# Withdrawal/Redaction Sheet
## Clinton Library

| DOCUMENT NO. AND TYPE | SUBJECT/TITLE | DATE | RESTRICTION |
|---|---|---|---|
| 001. memo w/attach | Chris Jennings to Hillary Clinton<br>Re: Update on Congressional Strategy/Developments (8 pages) | 9/2/93 | P5 |
| 002. memo | Chris Jennings to Hillary Clinton<br>Re: Calls Prior to Meet the Press on Sunday (1 page) | 9/3/93 | P5 |

**COLLECTION:**
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Health Security Act)
OA/Box Number: 23754

**FOLDER TITLE:**
September 1993 HSA [1]

gf103

### RESTRICTION CODES

**Presidential Records Act - [44 U.S.C. 2204(a)]**

**P1** National Security Classified Information [(a)(1) of the PRA]
**P2** Relating to the appointment to Federal office [(a)(2) of the PRA]
**P3** Release would violate a Federal statute [(a)(3) of the PRA]
**P4** Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
**P5** Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
**P6** Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

**C.** Closed in accordance with restrictions contained in donor's deed of gift.
**PRM.** Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
**RR.** Document will be reviewed upon request.

**Freedom of Information Act - [5 U.S.C. 552(b)]**

**b(1)** National security classified information [(b)(1) of the FOIA]
**b(2)** Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
**b(3)** Release would violate a Federal statute [(b)(3) of the FOIA]
**b(4)** Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
**b(6)** Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
**b(7)** Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
**b(8)** Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
**b(9)** Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

September 1, 1993

TO: Melanne/Interested Parties

FROM: Chris Jennings

SUBJECT: Fifty Cent Per Prescription Profit Citation Made by Mrs. Clinton

Following Mrs. Clinton's presentation to the National Association of Chain Drug Stores, a number of pharmaceutical manufacturers raised major objections to the figure stated by Mrs. Clinton that pharmacists make an average 50 cent profit on each prescription they dispense. They challenged the credibility of this number. In response, I have attached a breakdown of this data that was provided by the University of Minnesota College of Pharmacy. This school and those associated with it are very well respected around the nation. As you can see, they provided a detailed breakdown of the cost components that were the basis of Mrs. Clinton's statement.

If you have any questions regarding this information, please call me at x2645.

## COMPONENTS OF A PRESCRIPTION PRICE

SOURCE: Pharmaceutical Research Institute of Management and Economics (PRIME)
University of Minnesota College of Pharmacy
Minneapolis, MN

1992 Average Rx Price = $26.04

Major Components:

| | | |
|---|---|---|
| Manufacturer: | 68% | = $17.70 |
| Pharmacy: | 28% | = $ 7.29 |
| Wholesaler: | 4% | = $ 1.04 |
| TOTAL: | | $26.04 |

Breakdowns:

Manufacturer = $17.70

| | | |
|---|---|---|
| Cost of Goods: | (30.1%) | $ 5.31 |
| Marketing/Advertising: | (22.5%) | $ 3.98 |
| Profits: | (13.0%) | $ 2.30 |
| Research: | (16.0%) | $ 2.83 |
| Taxes: | (8.4%) | $ 1.49 |
| Distribution: | (10.0%) | $ 1.77 |

Pharmacy = $7.29

| | | |
|---|---|---|
| Salaries: | (48%) | $ 3.53 |
| Rent: | (7.5%) | $ 0.55 |
| Profit | (6.8%) | $ 0.50 |
| Other Expenses: | (37%) | $ 2.70 |

Numbers may not add up exactly due to rounding.

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## MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Two years from the date of enactment of the plan, but no later than July 1, 1996 benefits offered under the Medicare program expand to cover outpatient prescription drugs. Thus, assuming enactment in December 1993, the new drug benefit would be in effect beginning in January 1996.

Any Medicare beneficiary who elects to enroll in the Part B program (97 percent of the Medicare population) automatically enrolls in the new prescription drug benefit.

As with other Part B benefits, the Medicare prescription drug benefit is funded by both general revenues and beneficiary premiums. The Part B premium increases to cover the new benefit. Premiums currently finance 25 percent of the cost for Part B coverage. Thus, beneficiaries would pay 25 percent of the cost of the new drug benefit. Other rules related to enrollment in Medicare Part B also apply to the prescription drug benefit.

### COINSURANCE, DEDUCTIBLES AND CAPS

The new drug benefit carries a $250 annual deductible. Once the deductible has been met, beneficiaries pay 20 percent of the cost of each prescription with an annual limit on out-of-pocket expenditures of $1,000.

Both the annual deductible and out-of-pocket cap are indexed each year to assure that the same percentage of beneficiaries continue to receive benefits as did with the initial $250 deductible and $1000 out-of-pocket cap.

### COVERAGE

The Medicare drug benefit covers all drugs, biological products and insulin approved by the Food and Drug Administration (FDA) for their medically accepted indications as defined in at least one of the three compendia which are the American Medical Association Drug Evaluations, the American Hospital Formulary Service and the United States Pharmacopeia, or other authoritative compendia identified by the Secretary or as determined by the carrier based on evidence presented in peer reviewed medical literature.

