies call this scenario "the dangers of indiscriminate interchange."

This scenario sends a clear message to doctors: Generics may differ from each other in bioavailability. So play it safe and stick with the dependable brand-name product.

Actually, the differences are extremely small. The FDA recently reviewed all new generics it has approved since 1984. It calculated that the average difference in bioavailability between brand-name drugs and their generic copies is only 3.5 percent—no greater than the difference between one batch of a brand-name drug and another batch off the same assembly line. So far, about 5000 generics have been approved as bioequivalent to brand-name products. The FDA recently stated that it's not aware of a single documented case in which any of the 5000 generics has caused a treatment problem.

Those claiming it's dangerous to switch from one generic to another "are fooling themselves and, more importantly, fooling the public," says Dr. Leslie Benet, president of the American Association of Pharmaceutical Scientists.

The only exceptions, say CU's medical consultants, are a few "critical" drugs that have a narrow range between blood levels that are ineffective, effective, or toxic. These drugs include digoxin (*Lanoxin*), levothyroxine (*Synthroid*, *Levothroid*), and warfarin (*Coumadin*). For this small number of drugs, blood levels should be monitored when patients switch from one formulation to another.

The threat of competition

Over the past decade, organizations that pay health-care bills—the Federal Government, the states, and insurance companies—have sought ways to brake the rapid rise in health-care costs. In this climate, lobbying efforts by generic companies stimulated Congress to consider legislation that would make lower-priced generic drugs more widely available. The result was a new Federal law, the Drug Price Competition and Patent Term Restoration Act of 1984.

The law represented a painstaking compromise between the generic drug companies and the Pharmaceutical Manufacturers Association, the trade association that represents the innovator drug companies. The innovator companies got what they wanted: longer patent protection on new drugs. Generic companies, in turn, won the right to eventually market the same chemical under its generic name without having to prove again what the innovator companies had already proven—that the

If the price is right . . .

Many of the best-selling prescription drugs are now available in generic form. Below are recent retail prices for brand-name and generic versions of 11 of the most frequently pre-

scribed drugs, as posted by a major national pharmacy chain. Overall, the brand names cost 70 percent more than the generics. In the case of Valium, the difference is 223 percent.

Brand name	Generic name	Dosage	Retail price*	
			Brand	Generic
Amoxil	amoxicillin	250 mg	22.46	8.52
Ativan	lorazepam	1	31.99	17.99
Darvocet-N 100	propoxyphene	100	28.01	17.88
	acetaminophen	650		
Dilantin	phenytoin	100	7.49	5.79
EES 400	erythromycin ES	400	17.99	14.97
Inderal	propranolol HCL	40	19.56	10.49
Keflex	cephalexin	250	77.34	48.99
Lasix	furosemide	40	15.74	5.89
Motrin	ibuprofen	600	18.25	8.93
Tylenol No. 3	acetaminophen	300	14.89	6.88
	codeine	30		
Valium	diazepam	5	27.47	8.49

*For 100 tablets or capsules.

chemical works. Until the 1984 law, the need to redo costly clinical trials for drugs introduced since 1962 had effectively barred generic companies from marketing some of the most frequently prescribed drugs in medicine. Already, the law has helped spur the introduction of generic competitors for many of the leading brands. (See the table on page 481.)

The increased competition promises special benefit to consumers who pay for prescription drugs completely out of their own pockets, including the majority of people 65 or older. Suppose you were a diabetic taking *Diabinese*, Pfizer Labs' brand of chlorpropamide, a drug that reduces blood-sugar levels. A major national pharmacy chain charges \$31.54 for 100 tablets of *Diabinese*. By contrast, the same chain charges \$7.59 for 100 tablets of generic chlorpropamide. If you were taking one tablet per day, the cost would be about \$115 a year for *Diabinese*, versus about \$28 for the generic version.

