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001. memo	Chris Jennings to Hillary Clinton Re: Meeting with House and Senate Leadership (2 pages)	7/30/93	P5

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

FOLDER TITLE:
July 1993 HSA [6]

gf98

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]

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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]

MEMORANDUM

To: Ira Magaziner
Judy Feder
Carolyn Getz
Greg Lawler

From: Chris Jennings CJ

Date: July 26, 1993

RE: Medicare drug benefit draft paper

==========

The attached is a working group draft submitted by HHS on the Medicare outpatient prescription drug benefit. These recommendations were discussed previously and I see no problems with the content.

Unfortunately, HHS thought these suggestions had been incorporated into the original comments sent to the Department when, in fact, they had not. The Department assumed I had given them to you and vice versa. I apologize for the confusion.

Please review the enclosed. It is important that we incorporate the Department's suggestions into the current version of the legislative specifications.

If you have any questions, please call me at x2645. Thanks.

WORKING GROUP DRAFT PRIVILEGED AND ~~CONFIDENTIAL~~

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Beginning in January, 1996, the Medicare program expands to cover outpatient prescription drugs.

Any Medicare beneficiary who elects to enroll in the Part B program (as 97 percent of the Medicare population currently do) is automatically enrolled 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 would be increased to cover the new benefit. Beneficiary premiums currently finance 25 percent of Part B costs. 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.

DEDUCTIBLES, COINSURANCE AND CAPS

A $250 annual deductible applies to the new drug benefit. Once the deductible has been met, a 20 percent coinsurance per prescription applies. In addition, a $1,000 annual out-of-pocket cap is in effect for each Medicare beneficiary.

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 cap.

COVERAGE

The Medicare drug benefit covers all FDA approved drugs, biologicals and insulin for their medically accepted indications 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 Pharmacopeia.

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.

The Secretary has the authority to establish maximum quantities per prescription or limit the number of refills in order to discourage waste.

The Secretary has the authority to subject medications to requirements for prior approval, meaning that physicians or pharmacists could be required to obtain prior approval before prescribing or dispensing a particular medication. Particular drugs become subject to prior approval 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. In the case of new drugs that the Secretary determines are excessively or inappropriately priced, the Secretary has the authority to establish a price for Medicare's purposes based on negotiations with manufacturers. If a manufacturer refuses to negotiate or the Secretary is unable to negotiate a price that the Secretary determines to be reasonable, the Secretary would have the authority to exclude the drug from coverage under Medicare.

COST CONTAINMENT

As a condition of participation in Medicare and Medicaid, drug manufacturers must sign rebate agreements with the Secretary. Rebates are required for non-innovator multiple source drugs (generic) but will be less than those currently required under the Medicaid rebate program.

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.

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 will be the AMP for the prescription between April and June, 1993.

Rebates are paid to the Secretary on a quarterly basis.

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

The Secretary has the authority to conduct verification surveys of the AMP.

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. Only generic versions of brand-name drugs are covered unless the physician indicates that a brand name medication is necessary. The Secretary also has the authority to subject a brand-name product to a prior approval requirement if a generic substitute is available.

REIMBURSEMENT

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

For generic drugs, payment is the lower of the pharmacist's usual and customary 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

Private insurance plans provided by former employers are required to either reduce the amount of the premium charged to Medicare beneficiaries to account for the coverage of prescription drugs, or increase coverage of other health services by the actuarial value of the prescription drug benefit under the private plan.

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 to counsel Medicare recipients 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: Strike "subscribes to" and insert "elects to enroll in". Strike "coverage" and insert "program."

   Rationale: Terminology clarification.

2. Proposed change: Strike entire third paragraph and insert "As with other Part B benefits, the Medicare prescription drug benefit is funded by both general revenues and beneficiary premiums. The Part B premium would be increased to cover the new benefit. Beneficiary premiums currently finance 25% of Part B costs. Thus, beneficiaries would pay 25% of the cost of the new drug benefit. Other rules related to enrollment in Medicare Part B also apply to the presoription drug benefit."

   Rationale: Beneficiaries will not pay the same amount for new coverage as they do for current coverage. They will pay the same percentage -- 25%.

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.

   Rationale: Assures the same percentage of beneficiaries over time.