The Medicare drug benefit includes coverage of home IV drugs. In addition, the current limited coverage of outpatient drugs under Medicare such as immunosuppressive drugs are incorporated into the drug benefit.

The Secretary of Health and Human Services has the discretion not to cover certain pharmaceutical products listed in Section 1927(d) of the Social Security Act. Examples include fertility drugs, medications used to treat anorexia and drugs used for cosmetic purposes. However, benzodiazepines and barbiturates would be covered under the Medicare drug benefit. Further, the Secretary has the authority to establish maximum quantities per prescription or limit the number of refills in order to discourage waste.

The Secretary may require physicians or pharmacists to obtain approval before prescribing or dispensing certain medications based on evidence that they are subject to clinical misuse or inappropriate use or because the Secretary determines that they are not cost effective.

## COST CONTAINMENT

As a condition of participation in Medicare and Medicaid, drug manufacturers must sign rebate agreements with the Secretary. Rebates are paid to the Secretary on a quarterly basis.

For single source and innovator multiple source drugs, manufacturers pay a rebate to Medicare for each drug based on the difference between the average manufacturer price (AMP) to the retail class of trade and the weighted average of the prices of the drug in the non-retail market, or 15 percent of the AMP, whichever is greater. The Secretary has the authority to verify the AMP.

For single source and innovator multiple source drugs, an additional rebate is required on a drug-by-drug basis for manufacturers who increase prices at a higher rate than inflation. The baseline indexed price is the average manufacturers price from April through June 1993.

In the case of new drugs that the Secretary determines are excessively or inappropriately priced, the Secretary has the authority to negotiate a special rebate with the manufacturer. Such a determination by the Secretary would be based on such factors as the prices of other drugs in the same therapeutic class, cost information supplied by the manufacturer to the Secretary, prices of the drug in other comparable countries, and other

relevant factors. If a manufacturer refuses to negotiate or the Secretary is unable to negotiate a price that the Secretary determines to be reasonable, the Secretary may exclude the new drug from coverage under Medicare.

In the case of dual eligibles, to prevent manufacturers from paying rebates to Medicare and Medicaid, Medicare will be the recipient of the rebate.

A manufacturer is the entity holding legal title to or possession of the new drug code (NDC) for the covered outpatient drug.

The new program provides incentives to encourage the use of generic drugs. The benefit only covers generic drugs unless the physician indicates that a brand name medication is required. The Secretary may require that physicians obtain prior approval before prescribing specific brand-name products if a generic substitute is available.

## REIMBURSEMENT

For brand name drugs, reimbursement is the lower of the 90th percentile of actual charges in a previous period, or the estimated acquisition cost (EAC) plus a dispensing fee.

For generic drugs, Medicare pays the lower of the pharmacist's actual charge or the median of all generic prices (times the number of units dispensed) plus a dispensing fee.

For participating pharmacies, the dispensing fee is $5, indexed to the Consumer Price Index (CPI). Participating pharmacies are required to accept assignment on all prescriptions. Non-participating pharmacists receive $2 less per prescription.

## CHANGES IN PRIVATE INSURANCE REQUIREMENTS

The National Association of Insurance Commissioners (NAIC) will be instructed to make the necessary adjustments to Medigap policies to reflect the prescription drug coverage under Medicare. Private insurance plans may cover Medicare deductibles and co-payments for prescription drugs.

## SUBSIDIES

Low-income Medicare beneficiaries receive the same financial assistance for out-of-pocket costs associated with the drug benefit as provided for other cost-sharing amounts.

## REVIEWS

The Medicare DUR program parallels the program established in OBRA 1990 for Medicaid. Participating pharmacists are required to offer counseling to Medicare customers on the use of medications.

The Secretary establishes a national system of Electronic Claims Management as the primary method for determining eligibility, processing and adjudicating claims, and providing information to the pharmacist about the patient's drug use under the Medicare drug program.

Chris J

Try this version. If it's not right, someone is messing around with you.

Greg

See change in first line ↑ need drug benefit in '96

Final Spec Piece Prior To Cong. Briefing – 9/6/93



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The Medicare DUR program parallels the program established in OBRA 1990 for Medicaid. Participating pharmacists are required to offer counseling to Medicare customers on the use of medications.

The Secretary establishes a national system of Electronic Claims Management as the primary method for determining eligibility, processing and adjudicating claims, and providing information to the pharmacist about the patient's drug use under the Medicare drug program.

WORKING GROUP DRAFT PRIVILEGED AND ~~CONFIDENTIAL~~

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The amount of the deductible is set at a variable rate to assure that the same ~~number~~ of beneficiaries meet the deductible each year as during the first year of coverage. Both the annual deductible and ~~out-of-pocket~~ cap are indexed each year to assure that the same ~~percentage~~ of beneficiaries continue to receive benefits as did with the initial $250 deductible and $1000 out-of-pocket cap.