A recent Federal Trade Commission report estimated that, in 1984 alone, generic drugs saved consumers approximately \$236-million. Such savings are especially important to anyone who must take drugs regularly, as elderly people often do. People over 65 constitute 12 percent of the population but consume about 30 percent of all prescription drugs.

The campaign against generics

Beginning in 1983, with increased price competition from generic companies in sight, the major pharmaceutical firms opened a campaign of disparagement that continues to this day, confusing and frightening doctors, pharmacists, and patients alike.

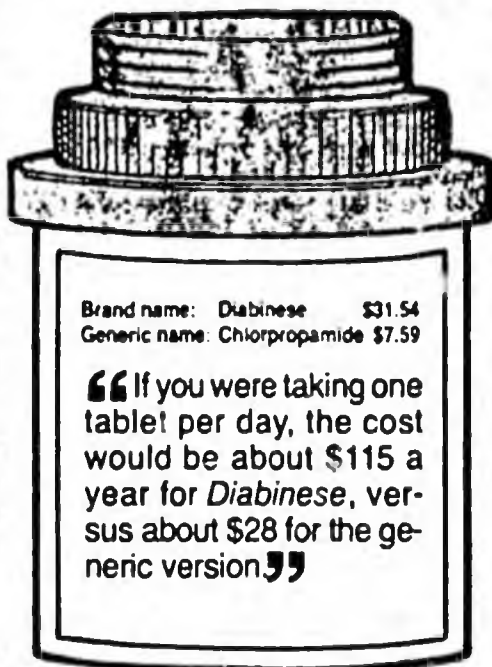
Consider the propaganda put out by Ayerst Laboratories, a division of American Home Products, when it realized it would soon face competition from generic versions of *Inderal*, its brand name for propranolol, a drug used for hypertension and other disorders. *Inderal* rang up yearly sales of \$350-million and was Ayerst's most profitable drug.

Ayerst Laboratories, like all major drug companies, employs hundreds of sales representatives, called "detail persons," who make the rounds of doctors' offices. Just before generic propranolol became available, Ayerst indoctrinated its sales force with a "sales simulation" videotape. It shows a detail person telling a doctor that patients on *Inderal* "are high-risk patients," who "need *Inderal's* proven therapeutic efficacy." With a generic propranolol, the doctor is told, "there's always that chance that patient response may be compromised."

Lest the doctor dare compromise the patient's treatment by permitting the

pharmacist to substitute a cheaper propranolol for the high-priced brand, Ayerst also sent out "Dear Pharmacist" letters. They discussed a pharmacist's "potential liability" if generic propranolol were dispensed instead of *Inderal* and something went wrong. The letter warned of "troublesome and expensive" lawsuits that would "generate adverse publicity."

The letter was labeled false and misleading by the FDA. "It serves only to confuse and intimidate pharmacists into



dispensing only *Inderal*... by suggesting unknown perils," the agency wrote in a regulatory notice it sent to Ayerst. Laws in most states protect pharmacists from incurring any increased liability when they dispense an approved generic product.

The FDA has challenged similar "Dear Pharmacist" and "Dear Doctor" letters sent by other companies, including Sandoz and A.H. Robins. The FDA regards such letters from drug firms as part of a drug's labeling; the agency can thus take action when a letter is false or misleading. But the FDA has no authority over similar letters sent by "public interest" groups.

A passion for "education"

In the summer of 1985, California pharmacists received a notice headlined "Generic Alert!!!!" It was sent by Pharmacists Planning Service Inc., a nonprofit educational organization headed by Frederick S. Mayer, a Sausalito pharmacist. Pharmacists were warned of lawsuits that could arise if they didn't dispense "brand-name propranolol." A short time later, Mayer received a \$10,000 check from Ayerst "to support the educational goals of the Pharmacists Planning Service."

Another Ayerst "educational" grant

went to the Philadelphia College of Pharmacy and Science, the country's oldest pharmacy school. In exchange, the college agreed last year to sponsor a new organization with the avowed aim of educating professionals and the public about "the critical role research-intensive pharmaceutical firms play in preserving health care." The organization's educational thrust tended to run in a narrow groove. "Pharmaceutical research... is threatened by widespread consumer use of generic drugs," said its press release. Increased generic drug use, it said, "could be catastrophic." The college disbanded the organization six months after its creation because the antigeneric theme had become so dominant.

