Withdrawal/Redaction Sheet
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo w/attach	Chris Jennings, Steve Edelstein to Hillary Clinton Re: Meeting with Senate Small Business Committee (15 pages)	8/4/93	P5
002. memo	Chris Jennings to Hillary Clinton Re: Meeting with Senator Rockefeller (2 pages)	8/9/93	P5
003. memo	Chris Jennings, Steve Edelstein to Hillary Clinton Re: Meeting with Chairman Rostenkowski (2 pages)	8/9/93	P5
004. memo w/attach	Chris Jennings, Steve Edelstein to Hillary Clinton Re: Meeting with Chairman Dingell (5 pages)	8/9/93	P5
005. memo	Chris Jennings, Steve Edelsten to Hillary Clinton Re: Congressman Waxman (3 pages)	8/10/93	P5

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

FOLDER TITLE:
August 1993 [3]

gf101

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]
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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]
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MEMORANDUM

TO: Hillary Rodham Clinton August 5, 1993

FR: Chris Jennings

RE: Workers Compensation

Because the workers compensation issue has received so much interest, I asked Gary Claxton to provide some background information regarding this topic. Attached you will find a one paragraph summary of this policy, followed by a three page description, and a detailed backgrounder on this topic.

If you desire a briefing, I can ask Gary to come in. I hope that this information is helpful.

INTEGRATION OF WORKERS' COMPENSATION INSURANCE

Summary of Policy

Individuals would receive treatment from their health plan for work-related injuries and illnesses. Workers' compensation insurers (including self-funding employers) would be remain responsible for the costs of treatment (based on current law), and would reimburse the health plan for services provided. Reimbursement would be based on a fee schedule or on an alternative arrangement established by the alliance or negotiated between the workers' compensation insurer and the health plan.

A National Advisory Committee on the Integration of Medical Insurance Benefits would be created to study the feasibility and appropriateness of integrating the financial responsibility for work-related injuries and automobile accidents into the new health care system.

Suggested agenda for meeting at 11:30, Fri. Aug. 6

1. Melanne and Judy describe the policy (benefit language, state non-preemption language, subsidies [including exclusion/deduction])

2. open discussion of why (or if) this is the right compromise position, and how to sell it to Members on both sides of the issue

3. Member outreach planning

4. acknowledgment of need to look at Floor situation later

Subsidy pool

- Immediate offsets:
  - Medicaid workers
    Medicare workers → $19 Billion a year
  - Uncompensated care at $22 Billion →
    Calculate it into baseline
    in premium. ✓
    prefer this
    approach to
    taxing
  - Private sector health care costs. Texas → $20 Billion or more
    Reducing the deductibility liability

Cap Medicare costs

Letter to Dole/Michel

INTEGRATION OF WORKERS' COMPENSATION INSURANCE

Health plans provide treatment for individuals with work-related injuries covered under workers' compensation insurance.

Workers' compensation insurers (including self-funding employers) continue to be responsible for the costs of treatment based on current law and reimburse health plans for services provided. Reimbursement is based on a fee schedule or on an alternative arrangement established by alliances or negotiated between workers' compensation insurers and health plans.

To obtain state certification, a health plan demonstrates its ability to provide or arrange for comprehensive medical benefits for work related-injuries and illnesses, including rehabilitation and long-term care services.

- Health plans employ or enter into contracts with specialists in industrial medicine and occupational therapy.
- Health alliances are responsible for coordinating access to specialized health providers or centers of excellence in industrial medicine and occupational therapy.
- Alliances may enter into contracts with health care professionals and institutions that provide specialized services for the treatment of work-related injuries and illnesses on behalf of all health plans serving the alliance region.

Individuals enrolled in health plans within the alliance receive treatment for work-related injuries or illnesses from their health plans, although emergency treatment may be obtained from any provider.

State laws regarding choice of provider for workers' compensation cases are overridden with respect to individuals covered through health alliances. Exceptions may be necessary in cases of disputes.

Each health plan designates a workers' compensation case manager to coordinate the treatment and rehabilitation of injured workers. The case manager ensures that:

- The plan of treatment for an injured worker meets appropriate protocols and is designed to assure rapid return to work.

- The plan of treatment is coordinated with the workers' compensation insurance carrier and/or the employer to facilitate rapid return to work.

- The health plan complies with medical and legal requirements related to workers' compensation.

- If the health plan is unable to provide a needed service to treat a work-related injury or illness, the workers' compensation case manager, in consultation with the workers' compensation carrier, refers the worker to an appropriate provider.

Health plans are reimbursed by workers' compensation insurance carriers or self-funded employers for work-related medical benefits in accordance to the fee-for-service schedule in the alliance.