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Business Responses

THE WHITE HOUSE

WASHINGTON

September 1, 1993

TO: Ira Magaziner
Caren Wilcox
Amy Zisook
Chris Jennings
Mike Lux
Marilyn DiGiacobbe
Jonathon Silver

FROM: Marilyn Yager

RE: Business Status List

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The attached list of business associations and companies have met with some member of the health care task force during the past eight months. Where possible I have listed my assessment of the status of their support. Please make changes where you deem appropriate and add companies not currently listed.

As our business outreach kicks into high gear during the next two weeks, many businesses currently listed in the maybe/unclear column will likely be placed in the support column or the unlikely column. Therefore, if this document is useful, we can use it as a tool to track the status of our outreach.

Please return to me with your changes and additions.

cc: Alexis Herman
Steve Hilton
Melanne Verveer

(*Active opposition)

| NAME/ORGANIZATION | Likely support | Maybe or unclear | Helpful, but not endorse | Unlikely |
|---|---|---|---|---|
| Abbott Laboratories | | X | | |
| Acme Steel | | X | | |
| Alliance for Am. Insurance | | | | X |
| Allied Signal | X | | | |
| Am. Business Conference | | X | | |
| American Express | | X | | |
| American Family Life Assurance Company | | | | X |
| Am. Health Insurance Agents | | | | X |
| Am. Home Products | | | | X |
| Am. Insurance Assn. | | | | X |
| Am. Iron & Steel | | X | | |
| Am. Int'l Automobile Dealers Assn. | | X | | |
| Am. Pharmaceutical Assn. | | X | | |
| Am. Resort Development Assn. | | X | | |
| Am. Stock Exchange | | X | | |
| Am Trucking Assn. | | X | | |
| Ameritech | | X | | |
| AMI | | X | | |
| Anheuser Busch | | X | | |
| Assn. for Electronic Healthcare Transactions<br>Tom Gilligan<br>202/244-6450<br>fax 202/244-6570 | X | | | |
| Assn. of Private Pension & Welfare Plans | | | X | |
| ARCO | X | | | |

| NAME/ORGANIZATION | Likely support | Maybe or unclear | Helpful, but not endorse | Unlikely |
|---|---|---|---|---|
| AT&T | X | | | |
| Bankers Life | | | | X |
| Bethleham Steel | | X | | |
| Biotechnology Industry Organization | | | | X |
| Boeing | X | | | |
| Bristol-Myers Squibb | | | | |
| Business Rountable | | | | X |
| Can Manufacturers Assn. | | X | | |
| Caterpillar | | X | | |
| Central Reserve Life | | | | *X |
| Chamber of Commerce | | | | X |
| Chysler Corp | X | | | |
| CIGNA Corp | | X | | |
| Coalition to Preserve Health Benefits | | | | X |
| Committee 200 | X | | | |
| Coopers & Lybrand | | X | | |
| Corporate Healthcare Coalition | | X | | |
| Larry Atkins 202/457-9500 | | | | |
| Council of Economic Development | | X | | |
| CSIS (Communications | | X | | |
| Dayton Hudson Ed Wingate 612/370-6698 | X | | | |
| Dupont | | | | |
| Economic Alliance | | X | | |
| EDS | X | | | |

| NAME/ORGANIZATION | Likely support | Maybe or unclear | Helpful, but not endorse | Unlikely |
|---|---|---|---|---|
| Electronic Data Interchange | | X | | |
| Eli Lilly | | | | x |
| ERIC | | | | X |
| Executive Club of Chicago | | X | | |
| Food Marketing Institute | | X | | |
| Ford Motor | X | | | |
| Fruit of the Loom | | X | | |
| The Gap<br>Lauri Shanahan<br>415/737-4085<br>fax 415/737-7620 | X | | | |
| General Am. Life Insurance | | | | X |
| General Electric<br>Chuck Buck<br>203/373-2211 | X | | | |
| General Mills | | X | | |
| General Motors | X | | | |
| Glaxo, Inc. | | X | | |
| Global Business Forum | | X | | |
| GTE | | | | |
| HDX (Health Data Exchange Corporation | | X | | |
| Health Care Leadership Council | | X | | |
| Health Care Management Alternatives | | X | | |
| Health Care Purchasers Assn | | X | | |
| Health Executive Roundtables | | X | | |

| NAME/ORGANIZATION | Likely support | Maybe or unclear | Helpful, but not endorse | Unlikely |
|---|---|---|---|---|
| Health Industry Distributors Assn. | | X | | |
| Health Industry Manufactures Assn. | | | | X |
| Health Insurance Assn. of America | | | | X |
| Hershey | | X | | |
| HIAA | | | | *X |
| IBM<br>Chris Caine<br>202/515-5036 | X | | | |
| IGA | | X | | |
| Independent Bakers Assn. | | X | | |
| Independent Insurance Agents of Am. | | | | X |
| Inland Steel | | X | | |
| International Mass Retail Assn. | | X | | |
| Invacare<br>Mal Mixon<br>216/329-6201<br>fax 216/366-9008 | X | | | |
| ~~ISytems, Inc.~~ | | ~~X~~ | | |
| ITT Hartford | | X | | |
| Johnson & Johnson | | X | | |
| Liberty Mutual | | | | X |
| The Limited | | X | | |
| LTV | | X | | |
| Massachusetts Biotech Council | | X | | |
| Merck & Co. | | | | X |
| Midwest Business Group on Health | | X | | |