Ayerst now gets its message across through a speakers bureau staffed by doctors and pharmacology professors. Ayerst pays them to travel around the country on media tours. By CU's count, the tours have resulted in at least 25 newspaper articles, with headlines such as "Warning Sounded on Generic Drugs," and "Some Doctors Still Uneasy About Generics." The articles often omit the speakers' affiliation with Ayerst.

Such antigeneric campaigns now occur with "predictable regularity," says Dr. Peter Weinstein, director of the FDA's office of drug standards. "Every time a brand-name drug becomes vulnerable to generic competition, the makers do whatever they can to protect their market."

The campaigns seem to have an impact. Surveys show that doctors, pharmacists, and consumers prefer brand-name drugs over generics. According to a 1985 Federal Trade Commission report, when prescriptions gave pharmacists a choice between dispensing a brand-name drug or its generic equivalent, they dispensed the generic only about 15 percent of the time. Their reluctance stemmed partly from fear of liability, the FTC report found.

The FTC report also found that consumers tend to "equate price with quality," especially for "high perceived risk" products like drugs. Doubts about generics make some consumers refuse them or even switch to a different pharmacy—another reason pharmacists haven't embraced generics.

A case of epilepsy

Last April during a Congressional hearing, Gerald Mossinghoff, president of the Pharmaceutical Manufacturers Association, was asked if he could assure consumers that generics were as effective as brand-name drugs.

He could not. "We have trouble with the Food and Drug Administration's tests for generic drugs," said Mossinghoff. "In some cases that test, we think, is not

sharply defined. It led, for example, in November to the Epilepsy Institute putting out a physicians' alert saying some anti-convulsive drugs were *not* effective. So I am not in a position, Congressman, to give you that assurance."

The Epilepsy Institute is a nonprofit organization in New York City. On November 3, 1986, the institute issued a three-page medical-alert bulletin, "GENERIC MEDICATIONS LINKED TO RENEWED SEIZURE ACTIVITY IN PEOPLE WITH EPILEPSY," read the headline. The bulletin warned against generic versions of three brand-name drugs: *Tegretol*, *Dilantin*, and *Depakene*, made by Ciba-Geigy, Warner-Lambert, and Abbott, respectively. The warning went to 7000 physicians and to some 100 media outlets.

The Epilepsy Institute's bulletin has been cited many times as proof that generic drugs can endanger health.

Boston's CBS affiliate broadcast a segment, seen by 300,000 people, that began, "Well, the health of nearly five million people with seizure disorders might be in jeopardy now because of a generic drug that's been approved by the FDA." Articles conveying the warning appeared in *Medical World News*, *Woman's Day*, the *Boston Globe*, the *Arizona Republic*, and other publications.

Four months earlier the Epilepsy Institute's president, Ira Brody, had written a letter soliciting money from three drug companies: Ciba-Geigy, Warner-Lambert, and Abbott. In his letter, Brody listed various institute "programs" that needed financial support: educational pamphlets for drugstores, seminars for physicians, and the institute's *New York Journal of Epilepsy*, which needed advertising so it could appear quarterly.

Brody scored with all three firms. Ciba-Geigy agreed to pay \$4000 for a five-page ad in the Spring 1987 issue of the journal. Warner-Lambert agreed to advertise in the Summer 1987 issue. Abbott would sponsor the Fall 1987 issue and would also donate \$22,000 for brochures and another \$8000 to sponsor a seminar.

Brody said there was "no connection whatsoever" between their contributions and the decision to issue the medical-alert bulletin. "It's just doing good fund-raising," Brody said. "We solicit funds from companies that have a vested interest in us," he said.