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

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

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

COVERAGE

1. Proposed change: Reference to compendia should read "as found in at least one of the three national compendia, which are..."

   Rationale: Current language requires that the medically accepted indication for a drug or biological be listed in all three compendia.

2. Proposed change: Insulin should be covered under the new benefit.

   Rationale: Insulin needs to be explicitly listed since it is neither a drug or biological. Including insulin is consistent with the Medicare Catastrophic Coverage Act of 1988 (MCCA).

3. Proposed change: A home IV therapy benefit should be covered under the new drug benefit. Drugs provided through the home IV benefit would be subject to the new benefit's deductible and co-payment. Current limited coverage of home IV therapy under the DME benefit would be eliminated.

   Rationale: Including home IV therapy is consistent with the MCCA and eliminates quality assurance concerns under the DME program. According to HCFA actuaries, the cost of the home IV benefit will total $263 million for CY 1995.

4. Proposed change: Current coverage of immunosuppressive drugs, blood clotting factors and osteoporosis drugs should be covered under this new benefit.

   Rationale: Medicare currently covers immunosuppressive drugs for the first year after a covered transplant. After the first year of immunosuppressive therapy, the beneficiary would then be covered under the new drug benefit. Covering the beneficiary under the new benefit from the outset would be administratively simpler. Medicare also currently covers blood clotting drugs for hemophiliacs and osteoporosis drugs.

5. Proposed change: The 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: 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.

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

6. Proposed change: Add a provision that gives the Secretary the authority to establish maximum quantities per prescription and limits on the number of refills.

   Rationale: This provision will discourage wasteful dispensing of pharmaceuticals.

7. 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.

8. Proposed change: In the case of new drugs that the Secretary determines are excessively or inappropriately priced, the Secretary has the authority to establish a price for Medicare's purposes based on negotiations with the manufacturers. If a manufacturer refuses to negotiate or the Secretary is unable to negotiate a price that the Secretary determines to be reasonable, the Secretary would have the authority to exclude the drug from coverage under Medicare.

   Rationale: Mandating that ALL of a manufacturer's drug products not be reimbursed by any federal program is too punitive and as such will never be enforced. In addition, a manufacturer may agree to negotiate but not negotiate in good faith.

COST CONTAINMENT

1. Proposed change: As a condition of participation in Medicare AND MEDICAID, drug manufacturers must sign rebate agreements with the Secretary to be reimbursed for covered drugs under Medicare.

   Rationale: This provision increases likelihood that manufacturers will sign rebate agreements when both Medicare and Medicaid participation included.

2. Proposed change: Include rebates for generic as well as brand name drugs. The rebates for generic drugs would be at a lower level than is currently mandated under the Medicaid program (currently 10% of AMP, 11% of AMP in 1994). The reductions in savings would be offset by stricter enforcement of state laws mandating generic substitution. Medicare's generic rebate percentage would equal the revised Medicaid percentage.

   Rationale: Mandating generic drug rebates is consistent with the current

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Medicaid drug rebate program. Not mandating generic drug rebates would reduce the total rebates that could be collected by the Federal government. Not including generic rebates could also make the manufacturing of generic drugs too attractive relative to the manufacturing of innovator drugs.

3. Proposed change: Delete reference to carriers or intermediaries.

   Rationale: Having drug claims processors also administer the rebate program raises conflict of interest and confidentiality issues.

4. Proposed change: The rebate formula should use a weighted average of the prices offered by the manufacturer of a given drug in the non-retail market rather than the median price of the drug in the non-retail market.

   Rationale: Using the median rather than the weighted average may result in significantly reduced rebates. For example, if a few HMOs and hospitals receive substantial discounts from drug manufacturers but the majority of other providers receive minor discounts, the median will be skewed towards the lower discounts.

5. Proposed change: Change "average price charged" to "average manufacturers price."

   Rationale: Consistency of terminology.

6. Proposed change: The baseline index price will be the average manufacturers price (AMP) for the prescription from April through June 1993.

   Rationale: A span of several months is desirable to calculate the AMP to get the most accurate estimate of price.

7. Proposed change: 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.

8. Proposed change: Add a provision which allows the Secretary to conduct verification surveys of the AMP.

   Rationale: Drug manufacturers provide the Secretary with the AMP. Oversight is

required to determine that the information supplied is accurate. This provision is consistent with the Medicaid rebate program.