| NAME/ORGANIZATION | Likely support | Maybe or unclear | Helpful, but not endorse | Unlikely |
|---|---|---|---|---|
| MMI<br>Fredrick Becker<br>708/940-7550<br>fax/708/374-1332 | X | | | |
| Motion Picture Industry | | X | | |
| Mutual of Omaha | | | | X |
| Nat. Alcohol Tax Council | | X | | |
| Nat. Assn. of Chain Drug Stores | X | | | |
| Nat. Assn. of Health Underwriters | | | | X |
| Nat. Assn. of Independent Insurers | | | | X |
| National Assn. of Life Underwriters | | | | X |
| NAM<br>Sharon Canner<br>202/637-3124<br>fax 202/637-3182 | | | X | |
| Nat. Assn. of Medical Equipment Suppliers | | X | | |
| Nat. Assn. of Minority Contractors | | X | | |
| Nat. Assn. of Pharmaceutical Manufacturers | | | | X |
| Nat. Assn. of Private Enterprise | | | | X |
| Nat. Assn. of Professional Insurance Agents | | | | X |
| Nat. Assn. of Retail Druggists | X | | | |
| Nat. Assn. of Small Business Investment Comp | | X | | |

| NAME/ORGANIZATION | Likely support | Maybe or unclear | Helpful, but not endorse | Unlikely |
|---|---|---|---|---|
| Nat. Assn. of Women Business Owners<br>Sharon Hadary<br>301/495-4975<br>fax 301/495-4979 | | | X | |
| Nat. Business League | | X | | |
| NFIB | | | | *X |
| Nat. Grocers Assn. | | X | | |
| Nat. Minority Business Council | | X | | |
| Nat. Moving and Storage Assn. | | X | | |
| Nat. Pharmaceutical Alliance | | X | | |
| Nat. Pharmaceutical Assn. | | X | | |
| Nat. Restaurant Assn. | | | | *X |
| Nat. Retail Federation<br>Steve Pfister<br>202/783-7971<br>fax 202/737-2849 | | | X | |
| Nat. Small Business Legislative Council | | | X | |
| Nat. Small Business United<br>John Galles<br>202/293-8830<br>fax 202/887-5549 | | | X | |
| National Steel | | X | | |
| Nat. Tooling & Machine | | X | | |
| Nat. Venture Capital Assn. | | X | | |
| Nat. Wholesale Druggist Assn. | | X | | |
| Nat. Wooden Pallet and Container Manufacturers | | | | X |

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|---|---|---|---|---|
| New England Council | | X | | |
| PEPCO | X | | | |
| Pepsico | | X | | |
| Pfizer | | X | | |
| Pharmaceutical Man. Assn. | | | | X |
| Phillip MOrris | | | | *X |
| Picker Corp | | X | | |
| Price Waterhouse | | X | | |
| Principal Financial Group | | X | | |
| Prudential Life Insurance | | | | X |
| PRX International | | X | | |
| Ryder | | X | | |
| Schering-Plough | | | | X |
| Seagrams and Sons | | | | X |
| Searle | | X | | |
| Siegel Company | | X | | |
| Sm. Business Legislative Council<br>John Satagaj<br>202/639-8888<br>fax 202/296-5333 | | | | X |
| Smithkline Beecham | | | | X |
| So. California Gas | X | | | |
| Super Value<br>Jon Seltzer<br>612/828-4497<br>fax 612/828-4403 | | X | | |
| SYNTEX | | X | | |
| T. Cell Sciences, Inc. | | X | | |
| Towers Perron | | X | | |
| Travelers Insurance | | | | X |

| NAME/ORGANIZATION | Likely support | Maybe or unclear | Helpful, but not endorse | Unlikely |
|---|---|---|---|---|
| TRW<br>Michael McShane<br>703/276-5040<br>fax 703/276-5057 | X | | | |
| Upjohn Company | | | | X |
| VITAS Healthcare Corp | | X | | |
| Walt Disney | | X | | |
| Warner Lambert Company | | X | | |
| Washington Business Grp on Health<br>Anne Marie O'Keefe<br>202/408-9320<br>fax 202/408-9332 | | | | Neutral |
| Wheeling Pittsburgh Steel | | X | | |
| William Mercer | | X | | |
| Wine Institute | | | | X |
| Xerox Corp | | X | | |

September 2, 1993

TO: Greg Lawler
Carolyn Gatz

FROM: Chris Jennings

SUBJECT: Medicare Drug Benefit Modifications

Attached are the modifications to the Medicare benefits that I mentioned to you yesterday. They are presented in three formats: with deletions and additions, clean text, and as a summary of the changes.

I have talked with both Mrs. Clinton and Ira Magaziner about these changes which are based on ongoing discussions with the Department of Health and Human Services and were prepared by the Office of Legislation and Policy of the Health Care Financing Administration. Bruce Vladeck is fine with these changes. Although I am not absolutely certain that these are "final-final" -- but what is around here -- the changes come very close to being final as it relates to Medicare.