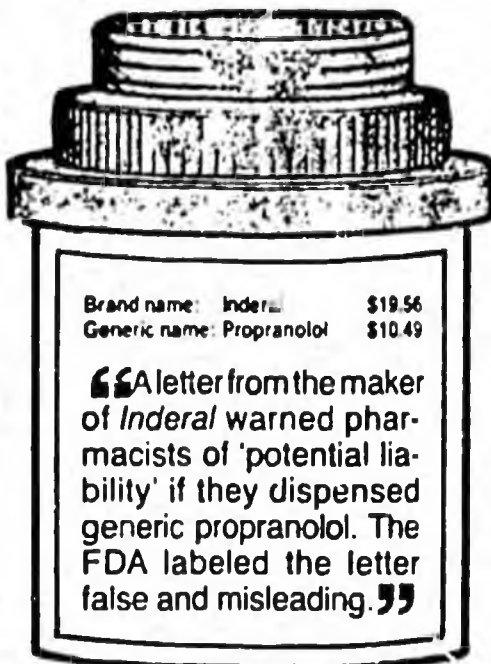
The Epilepsy Institute decided to sound the alarm, its bulletin said, "after receiving and confirming scores of reports" showing that seizure-free epileptics had convulsions after being "switched from brand-name pharmaceuticals to generics."

Scores of reports? A "typist's exaggeration," Brody acknowledges. He now says the actual number of cases was 23. The in-

stitute "confirmed" eight of those, says Brody.

The bulletin quoted Dr. Hart deC. Peterson, professor of neurology and pediatrics at New York Hospital-Cornell Medical Center and former chairman of the Epilepsy Institute's professional advisory board. CU asked Peterson about the reports. "They're hearsay," he said, "but the inclination is to believe at least some of it."

"If I get any good solid cases and I could prove them, I certainly would," Peterson



said. "I personally haven't seen any really good cases where switching to a generic has caused problems."

The bulletin prompted the FDA to contact Peterson. In a November 21 letter, the agency asked him for "all available data that you have on these alleged therapeutic failures." It offered to send an investigator to look at records. As of this writing, Peterson hasn't replied.

Dinner, then a slice dish

Meanwhile, foes of generic drugs were having a field day with the Epilepsy Institute's bulletin. Ciba-Geigy, maker of *Tegretol*, paid eight New York neurologists \$100 each to attend a dinner discussion of their product. While the restaurant served pasta, Ciba-Geigy served up the Epilepsy Institute's medical-alert bulletin.

"It made us feel anxious about switching our patients to a generic drug," said a doctor who was present. "After all, this reputable institution had issued the alert."

The *Medical Tribune*, a medical-news tabloid that is mailed free to more than 100,000 doctors, gave the story page-one treatment. The paper, which has long crusaded against generic drugs, had been published until recently by Dr. Arthur

Sackler, who died last May. Sackler concurrently owned an advertising agency that serves many innovator drug firms.

Dr. Louis Lasagna, one of the nation's most outspoken opponents of generic drugs, also stressed the epilepsy theme in a debate presented in *USA Today*. Lasagna is dean of Tufts University's Sackler School of Graduate Biomedical Sciences.

"Doctors," he said, "hear stories, like those from the Epilepsy Institute, and are justifiably concerned. It only takes a few cases to engender anxiety."

That, of course, is the purpose of such anecdotal reports.

Another nonprofit organization has also fronted for a major drug company in spreading fear of generics. Last December, local news shows on 23 television stations ran a chilling two-minute segment that featured an 11-year-old girl clutching her throat as she demonstrated what happened when she was switched from her brand-name asthma medication to a generic version. "It's like someone strangling you," said the girl, Billie Bloom, of North Hollywood, Calif. "And it hurts, and you can't get enough air through."

The reporter concluded with this advice: "If you take a medication for a chronic illness—diabetes, asthma, epilepsy, or heart disease—you should ask your physician to indicate—in writing—'Dispense As Written' or 'Do Not Substitute' on your next prescription."