9. 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.

10. Proposed change: Strike "high quality" before "generic substitutes."

    Rationale: Not clear what high quality means in relation to generic drugs or whether this reference is meaningful given current FDA practice.

REIMBURSEMENT

1. Proposed change: Insert "in a previous period" after "charges."

   Rationale: More precise.

2. Proposed change: Change "actual acquisition cost" to "estimated acquisition cost."

   Rationale: Actual acquisition cost is very difficult to administer, requiring a survey of acquisition costs of pharmacists. Estimated acquisition cost could be simply calculated as a percentage of average wholesale price (AWP).

3. Proposed change: Separate discussion of dispensing fees from costs of drugs.

   Rationale: Clarity.

MEDICARE HMOS

1. Proposed change: Omit this section.

   Rationale: Since outpatient drugs are added to the benefit package, HMOs would be required to provide such benefits.

CHANGES IN PRIVATE INSURANCE REQUIREMENTS

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

1. Proposed change: This provision should be limited to policies paid for by former employers.

   Rationale: The new benefit's impact on Medigap policies would be dealt with through loss ratio requirements. NAIC would have to revise the standard benefit package to account for the new benefit.

SUBSIDIES

1. Proposed change: Replace this provision with "Low income beneficiaries receive the same financial protection for out-of-pocket costs associated with the drug benefit as provided for other Medicare cost-sharing amounts."

   Rationale: This provision clarifies the provision's intent. Also, financial assistance implies a cash payment.

REVIEWS

1. Proposed change: Strike "and medical history" and insert "use."

2. Rationale: The pharmacist will not have access to the patient's entire medical history.

PRIVILEGED AND ~~CONFIDENTIAL~~ MEMORANDUM

TO: Judy Feder
Ira Magaziner

FROM: Richard A. Veloz

RE: Puerto Rico and the Territories

DATE: 7/30/93

c.c. Chris Jennings, members of team

BACKGROUND:

I've attached the data sent to us by Puerto Rico and the territories of Guam, the Virgin Islands and American Samoa.

A team composed of Atul (leaving on Friday), Don Johnson, Eugene Moyer, Tom Ault and myself has formed to go over this material and provide follow up analysis. Tom Ault will lead this team effort.

TIMELINE:

Since our initial meeting I have met several times with the Congressional representatives of the territories and Puerto Rico. Now that they have submitted the requested data they are anxious to meet with us. Puerto Rico especially, would like to begin this process by next week. A consensus on our working team is to have two meetings. The first, to walk through the cost estimates and rationale for the figures that we're working with. The second meeting, to propose a framework for inclusion in the health plan.

We need to be clear on our position before we meet. However, If we can agree on a position, a first meeting can be arranged for Thursday the 5th of August. At this meeting the Puerto Rican health members would like to walk us through their figures and present an overview of their new health reform program.

I can be reached at 202-401-4507, or 202-401-5193.

Congress of the United States
Congressional Hispanic Caucus
103rd Congress

July 19, 1993

Mr. Ira Magaziner
Assistant to the President for Domestic Policy
The White House
1600 Pennsylvania
Washington, D.C. 20500

Dear Mr. Magaziner:

As Chairman of the Congressional Hispanic Caucus (CHC), I would like to thank you for accepting our invitation to discuss health care reform issues of interest to Hispanics with our Membership.

Unfortunately, we were forced to cancel our July 15, 1993, meeting with you due to an emergency meeting with Secretary Bentsen at that same time. The Caucus considers health care reform an important issue and value our ongoing discussion with you on key issues of concern to the Hispanic community. We would look forward to rescheduling our discussion with you for Thursday, July 22, 1993, at 11:30 a.m., if that is convenient for you.

Thank you for your consideration of my invitation, and please accept my apologies for any inconvenience the cancellation may have caused you. I look forward to meeting with you again.