- Alliance fee schedules include rehabilitation, long-term care and other services commonly used for the treatment of work-related injuries and illnesses.

- Alliances are permitted to adopt varying arrangements with health plans for providing work-related medical benefits, including negotiating per case capitation payments.

- Health plans are permitted to negotiate fees that vary from the fee-for-service rate schedule with workers' compensation insurers and employers.

Health plans and providers are not allowed to bill patients with work-related injuries or illnesses for additional charges beyond those covered by the health plan.

Information related to provider and health plan performance in treating work-related injuries and illnesses (including the health plan performance in facilitating injured workers' returning to work) are included in reporting information about the quality of care provided by the health plan.

Nothing in this policy alters or diminish the effects of state workers' compensation

laws as the exclusive remedy for work-related injuries or illnesses. [See language in OSHA 29 USC Sec. 653(b)(4)]. Disputes related to whether an injury or illness is work-related are resolved in accordance with existing state laws.

Health benefits for work-related injuries and illnesses continue to be defined by states.

For regional alliances, the federal requirements related to workers' compensation become effective two years after implementation of the state health reform program. For corporate alliances and federal workers' compensation programs, the federal requirements become effective in 1998.

Compensation programs under FECA, the Jones Act and the Longshoreman's Act are subject to similar requirements.

The Department of Labor and the Department of Health and Human Services study the feasibility and appropriateness of transferring the financial responsibility for all medical benefits (including those now covered under workers' compensation and automobile insurance) to the new health system. These departments report to the President, and present a detailed plan for integration if it is recommended, on or before July 1, 1995.

The Department of Health and Human Services and the Department of Labor are authorized to conduct a demonstration program in one or more states related to treatment of work-related injuries and illnesses.

- The Department of Health and Human Services and the Department of Labor, in consultation with states and experts on work-related injuries and illnesses, develop protocols for the appropriate treatment of work-related conditions.

- The Department of Health and Human Services and the Department of Labor enter into contracts with one or more alliances to test the validity of protocols.

- The demonstration may include the development of per-case capitation payments to health plans for the treatment of work-related injuries and illnesses.

FACSIMILE TRANSMISSION REQUEST

ADDRESSEE: (Name, Organization, Address)	FROM: (Name, Organization, Address)
CHRIS JENNINGS Phone: 202/456-2645	PETER HICKMAN 690 – 5950 Phone: 202/[illegible] – [illegible]

TOTAL PAGES: (Without Cover)	ADDRESSEE'S FAX MACHINE PHONE NUMBER: (If Known)	DATE:
2	202/456-7739	8/6/93

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6 pp 8284
Ask Peter
why not 5 days
that are excluded/
inappropriately priced + used.

Memorandum

TO: Chris Jennings

FR: Peter Hickman and Lucia Giudice

RE: Modifications to Working Group Draft/Medicare Outpatient Drug Benefit

DT: August 6, 1993

PRIOR APPROVAL PROCESS

Under the Medicaid program, prior authorization can apply to either the prescribing and dispensing of a particular drug or the prescribing and dispensing practices of individual providers. Therefore, we believe that the description of the prior approval program should remain general. We may want to add requirements similar to those in Medicaid that define procedural limits on the prior approval program.
For example, the prior approval program must provide response by telephone or other telecommunications device within 24 hours of a request for prior authorization and provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation as defined by the Secretary.

PRICE NEGOTIATIONS FOR NEW DRUGS

We suggest using the Food and Drug Administration's (FDA)current system for classifying the treatment potential of new drugs. The FDAclassifies the treatment potential of new drugs as either Type P or Type S. Type P drugs appear to represent a therapeutic advance with respect to available therapy by (1) providing effective treatment or diagnosis for a disease not adequately treated or diagnosed by any marketed drug or (2) providing improved treatment of a disease through greater effectiveness or safety (including decreased abuse potential) or (3) having a modest, but real advantage over available marketed drugs such as: significantly greater patient convenience; elimination of an annoying but not necessarily dangerous, adverse reaction; and usefulness in a specific subpopulation of patients with disease such as the elderly. Type S drugs appear to have therapeutic qualities similar to those of one or more already marketed drugs.

unless

The provision for price negotiation would be limited to Type P drugs. The price would be considered excessive if it is significantly greater than the price of other products in the same therapeutic class and if the price exceeds the price at which the drug is available in other industrialized nations. This systems parallels the new drug review process used by the Canadian government.