The story was seen by an estimated 1.3 million people. News? No. It was a "video news release"—a commercial message masquerading as news. The sponsor of this commercial message was listed as the "Asthma and Allergy Foundation of America, Los Angeles chapter." But its \$30,000 cost was paid by Key Pharmaceuticals. Key (now part of Schering-Plough Corp.) makes *Theo-Dur*, a drug for asthma. *Theo-Dur* had lost 20 percent of its \$100-million a year market to the generic product vilified in the commercial.

Schering-Plough claims that the commercial message was an "important public service announcement." But the Asthma and Allergy Foundation feels differently. "The Los Angeles chapter saw it as an opportunity to get some publicity," said David Branson, president of the national foundation. "But it was a mistake. They shouldn't have done it."

CU recently spoke with one of Billie Bloom's doctors. He reported that the girl's physicians made no effort to confirm that the generic drug was actually the cause of her breathing problem.

The FDA has followed up on these publicized reports of "bad" generics. According to FDA's Rheinstein, the result is always the same: "You ask for documentation and you get evasion." Yet

such reports proliferate. FDA officials say that these anecdotes are now a key part of the antigeneric campaign. By having a non-profit organization spread the word, the drug company avoids FDA charges of deceptive advertising.

Getting the message across

Promotional efforts, whether deceptive or not, are the lifeblood of the prescription-drug business. Major drug companies generally spend more each year on promotion than on research. Most of that promotion money is lavished on doctors, and it has an impact.

"Most doctors are brainwashed," says the director of medicine at a hospital in Westchester County, N.Y. "I know some very intelligent practitioners who always prescribe brand-name medications and would never think of prescribing a generic product."

Years ago, doctors had some cause to be wary of generic drugs. In 1969, millions of capsules of ineffective tetracycline were recalled. In 1971, problems were reported involving a generic version of digoxin. Now, however, the FDA's more rigorous generic approval process makes such failures extremely unlikely.

Isolated cases of illegal generics have also influenced doctors' perceptions. In 1979 the FDA found that three firms were illegally marketing unapproved and ineffective versions of furosemide, a diuretic. To this day, many doctors still refuse to prescribe generic furosemide, turning instead to the more expensive brand-name drug, Lasix.

Problems with low-quality or illegal generics have been extremely rare. But doc-

tors remember those incidents. And innovator companies try to make sure they never forget.

The effort to influence doctors starts while they are still in training. To familiarize interns and residents with their brands, companies practically give drugs away to hospital pharmacies. (See "How do drugs become 'the ones hospitals use most?'" CONSUMER REPORTS, June 1987.)

The practicing physician encounters drug-company influence everywhere. Drug companies sponsor seminars, conferences, breakfasts, luncheons, dinners, and awards. They give away books, slides, and audio and video tapes. They entertain lavishly at medical conventions. (For a recent meeting of the American Academy of Family Physicians, SmithKline Beckman rented Disneyland for an evening to entertain doctors and their families.)

A major part of a drug company's promotional budget goes to two areas: advertising in medical journals and fielding a marketing sales force.

In leafing through the journals, a doctor will encounter thousands of ads each year. They rarely mention drug prices. As a result, most doctors know very little about the cost of the medicines they prescribe.

Drug company sales representatives provide doctors with much of the information they receive about drugs. They also give doctors free drug samples as well as pens, scratch pads, prescription pads, calendars, and other merchandise.

But increasingly, sales reps influence doctors in other ways. Ciba-Geigy, for example, places special emphasis on "Peer Influence" programs. They're designed to get physicians to influence other physi-

cians. Ciba-Geigy spends more than \$6-million a year on such activities.

One type of program involves clinical conferences. Here, a sales rep gets a group of doctors together for lunch or dinner. They're shown a videotaped case history and then asked for their ideas on possible therapy. The idea, a sales rep says, is to include at least one or two doctors who use the Ciba-Geigy product. That way, "they can tell success stories of their therapy that may rub off" on the other doctors.