Sincerely,

José Serrano

José E. Serrano, Chairman
Congressional Hispanic Caucus

JES/ma

557 Ford House Office Building, Washington, D.C. 20515 • (202) 226-3430 Fax: (202) 225-7569

PRIVILEGED AND ~~CONFIDENTIAL~~ MEMORANDUM

DETERMINED TO BE AN ADMINISTRATIVE
MARKING Per E.O. 12958 as amended, Sec. 3.2 (c)
Initials: RA Date: 8.16.05

TO: **Judy Feder**
Ira Magaziner

FROM: Richard A. Veloz (Rav)

RE: Puerto Rico/Territories meeting held on July 14, 1993

DATE: 7/19/93

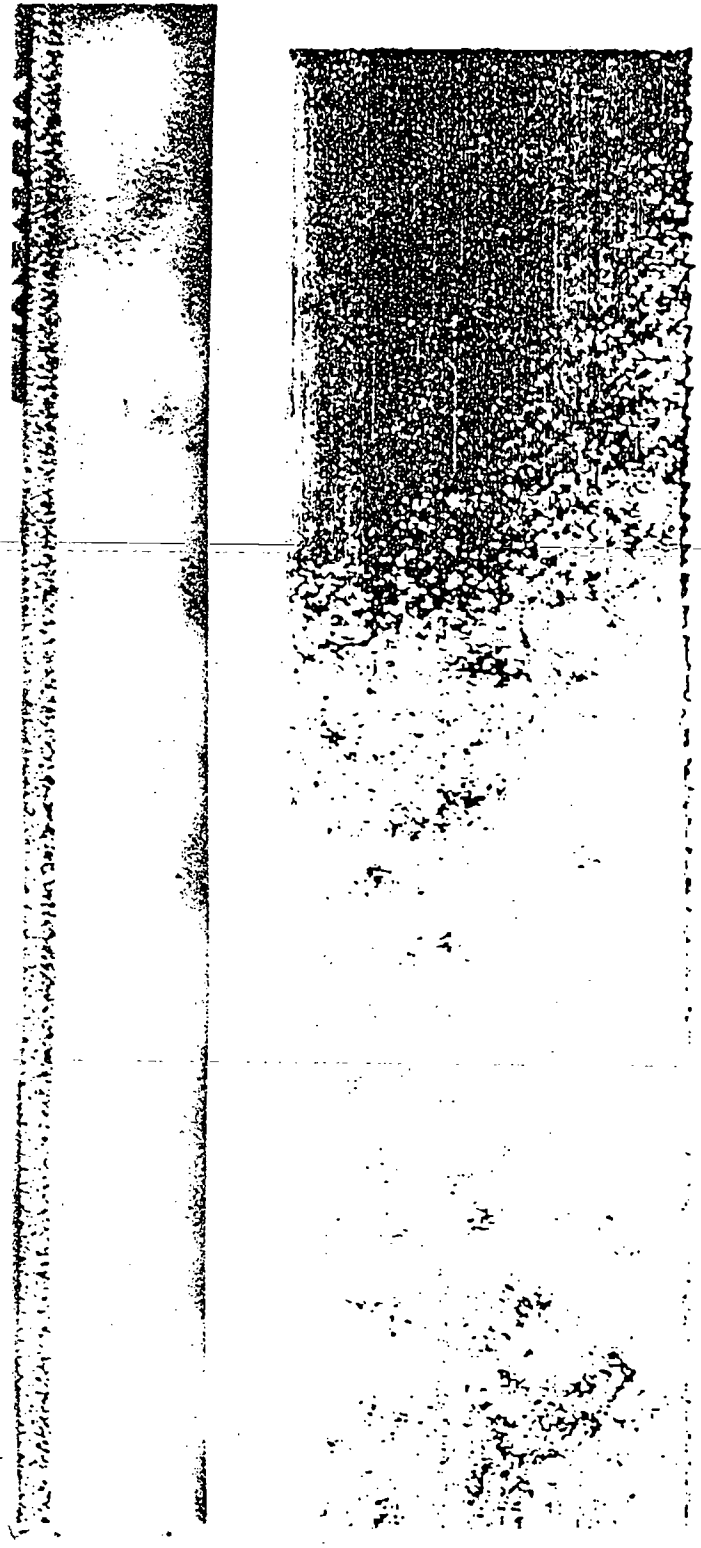
The meeting went very well. Congressmen Romero Barcelo (D-Puerto Rico), Ron De Lugo (D-Virgin Islands), and Robert Underwood (D-Guam),as well as staff were pleased that we would be working closely with them in development of our health plan (see attached news release).