If you have any questions or concerns, we need to discuss them as soon as possible. Lastly, there are a number of other pharmaceutical issues that I need to talk with you about. These include the pharmacy class of trade issue, the voluntary price constraints, and the role and responsibility of the National Health Board as it relates to pharmaceuticals. Perhaps we can discuss these issues sometime tomorrow or Saturday.

WORKING GROUP DRAFT PRIVILEGED AND ~~CONFIDENTIAL~~

# MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Two years from the date of enactment of the Plan, benefits offered under the Medicare program expand to cover outpatient prescription drugs. Thus, assuming enactment in December 1993, the new drug benefit would be in effect beginning in January 1996.

Any Medicare beneficiary who elects to enroll in the Part B program (97 percent of the Medicare population) automatically enrolls in the new prescription drug benefit.

As with other Part B benefits, the Medicare prescription drug benefit is funded by both general revenues and beneficiary premiums. The Part B premium increases to cover the new benefit. Premiums currently finance 25 percent of the cost of Part B coverage. Thus, beneficiaries would pay 25 percent of the cost of the new drug benefit. Other rules related to enrollment in Medicare Part B also apply to the prescription drug benefit.

## COINSURANCE, DEDUCTIBLES AND CAPS

The new drug benefit carries a $250 annual deductible. Once the deductible has been met, beneficiaries pay 20 percent of the cost of each prescription with an annual limit on out-of-pocket expenditures of $1000.

The amount of the deductible is set at a variable rate to assure that the same number of beneficiaries meet the deductible each year as during the first year of coverage. Both the annual deductible and out-of-pocket cap are indexed each year to assure that the same percentage of beneficiaries continue to receive benefits as did with the initial $250 deductible and $1000 out-of-pocket cap.

## COVERAGE

The Medicare drug benefit covers all drugs, biological products and insulin approved by the Food and Drug Administration (FDA) for their medically accepted indications as defined in at least one of the three national compendia which are the American Medical Association Drug Evaluations, the American Hospital Formulary Service, and the United States Pharmacopeia, or other authoritative compendia identified by the Secretary or as determined by the carrier based on evidence presented in peer reviewed medical literature.

The Medicare drug benefit includes coverage of home IV drugs. In addition, the current limited coverage of outpatient drugs under Medicare such as immunosuppressive drugs are incorporated into the drug benefit.

The Secretary of Health and Human Services has the discretion not to cover certain pharmaceutical products listed in Section 1927(d) of the Social Security Act. Examples include fertility drugs, medications used to treat anorexia and drugs used for cosmetic purposes. However, benzodiazepines and barbiturates would be covered under the Medicare drug benefit. Further, the Secretary has the authority to establish maximum quantities per prescription or limit the number of refills in order to discourage waste.

The Secretary may require physicians or pharmacists to obtain prior approval before prescribing or dispensing certain medications based on evidence that they are subject to clinical misuse or inappropriate use or because the Secretary determines that they are not cost effective.

**COST CONTAINMENT**

As a condition of participation in Medicare and Medicaid, drug manufacturers must sign rebate agreements with the Secretary. Rebates are paid to the Secretary on a quarterly basis.

For single source and innovator multiple source drugs, manufacturers pay a rebate to Medicare for each drug based on the difference between the average manufacturer price (AMP) to the retail class of trade and the weighted average of the prices of the drug in the non-retail marketplace, or 15 percent of the AMP, whichever is greater. The Secretary has the authority to verity the AMP.

For single source and innovator multiple source drugs, an additional rebate is required on a drug-by-drug basis for manufacturers who increase prices at a higher rate than inflation. The baseline indexed price is the average manufacturers price from April through June 1993.

In the case of new drugs that the Secretary determines are excessively or inappropriately priced, the Secretary has the authority to negotiate a special rebate with the manufacturer. Such a determination by the Secretary would be based on such factors as the prices of other drugs in the same therapeutic class, cost information supplied by the manufacturer to the Secretary, prices of the drug in other comparable countries, and other relevant factors. If a manufacturer refuses to negotiate or the Secretary is unable to negotiate a price that the Secretary determines to be reasonable, the Secretary may exclude the new drug and any other drug product produced by the manufacturer from coverage under Medicare.

In the case of dual eligibles, to prevent manufacturers from paying rebates to Medicare and Medicaid, Medicare be the

recipient of the rebate.

A manufacturer is considered the entity holding legal title to or possession of the new drug code (NDC) for the covered outpatient drug.

The new program provides incentives to encourage the use of generic drugs. The benefit only covers generic drugs unless the physician indicates that a brand name medication is required. The Secretary may require that physicians obtain prior approval before prescribing specific brand-name drugs if a generic substitute is available.

**REIMBURSEMENT**

For brand name drugs, reimbursement is the lower of the 90th percentile of actual charges in a previous period, or the estimated acquisition cost (EAC) plus a dispensing fee.

For generic drugs, Medicare pays the lower of the pharmacist's actual charge or the median of all generic prices (times the number of units dispensed) plus

For participating pharmacies, the dispensing fee is $5, indexed to the Consumer Price Index (CPI). Participating pharmacies are required to accept assignment on all prescriptions. Non-participating pharmacists receive $2 less per prescription.