Then there are the seminars in paradise. Large firms regularly send the nation's most influential specialists and their spouses on all-expense-paid trips to tropical climes. Last year, for example, Ciba-Geigy flew 100 gynecologists to Cancun, Mexico, to bone up on *Estraderm*, the company's new estrogen skin patch.

In 1985, the top 50 pharmaceutical companies officially spent \$1.26-billion on "promotion," according to industry sources. But the total amount spent to influence doctors is actually far greater. According to FDA sources, drug companies often charge heavily promotional activities, such as costs on entertaining and the far-flung seminars, to their education or research budgets. The FDA sources estimate that total promotional spending by major drug companies exceeds \$4-billion a year, or almost \$9000 per doctor.

Casualties of the campaign

The antigeneric campaign numbers many consumers among its casualties. Some are patients who pay brand-name prices for medication available for a fraction of the cost. But the casualties also include all taxpayers.

Medicaid pays the prescription bills of many low-income people—and those costs are shared by the Federal Government and the states. The New Jersey Health Department recently reported on the cost of 2.6 million Medicaid prescriptions the state had paid for in 1985. All of the drugs were available in both brand-name and generic form. Each brand-name prescription cost the state an average of \$12.39; the average generic prescription cost \$6.66.

Recommendations

To realize the savings offered by generic drugs, you need the cooperation of both your doctor and your pharmacist.

Doctors usually write the brand name when they prescribe drugs. It's shorter and easier to remember than the generic name. And since the brand name had no generic competition during the long life of its patent, the doctor is probably accustomed to writing it.

That medical habit doesn't prevent you from buying generically. The laws in all 50

The empty research argument

Many doctors prescribe brand-name drugs to reward the companies that develop them. They figure the company will use the sales income on research that will lead to better drugs in the future.

Innovator companies encourage this attitude among doctors. They want the increased sales of generics will cut into their profits and prevent them from investing in the necessary research. But a recent Congressional study suggests that research doesn't get top priority.

Earlier this year, the House subcommittee on health and the environment investigated recent hikes in prescription-drug prices—a 12% percent increase between July 1985 and April 1987 versus only a 2.7 percent in-

crease in the Consumer Price Index during that time).

The subcommittee staff obtained revenue data from the nation's 25 largest drug companies and prepared a report. Subcommittee chairman Henry Waxman summarized the findings at a hearing last April.

"Most of the money generated by the recent enormous price increases is not going to fund R&D. Between the years 1962 and 1986, drug-price increases produced revenue gains of \$4.7 billion. During the same period, R&D expenditures rose only \$1.6 billion—or about a third of the revenue gains from price increases.

"In short, the money was arriving in backyards, but was going to R&D in sporadic amounts," Waxman said.

states allow pharmacists to substitute a less expensive generic version when the doctor prescribes by brand. Indeed, the doctor must make a conscious effort to limit you to the brand name. In some states, that means he or she must write out "dispense as written" or some other phrase. In other states, the doctor chooses which of two lines on the prescription form to sign. Signing on one line means the patient must receive the brand specified; signing on the other means the pharmacist may substitute a generic.

The major drug companies lobby fiercely for two-line prescription pads. Doctors seldom bother to write out "dispense as written"; but studies show that when doctors must merely choose one of the two lines, they sign the brand-name line more than half the time.

Some drug companies try to make the choice for both patient and doctor. They give doctors preprinted prescription pads with the brand name and the words "dispense as written," in the doctor's handwriting, on each form. This "professional courtesy" sticks you with the brand-name drug and its premium price. It's also considered illegal in several states.

Your doctor, therefore, may represent a hurdle to your getting a generic drug. You must explicitly ask your doctor to write the prescription so that it permits a generic version to be dispensed.

What if your doctor doesn't know whether a generic version of the drug you need is yet available? That doesn't matter; the pharmacist will know. Whether the pharmacist will dispense the generic is a different question. Pharmacists should jump at the chance, since they usually make a greater profit on generics than on brand-name drugs. But drug-company propaganda has led many pharmacists to fear that dispensing generic drugs may result in lawsuits.