At the meeting it was agreed to set up two work groups, one for Puerto Rico and one for the Territories. It was further agreed to meet within the next several weeks to compare existing data and agree on a health plan with financing estimates that both sides can live with. In addition, everyone was in agreement to immediately (or as fast as humanly possible) exchange financial and resource data now being used to calculate current health estimates.

Subsequent to the meeting I have contacted the offices of the territory representatives and Puerto Rico and have shared a summary of what our health benefit package will offer. I have met with Ken Thorpe who has agreed to see what statistical data he can gather and share. I have also met with and listed for the respective parties needed financial and resource data for our upcoming meetings. By this Friday, July 23rd, Puerto Rico and the territory representatives hope to have this needed data.

In regard to our current position, I'd like to discuss where we stand now (see attached memo) and what further steps need to be taken with both working groups to assure an acceptable proposal. I will call shortly to arrange a time to meet. I can be reached at 202-401-4507.

c.c. Chris Jennings
Don Johnson
Atul Gawande
Tom Gustafson
Ken Thorpe



LOCAL NEWS

Special panel to work on P.R.'s role in health plan

The Associated Press

WASHINGTON — Puerto Rican and White House officials will work together in a "special panel" to negotiate the island's inclusion in the Clinton administration national health care reform plan, Resident Commissioner Carlos Romero Barceló announced Thursday.

"It is clear that Puerto Rico will be included in the national health care reform proposal," the resident commissioner said, adding that the group will work "to negotiate the details of how the reform proposal will be implemented in Puerto Rico, both in terms of financing and integration with our local health reform effort."

The creation of the special panel was agreed to at a meeting between Romero and Ira Magaziner on Wednesday.

Magaziner is the principal adviser to first lady Hillary Rodham Clinton on national health care issues.

In addition to Romero and Magaziner, the working group will include a mix of island and federal officials, including Puerto Rico Secretary of Health Enrique Vázquez Quintana and Gov. Rosselló's chief adviser on health care reform Norman Maldonado.

U.S. officials on the panel will include White House Health Care Task Force advisor Richard Veloz, Health Care Financing Administrator Bruce Vladeck and a health care reform adviser to the Department of Health and Human Services, Atul Gawande.

The special working group will meet throughout the remainder of July and August and hopes to have a plan for Puerto Rico's inclusion ready in advance of the official announcement of a national health care reform plan scheduled for September.

AGUA QUE NO HAS DE BEBER,

TO: Ira Magaziner, Judy Feder
FR: Atul Gawande, Richard Veloz, Don Johnson
RE: 7/12 meeting with Barcelo re: territories and Puerto Rico
DT: 12:23pm July 8, 1993

On 7/12 you have a meeting with Resident Commissioner Carlos Romero-Barcelo. The meeting's purpose is to establish a process for formulating an acceptable plan for the territories and Puerto Rico.

To establish a successful process, you will need to lay out the framework for the territories in the health plan and the negotiations/discussions to follow.

The current proposal:

1. Territories and Puerto Rico are fully included in reform.

2. Coverage and benefits. Alliances and health plans will function under the same rules as for States. However, the territories will have greater flexibility in the following areas:

   - The comprehensive benefit package can be changed to suit the service availability and infrastructure of the territory.

   - The territories may implement reform on their own timeline without penalty.

3. Financing.

   We have concerns that current financing structures in the territories are dramatically different from those in States. In Puerto Rico, for example, health care is not employer-based, but rather a universal, general revenue financed public health system. We do not want to destroy the revenue base for health care in the territories. Therefore, we will provide flexibility on financing:

   - A territory may adopt the financing structure of the health plan or design a financing structure more suited to its own circumstances.

   - To allow for this flexibility and provide for predictable federal expenditure, the federal government will provide a health care block grant at a level significantly above the current Medicaid cap to provide for low-income subsidies.

Moving forward -- the process:

- A small group of three or four people is formed to work with Mr. Romero-Barcelo and others in developing the details for

this proposal in order to assure its acceptability to the territories and Puerto Rico.

- A meeting will be arranged for a negotiation on the level of the health care block grant for the territories and Puerto Rico.