As an alternative to the system described above, the following process parallels the program used by the Australian government. The Secretary would consider the following factors in pricing negotiations with drug manufacturers -- the prices of drugs in the same therapeutic class, cost information supplied by the manufacturer or estimated by the Secretary, prescription volumes, economies of scale, product stability, special manufacturing requirements, prices of the drug in other comparable countries and other relevant factors. We believe that the former alternative is desirable since it is less burdensome to manufacturers.

DRUG BUY OUT PLANS

Language discussing expenses incurred by beneficiaries enrolled in HMOs that are drug buy-out plans and how those expenses will be counted towards Medicare outpatient drug deductible if a beneficiary disenrolls is no longer necessary since under Health Reform Medicare beneficiaries will be required to remain in managed care plans for at least one year and since the proposed Medicare deductible is relatively low.

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DURATION OF AGREEMENT

Voluntary agreements continue in effect for a period of not less than three years.

In conjunction with the newly established Pharmaceutical Review Commission under the National Health Board, the Secretary makes an annual report to Congress on the extent to which managed competition affects the pharmaceutical market. Measurable impacts of competitive forces under health reform include the use of formularies, competitive purchasing and generic substitution.

Should the Secretary conclude that less than 75 percent of the pharmaceutical market is not affected by new competitive conditions, the Secretary makes a recommendation to the President and the Congress about extending voluntary price-control agreements for an additional period of time.

BREAKTHROUGH DRUG COMMITTEE

To encourage reasonable pricing of breakthrough drugs, a committee of the National Health Board has the authority to make public declarations regarding the reasonableness of launch prices. During any period when short-term price controls are in effect the Commission would have the authority to make public statements about all new drugs introduced, which normally is 20-30 per year.

After short-term price controls are lifted, the committee could address new drugs that represent a breakthrough or significant advance over existing therapies. The committee could also address all drugs subject to a "reasonable price" clause in a contract with the National Institutes of Health.

The committee could investigate drug prices only in those cases where available evidence suggests that the price may be unreasonable. The committee could make an initial determination about the reasonableness of a drug price based on a comparison of prices for therapeutically similar drugs in the United States and seven other industrialized countries.

If the drug price exceeds what the committee thinks to be reasonable based on the information available, or if there is insufficient data, the committee would have the authority to obtain information from the company about the drug's price. The committee could then issue a report regarding the reasonableness of the drug price. The committee would have no authority to set or control drug prices.

Procedure w/ vaccines

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 (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 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, CO[redacted] AND CAPS

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

[redacted] 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 a initial $250 deductible and $1000 out-of-pocket cap.

COVERAGE

The Medicare drug benefit covers all drugs, biologicals and insulin approved by the Food and Drug Administration (FDA) 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, or other authoritative compendia identified by the Secretary. The Medicare drug benefit does not cover a drug if its use is unfavorably reported in one or more compendia or the Secretary determines that the drug is not medically appropriate.

The Medicare drug benefit includes coverage of home IV drugs. In addition, the current law 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 categories or types of drugs listed in Section 1927(d) of the Social Security Act. Examples include fertility drugs, medications used to treat anorexia and drugs used

[redacted] 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 [redacted] to obtain prior approval before prescribing [redacted] 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. 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 [redacted] sign rebate agreements with the Secretary. Rebates are paid to the Secretary on a quarterly basis.

[redacted]

[redacted], 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, [redacted], whichever is greater. The Secretary has the authority to conduct verification surveys of the AMP.

[redacted] an additional rebate is required [redacted] 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.

[redacted]

[redacted]

[redacted]

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 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 usual and customary charges in a previous period, or the estimated acquisition cost (EAC) plus [redacted]

For generic drugs, pays the lower of the pharmacist's usual and customary charge or the median of all generic prices (times the number of units dispensed) plus [redacted]

[redacted]

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 [redacted].

REVIEWS

The Medicare DUR program parallels the program established in OBRA 1990 for Medicaid. Participating pharmacists are required to offer to counsel Medicare [redacted] 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: 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 Pharmacopeia, or other authoritative compendia identified by the Secretary. The Medicare drug benefit does not cover a drug if its use is unfavorably reported in one or more compendia or the Secretary determines that

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

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.

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: Include rebates for generic as well as brand name drugs. The rebates for generic drugs would be at a lower level -- 7 percent -- 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. See rewritten provisions in attached draft.

   Rationale: Mandating generic drug rebates is consistent with the current 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.

MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

3. 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.

4. 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.

5. 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.

6. 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.

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: Omit this section.

   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.

REVIEWS

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

2. Rationale: Typographical error.

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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
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
005. memo	Chris Jennings, Steve Edelsten to Hillary Clinton Re: Congressman Waxman (3 pages)	8/10/93	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:
August 1993 [3]

gf101

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]
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