So once again, you must take the initiative. Tell your pharmacist that you want the least expensive version of the drug that's been prescribed for you. Usually, that will be the generic version. But occasionally the brand-name version may be cheaper—if the pharmacist has gotten a special deal from the maker, for example.

Drug prices vary widely from pharmacy to pharmacy. So shop around, checking both chain stores and independent pharmacies. Many pharmacies now give out price information over the phone.

If you switch from a brand-name to a generic, don't worry if its color and shape are different from the brand-name product you've been taking. (Brand-name makers sue generic firms whose products duplicate the appearance of brand-name drugs.) Keep in mind that the pill's appearance won't affect how the drug works. ■

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State	Fiscal Year 1980				Formulary Status		#State HAC'd drugs	Vendor Drug Payments	Avg Ingrad- ient Cost Per Claim	Average Prescription Price*	Number of Prescriptions Processed
	Dispensing Fee Copayment	Ingredient Reimbursement Rate	Formulary	State MAC	Formulary Status	State MAC					
Alabama	\$3.75	.50-3.00	MAC-9.2%	Yes	C	Yes	17	\$31,001,371	\$8.00	\$12.05	3,710,767
* Alaska	7.40		AWP-5%	No	B	No	0	N/A	No History	21.00	130,000
Arizona	--- AHCCCS Capitation Plan ---										
Arkansas	\$4.01		AMP	Yes	C	Yes	25	\$41,719,545	\$12.97	\$16.32	2,877,274
California	\$4.05	\$1.00 (1)	EAC	Yes	C	Yes	155	\$369,810,119	\$10.30	\$14.43	27,605,245
Colorado	\$3.70	\$1.00	EAC (9)	Yes	C	Yes	200	\$22,444,056	\$15.10	\$10.50	
Connecticut	\$3.55 (2)		AMP/EAC	Yes	C	No		\$37,603,536	\$11.87	\$14.53	2,696,141
Delaware	\$1.65		AAC	No	R	No		\$4,406,023	\$10.66	\$14.31	197,241
Dist of Columbia	\$4.25	\$0.50	AMP (8)	No	B	Yes	(11)	\$11,120,062		\$14.73	756,647
Florida	\$4.23		MAC-7%	No	B	No		\$116,229,853			
Georgia	\$4.26		AMP	Yes	C	Yes	85	\$111,007,153		\$16.59	7,517,592
Hawaii	\$3.22		AMP/EAC	Yes	C	No		\$9,863,075			555,144
Idaho	2.50-3.50		AMP/EAC	No	B	No		\$2,920,158	\$9.13	\$12.63	391,791
Illinois	\$3.47		AMP-7.5%	Yes	C	Yes	(4)	\$137,797,193			
Indiana	\$3.00		AMP-3%	No	B	No		\$75,389,618	\$15.41	\$18.41	4,252,774
Iowa	\$3.70 (2)	\$1.00	AMP (8)	No	B	Yes	35	\$33,777,984	\$10.15	\$13.57	2,508,728
Kansas	2.46-4.67	\$1.00	AMP/EAC	Yes	C	Yes	(4)	\$20,223,958	\$9.67	\$13.46	1,642,180
Kentucky	\$3.25		EAC (8)	Yes	C	Yes	229	\$36,446,526	\$6.58	\$9.83	4,084,725
Louisiana	\$3.51		EAC	No	R	Yes	733	\$86,566,603	\$10.66		6,109,545