A point of caution

- Expectations have been raised to very high levels as a result of the announcement of full inclusion of the territories and Puerto Rico in reform. They have interpreted this to mean the removal of any federal caps, a maintenance of effort on health spending and federal responsibility for all further low-income subsidies.

Congress of the United States
Congressional Hispanic Caucus
103rd Congress

Members of the Congressional Hispanic Caucus - 103rd Congress

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Appt. Sec.: Angie Borja

WORKING GROUP DRAFT PRIVILEGED AND ~~CONFIDENTIAL~~

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Beginning in January, 1996, the Medicare program expands to cover outpatient prescription drugs.

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

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COVERAGE

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As a condition of participation in Medicare and Medicaid, drug manufacturers must sign rebate agreements with the Secretary. Rebates are required for non-innovator multiple source drugs (generic) but will be less than those currently required under the Medicaid rebate program.

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.

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 will be the AMP for the prescription between April and June, 1993.

Rebates are paid to the Secretary on a quarterly basis.

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

The Secretary has the authority to conduct verification surveys of the AMP.

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. Only generic versions of brand-name drugs are covered unless the physician indicates that a brand name medication is necessary. The Secretary also has the authority to subject a brand-name product to a prior approval requirement if a generic substitute is available.

REIMBURSEMENT

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

For generic drugs, payment is the lower of the pharmacist's usual and customary 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

Private insurance plans provided by former employers are required to either reduce the amount of the premium charged to Medicare beneficiaries to account for the coverage of prescription drugs, or increase coverage of other health services by the actuarial value of the prescription drug benefit under the private plan.

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 to counsel Medicare recipients 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: Strike "subscribes to" and insert "elects to enroll in". Strike "coverage" and insert "program."

   Rationale: Terminology clarification.

2. Proposed change: Strike entire third paragraph and insert "As with other Part B benefits, the Medicare prescription drug benefit is funded by both general revenues and beneficiary premiums. The Part B premium would be increased to cover the new benefit. Beneficiary premiums currently finance 25% of Part B costs. Thus, beneficiaries would pay 25% of the cost of the new drug benefit. Other rules related to enrollment in Medicare Part B also apply to the prescription drug benefit."

   Rationale: Beneficiaries will not pay the same amount for new coverage as they do for current coverage. They will pay the same percentage -- 25%.

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.

   Rationale: Assures the same percentage of beneficiaries over time.

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

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

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

COVERAGE

1. Proposed change: Reference to compendia should read "as found in at least one of the three national compendia, which are..."

   Rationale: Current language requires that the medically accepted indication for a drug or biological be listed in all three compendia.

2. Proposed change: Insulin should be covered under the new benefit.

   Rationale: Insulin needs to be explicitly listed since it is neither a drug or biological. Including insulin is consistent with the Medicare Catastrophic Coverage Act of 1988 (MCCA).

3. Proposed change: A home IV therapy benefit should be covered under the new drug benefit. Drugs provided through the home IV benefit would be subject to the new benefit's deductible and co-payment. Current limited coverage of home IV therapy under the DME benefit would be eliminated.

   Rationale: Including home IV therapy is consistent with the MCCA and eliminates quality assurance concerns under the DME program. According to HCFA actuaries, the cost of the home IV benefit will total $263 million for CY 1995.

4. Proposed change: Current coverage of immunosuppressive drugs, blood clotting factors and osteoporosis drugs should be covered under this new benefit.

   Rationale: Medicare currently covers immunosuppressive drugs for the first year after a covered transplant. After the first year of immunosuppressive therapy, the beneficiary would then be covered under the new drug benefit. Covering the beneficiary under the new benefit from the outset would be administratively simpler. Medicare also currently covers blood clotting drugs for hemophiliacs and osteoporosis drugs.

5. Proposed change: The 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: 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.

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

6. Proposed change: Add a provision that gives the Secretary the authority to establish maximum quantities per prescription and limits on the number of refills.

   Rationale: This provision will discourage wasteful dispensing of pharmaceuticals.

7. 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.

8. Proposed change: In the case of new drugs that the Secretary determines are excessively or inappropriately priced, the Secretary has the authority to establish a price for Medicare's purposes based on negotiations with the manufacturers. If a manufacturer refuses to negotiate or the Secretary is unable to negotiate a price that the Secretary determines to be reasonable, the Secretary would have the authority to exclude the drug from coverage under Medicare.