**CHANGES IN PRIVATE INSURANCE REQUIREMENTS**

The National Association of Insurance Commissioners (NAIC) will be instructed to make the necessary adjustments to Medigap polices to reflect the prescription drug coverage under Medicare. Private insurance plans may cover Medicare deductibles and co-payments for prescription drugs.

**SUBSIDIES**

Low-income Medicare beneficiaries receive the same financial assistance for out-of-pocket costs associated with the drug benefit as provided for other cost-sharing amounts.

**REVIEWS**

The Medicare DUR program parallels the program established in OBRA 1990 for Medicaid. Participating pharmacists are required to offer counseling to Medicare customers on the use of medications.

The Secretary establishes a national system of Electronic Claims Management as the primary method for determining

eligibility, processing and adjudicating claims, and providing information to the pharmacist about the patient's drug use under the Medicare drug program.

WORKING GROUP DRAFT PRIVILEGED AND ~~CONFIDENTIAL~~

## MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

~~Beginning in January 1996,~~ Two years from the date of enactment of the Plan, benefits offered under the Medicare program expand to cover outpatient prescription drugs. Thus, assuming enactment in December 1993, the new drug benefit would be in effect beginning in January 1996.

Any Medicare beneficiary who elects to enroll in the Part B program (97 percent of the Medicare population) automatically enrolls in the new prescription drug benefit.

As with other Part B benefits, the Medicare prescription drug benefit is funded by both general revenues and beneficiary premiums. The Part B premium increases to cover the new benefit. Premiums currently finance 25 percent of the cost of Part B coverage. Thus, beneficiaries would pay 25 percent of the cost of the new drug benefit. Other rules related to enrollment in Medicare Part B also apply to the prescription drug benefit.

### ~~CO-PAYMENTS~~ COINSURANCE, DEDUCTIBLES AND CAPS

The new drug benefit carries a $250 annual deductible. Once the deductible has been met, beneficiaries pay 20 percent of the cost of each prescription with an annual limit on out-of-pocket expenditures of $1000.

~~The amount of the deductible is set at a variable rate to assure that the same number of beneficiaries meet the deductible each year as during the first year of coverage.~~ Both the annual deductible and out-of-pocket cap are indexed each year to assure that the same percentage of beneficiaries continue to receive benefits as did with the initial $250 deductible and $1000 out-of-pocket cap.

### COVERAGE

The Medicare drug benefit covers all drugs, biological products and insulin approved by the Food and Drug Administration (FDA) for their medically accepted indications as defined in ~~the~~ at least one of the three national compendia which are the American Medical Association Drug Evaluations, the American Hospital Formulary Service, and the United States Pharmacopeia, or other authoritative compendia identified by the Secretary or as determined by the carrier based on evidence presented in peer reviewed medical literature.

The Medicare drug benefit includes coverage of home IV drugs. In addition, the current limited coverage of outpatient drugs under Medicare such as immunosuppressive drugs are incorporated into the drug benefit.

~~Certain pharmaceutical products not covered by the Medicaid program under Section 1927(d) of the Social Security Act, including drugs for the treatment of infertility, medications used to treat anorexia and drugs prescribed for cosmetic purposes, are not covered. Exceptions to current Medicaid exclusions include barbiturates and benzodiazepines.~~ The Secretary of Health and Human Services has the discretion not to cover certain pharmaceutical products listed in Section 1927(d) of the Social Security Act. Examples include fertility drugs, medications used to treat anorexia and drugs used for cosmetic purposes. However, benzodiazepines and barbiturates would be covered under the Medicare drug benefit. Further, the Secretary has the authority to establish maximum quantities per prescription or limit the number of refills in order to discourage waste.

The Secretary may require physicians or pharmacists to obtain prior approval before prescribing or dispensing certain medications based on evidence that they are subject to clinical misuse or inappropriate use or because the Secretary determines that they are not cost effective.

~~All new drugs approved by the FDA are covered under the benefit. However, the Secretary has the authority to negotiate prices with manufacturers of new pharmaceutical products if the Secretary concludes that certain products are excessively or inappropriately priced. Manufacturers that refuse to negotiate lose eligibility for reimbursement of any drug product by any federal program or health alliance certified by the states. The Secretary also has the discretion to exclude from coverage drugs listed in Section 1927 (d) of the Social Security Act, except benzodiazepines and barbiturates.~~

**COST CONTAINMENT**

As a condition of participation in Medicare and Medicaid, drug manufacturers must sign rebate agreements with the Secretary. Rebates are paid to the Secretary on a quarterly basis.

For single source and innovator multiple source drugs, manufacturers pay a rebate to Medicare for each drug based on the difference between the average manufacturer price (AMP) to the retail class of trade and the weighted average of the prices of the drug in the non-retail marketplace, or 15 percent of the AMP, whichever is greater. The Secretary has the authority to ~~conduct verification surveys of~~ verify the AMP.