Maine	\$3.55	\$0.50	EAC (8)	No	R	Yes	32	\$21,086,107	\$11.91	\$15.26	1,316,180
Maryland	\$3.70	\$0.50 (3)	EAC	No	B	Yes	153	\$45,130,006		\$16.13	3,250,190
Massachusetts	\$3.72		AMP/EAC	No	A	Yes	(4)	\$89,829,373			
Michigan	\$3.45	\$0.50	AAC (8)	Yes	C	Yes	(4)	\$129,397,205	\$9.43	\$12.57	10,294,129
Minnesota	\$4.00		AMP-10%	Yes	C	Yes	120	\$47,430,302			
Mississippi	\$3.33	\$1.00	EAC	Yes	C	Yes	(4)	\$46,775,000	\$11.79	\$15.12	3,074,857
Missouri	\$3.00	.50-2.00	AMP/EAC	Yes	C	Yes	(4)	\$46,775,000		\$11.30	
Montana	2.00-3.75	\$1.00	EAC (8)	No	A	No		\$7,837,330			
Nebraska	4.30-5.12(7)		EAC (6,8)	No	B	Yes	395	\$18,284,744	\$10.20	\$13.20	1,267,284
Nevada	\$3.95		AMP-10%	No	B	No		\$4,751,057		\$18.94	252,306
New Hampshire	2.85-3.00	.50-1.00	EAC/AMP	No	B	No		\$7,296,685	\$9.42	\$12.32	592,417
New Jersey	3.61-3.97		EAC (8)	No	R	Yes	132	\$104,568,805	\$11.15	\$14.86	8,284,261
New Mexico	\$3.65		AMP/EAC	No	B	Yes	(4)	\$14,689,445	\$13.04	\$15.51	958,409
New York	\$2.60		EAC	Yes	C	No		\$385,312,110	\$10.82	\$13.42	
North Carolina	\$3.05 (10)	\$0.50	AMP/EAC	No	A	No		\$65,511,242	\$13.30	\$16.87	3,804,028
North Dakota	\$3.75		AMP/EAC	No	B	No		\$7,516,587	\$10.78	\$14.53	510,620
Ohio	\$3.12		EAC/AMP	Yes	C	Yes	317	\$150,570,202	\$9.45	\$12.57	12,709,041
Oklahoma	\$3.55 Max		AMP	Yes	C	Yes	(4)	\$31,075,000	\$14.60	\$18.09	1,717,668
Oregon	3.45-3.75		EAC/AMP	No	A	Yes	300	\$21,140,425	\$10.64	\$14.07	1,825,312
Pennsylvania	\$2.75	\$0.50	EAC/AMP	No	B	Yes	126	\$143,387,994	\$11.30	\$14.05	12,370,407
Rhode Island	\$3.40		EAC/AMP	No	R	Yes	28	\$14,426,849		\$13.97	1,055,045
South Carolina	\$3.30	\$1.00	EAC (8)	No	B	Yes	7	\$32,385,353	\$12.98	\$16.28	1,989,276
South Dakota	\$4.25	\$1.00	EAC (8)	No	B	Yes	40	\$5,767,588	\$10.78	\$15.03	356,090
Tennessee	\$4.21		AMP-7%	Yes	C	Yes	150	\$80,961,451	\$9.71	\$13.19	6,104,177
Texas	(5)		EAC (6,8)	No	B	Yes	145	\$123,297,069	\$11.69	\$15.87	7,697,796
Utah	\$3.40		EAC (8)	No	B	Yes	46	\$9,933,605		\$12.39	815,122
Vermont	\$2.75	\$1.00	AMP/EAC	No	B	Yes	352	\$8,082,218		\$14.45	559,324
Virginia	\$3.40	.50-1.00	EAC	No	B	Yes	82	\$55,496,164	\$10.73	\$13.13	4,225,285
Washington	3.05-3.85		80% AMP	Yes	C	Yes	282	\$43,891,312	\$9.15	\$12.55	4,728,011
West Virginia	\$2.75	.50-1.00	AMP	Yes	C	No		\$19,739,981	\$11.91	\$12.66	813,149
Wisconsin	\$3.70	\$0.50	AMP/EAC	No	B	Yes	291	\$66,232,967	\$8.40	\$12.39	2,847,030
Wyoming	--- No Vendor Drug Program ---										
								average	\$11.02	\$14.39	* Approx number