   Rationale: Mandating that ALL of a manufacturer's drug products not be reimbursed by any federal program is too punitive and as such will never be enforced. In addition, a manufacturer may agree to negotiate but not negotiate in good faith.

COST CONTAINMENT

1. Proposed change: As a condition of participation in Medicare AND MEDICAID, drug manufacturers must sign rebate agreements with the Secretary to be reimbursed for covered drugs under Medicare.

   Rationale: This provision increases likelihood that manufacturers will sign rebate agreements when both Medicare and Medicaid participation included.

2. Proposed change: Include rebates for generic as well as brand name drugs. The rebates for generic drugs would be at a lower level than is currently mandated under the Medicaid program (currently 10% of AMP, 11% of AMP in 1994). The reductions in savings would be offset by stricter enforcement of state laws mandating generic substitution. Medicare's generic rebate percentage would equal the revised Medicaid percentage.

   Rationale: Mandating generic drug rebates is consistent with the current

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

Medicaid drug rebate program. Not mandating generic drug rebates would reduce the total rebates that could be collected by the Federal government. Not including generic rebates could also make the manufacturing of generic drugs too attractive relative to the manufacturing of innovator drugs.

3. Proposed change: Delete reference to carriers or intermediaries.

   Rationale: Having drug claims processors also administer the rebate program raises conflict of interest and confidentiality issues.

4. Proposed change: The rebate formula should use a weighted average of the prices offered by the manufacturer of a given drug in the non-retail market rather than the median price of the drug in the non-retail market.

   Rationale: Using the median rather than the weighted average may result in significantly reduced rebates. For example, if a few HMOs and hospitals receive substantial discounts from drug manufacturers but the majority of other providers receive minor discounts, the median will be skewed towards the lower discounts.

5. Proposed change: Change "average price charged" to "average manufacturers price."

   Rationale: Consistency of terminology.

6. Proposed change: The baseline index price will be the average manufacturers price (AMP) for the prescription from April through June 1993.

   Rationale: A span of several months is desirable to calculate the AMP to get the most accurate estimate of price.

7. Proposed change: 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.

8. Proposed change: Add a provision which allows the Secretary to conduct verification surveys of the AMP.

   Rationale: Drug manufacturers provide the Secretary with the AMP. Oversight is

required to determine that the information supplied is accurate. This provision is consistent with the Medicaid rebate program.

9. 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.

10. Proposed change: Strike "high quality" before "generic substitutes."

    Rationale: Not clear what high quality means in relation to generic drugs or whether this reference is meaningful given current FDA practice.

REIMBURSEMENT

1. Proposed change: Insert "in a previous period" after "charges."

   Rationale: More precise.

2. Proposed change: Change "actual acquisition cost" to "estimated acquisition cost."

   Rationale: Actual acquisition cost is very difficult to administer, requiring a survey of acquisition costs of pharmacists. Estimated acquisition cost could be simply calculated as a percentage of average wholesale price (AWP).

3. Proposed change: Separate discussion of dispensing fees from costs of drugs.

   Rationale: Clarity.

MEDICARE HMOS

1. Proposed change: Omit this section.

   Rationale: Since outpatient drugs are added to the benefit package, HMOs would be required to provide such benefits.

CHANGES IN PRIVATE INSURANCE REQUIREMENTS

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

1. Proposed change: This provision should be limited to policies paid for by former employers.

   Rationale: The new benefit's impact on Medigap policies would be dealt with through loss ratio requirements. NAIC would have to revise the standard benefit package to account for the new benefit.

SUBSIDIES

1. Proposed change: Replace this provision with "Low income beneficiaries receive the same financial protection for out-of-pocket costs associated with the drug benefit as provided for other Medicare cost-sharing amounts."

   Rationale: This provision clarifies the provision's intent. Also, financial assistance implies a cash payment.

REVIEWS

1. Proposed change: Strike "and medical history" and insert "use."

2. Rationale: The pharmacist will not have access to the patient's entire medical history.

Withdrawal/Redaction Marker
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Chris Jennings to Hillary Clinton Re: Meeting with House and Senate Leadership (2 pages)	7/30/93	P5

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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]
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b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
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