~~Manufacturers that increase prices at a rate higher than inflation on a single source drug and innovator multiple source drugs pay an additional rebate on particular drugs.~~ For single source and innovator multiple source drugs, an additional rebate

is required on a drug-by-drug basis for manufacturers who increase prices at a higher rate than inflation. The baseline indexed price is the average manufacturers price from April through June 1993.

In the case of new drugs that the Secretary determines are excessively or inappropriately priced, the Secretary has the authority to negotiate a special rebate with the manufacturer. Such a determination by the Secretary would be based on such factors as the prices of other drugs in the same therapeutic class, cost information supplied by the manufacturer to the Secretary, prices of the drug in other comparable countries, and other relevant factors. If a manufacturer refuses to negotiate or the Secretary is unable to negotiate a price that the Secretary determines to be reasonable, the Secretary may exclude the new drug and any other drug product produced by the manufacturer from coverage under Medicare.

In the case of dual eligibles, to prevent manufacturers from paying rebates to Medicare and Medicaid, Medicare be the recipient of the rebate.

A manufacturer is considered the entity holding legal title to or possession of the new drug code (NDC) for the covered outpatient drug.

The new program provides incentives to encourage the use of generic drugs. The benefit only covers generic drugs unless the physician indicates that a brand name medication is required. The Secretary may require that physicians obtain prior approval before prescribing specific brand-name drugs if a generic substitute is available.

**REIMBURSEMENT**

For brand name drugs, reimbursement is the lower of the 90th percentile of ~~usual and customary~~ actual charges in a previous period, or the estimated acquisition cost (EAC) plus a ~~professional~~ dispensing fee ~~of $5 for participating pharmacies, indexed to the Consumer Price Index~~.

For generic drugs, Medicare pays the lower of the pharmacist's ~~usual and customary charge~~ actual charge or the median of all generic prices (times the number of units dispensed) plus ~~a $5 per prescription dispensing fee, indexed to the Consumer Price Index~~ a dispensing fee.

For participating pharmacies, the dispensing fee is $5, indexed to the Consumer Price Index (CPI). Participating pharmacies are required to accept assignment on all prescriptions. Non-participating pharmacists receive $2 less per

prescription.

CHANGES IN PRIVATE INSURANCE REQUIREMENTS

~~When the Medicare drug benefit takes into effect, private insurance policies provided by former employers either reduce the premium charged to Medicare beneficiaries to account for the change in coverage or increase coverage for other health services by an amount equal to the actuarial value of the drug benefit.~~

The National Association of Insurance Commissioners (NAIC) will be instructed to make the necessary adjustments to Medigap polices to reflect the prescription drug coverage under Medicare. Private insurance plans may cover Medicare deductibles and co-payments for prescription drugs.

SUBSIDIES

Low-income Medicare beneficiaries receive the same financial assistance for out-of-pocket costs associated with the drug benefit as provided for other cost-sharing amounts.

REVIEWS

The Medicare DUR program parallels the program established in OBRA 1990 for Medicaid. Participating pharmacists are required to offer counseling to Medicare customers on the use of medications.

The Secretary establishes a national system of Electronic Claims Management as the primary method for determining eligibility, processing and adjudicating claims, and providing information to the pharmacist about the patient's drug use under the Medicare drug program.

## MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

1. Proposed change: The effective date should be at least two years from the date of enactment.

   Rationale: The timeline for the administration of the new benefit was determined by the HCFA's Bureau of Program Operations (BPO) to be at least 24 months after enactment. The original January 1, 1996 effective date assumed that enactment would occur late in 1993. With enactment more likely to occur mid 1994 or early 1994, the effective date should be changed accordingly.

## DEDUCTIBLES, CO-PAYMENTS AND CAPS

1. Proposed change: Change "the same NUMBER of beneficiaries" to "the same PERCENTAGE of beneficiaries."

   Rationale: Use of "number" would lead to benefit reaching a smaller percentage of beneficiaries over time.

2. Proposed change: Strike "co-payment" and insert "coinsurance."

   Rationale: Copayment usually refers to a fixed amount while coinsurance refers to a fixed percentage.

3. Proposed change: Index the $1000 out-of-pocket cap in the same manner as the $250 annual deductible. See revised language in attached draft.

   Rationale: Assures the same percentage of beneficiaries over time.

4. Proposed change: Insert "Once the deductible is met" before "beneficiaries also pay 20 percent of the cost of each prescription...".

   Rationale: Beneficiaries only pay the 20 percent coinsurance after the deductible has been reached.

## COVERAGE

1. Proposed change: References to medically accepted indications for drugs should parallel the anti-cancer drug provisions in OBRA 93 which reference the drug compendia as well as peer reviewed literature. See attached draft. Reference to compendia should read " as found in at least one of the three national compendia which are the American Medical Association Drug Evaluations, the American Hospital Formulary Service, and the United States

## MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Secretary would have the discretion to exclude from coverage drugs listed in Section 1927(d) of the Social Security Act, except for benzodiazepines and barbiturates.

Rationale: The paragraph as rewritten is factually incorrect. Under Medicaid, the statutory exclusions are permissive; states may or may not cover the drugs listed in the categories. Applying the statutory exclusion to Medicare implies mandatory exclusion of the listed drugs. Furthermore, this paragraph is later repeated in the first paragraph of page 202 -- this is most likely a proofreading error.

6. Proposed change: Either physicians and PHARMACISTS may be required to obtain approval before prescribing and/or dispensing a particular medication.

   Rationale: In the Medicaid program, pharmacists rather than physicians generally request prior approval before dispensing a pharmaceutical product.

7. Proposed change: Strike two sentences beginning "However, the Secretary has the authority to negotiate prices...by any federal program and health alliance."

   Rationale: The revised provisions for new drug prices are restated below in the next paragraph. This is most likely another proofreading error.

8. Proposed change: The references to the negotiated rebates for new drugs is moved to the cost containment section rather than coverage. See attached draft.

   Rationale: These provisions refer to rebates which is a cost containment mechanism.

**COST CONTAINMENT**

1. Proposed change: Insert "must" before "sign rebate agreements."

   Rationale: Signing rebates agreements is a mandatory if drugs are to be covered by Medicare.

2. Proposed change: Insert "or 15 percent of the AMP, whichever is greater" after "the weighted average of the drug in the non-retail market."

   Rationale: Inadvertent admission of complete rebate formula. This formula is

parallels that used in the Medicaid drug rebate program.

3. Proposed change: Strike "on particular drugs" and insert in its place "on a drug-by-drug basis."

   Rationale: The use of phrase "on particular drugs" implies that only certain drugs will be subject to the additional rebate provisions.

4. Proposed change: Include a provision for dual eligibles must be included with Medicare serving as recipient of the rebate when Medicare is the primary payor.

   Rationale: Avoids situations in which drug manufacturers would pay double rebates.

5. Proposed change: A manufacturer is considered the entity holding legal title to or possession of the new drug number (NDC) number for the covered outpatient drug.

   Rationale: This provision clarifies the responsible manufacturer. This definition is consistent with the Medicaid rebate agreement.

6. Proposed change: Strike "conduct verification surveys" and insert "verify."

   Rationale: The Secretary has the authority to verify the AMP, but may not necessarily conduct a survey of the AMP.

**REIMBURSEMENT**

1. Proposed change: Separate discussion of dispensing fees from costs of drugs. See text in attached document.

   Rationale: Clarity.

**CHANGES IN PRIVATE INSURANCE REQUIREMENT**

1. Proposed change: References to private insurance policies provided by former employers.

   Rationale: This is the provision is from MCCA's Section 421 (Maintenance of Effort). This provision required any employer who provides health benefits that

duplicate Medicare benefits as a result of the catastrophic legislation (excluding outpatient drugs) by at least 50 percent of the national actuarial value of the catastrophic benefit, to provide additional benefits or refunds at least equal to the actuarial value of the duplicative benefits for one year only. This provision was included in MCCA since the time between enactment and the effective date for the statute was only about six months. The time between enactment and the effective date for the new drug benefit should be sufficient to allow the appropriate parties to negotiate reduced premiums for retiree group coverage that takes into account the new drug benefit.

2. Proposed change: Include a provision which instructs NAIC to make the necessary adjustments to Medigap policies to reflect prescription drug coverage under Medicare.

**REVIEWS**

1. Proposed change: Strike "and" after "patient's drug."

2. Rationale: Typographical error.

# Withdrawal/Redaction Marker
## Clinton Library

| DOCUMENT NO. AND TYPE | SUBJECT/TITLE | DATE | RESTRICTION |
|---|---|---|---|
| 001. memo w/attach | Chris Jennings to Hillary Clinton<br>Re: Update on Congressional Strategy/Developments (8 pages) | 9/2/93 | P5 |

**This marker identifies the original location of the withdrawn item listed above. For a complete list of items withdrawn from this folder, see the Withdrawal/Redaction Sheet at the front of the folder.**

**COLLECTION:**
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Health Security Act)
OA/Box Number: 23754

**FOLDER TITLE:**
September 1993 HSA [1]

gf103

**RESTRICTION CODES**

**Presidential Records Act - [44 U.S.C. 2204(a)]**

**P1** National Security Classified Information [(a)(1) of the PRA]
**P2** Relating to the appointment to Federal office [(a)(2) of the PRA]
**P3** Release would violate a Federal statute [(a)(3) of the PRA]
**P4** Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
**P5** Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
**P6** Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

**C.** Closed in accordance with restrictions contained in donor's deed of gift.
**PRM.** Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
**RR.** Document will be reviewed upon request.

**Freedom of Information Act - [5 U.S.C. 552(b)]**

**b(1)** National security classified information [(b)(1) of the FOIA]
**b(2)** Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
**b(3)** Release would violate a Federal statute [(b)(3) of the FOIA]
**b(4)** Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
**b(6)** Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
**b(7)** Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
**b(8)** Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
**b(9)** Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

# Withdrawal/Redaction Marker
## Clinton Library

| DOCUMENT NO. AND TYPE | SUBJECT/TITLE | DATE | RESTRICTION |
|---|---|---|---|
| 002. memo | Chris Jennings to Hillary Clinton<br>Re: Calls Prior to Meet the Press on Sunday (1 page) | 9/3/93 | P5 |

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September 1993 HSA [1]

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