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Tobacco Cessation: [Correspondence]

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From the desk of Michael C. Fiore

7/28/98

Jerry -

*Here is the updated
Executive order draft.
See you next week. Talk
to you late this week.*

Regards,

Michael Fiore



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MEMORANDUM

TO: Jerry Mande
FROM: Michael C. Fiore, M.D., M.P.H. M.F.
DATE: July 28, 1998
RE: Proposed Executive Order: **Increasing Access to Effective Tobacco Cessation Treatment**

Over the last week, my colleagues and I at the University of Wisconsin *Center for Tobacco Research and Intervention* have considered your request to draft an Executive Order addressing smoking cessation. To assist us in this endeavor, we used as a model the President's Executive Order dated August 9, 1997, *Protecting Federal Employees and the Public From Exposure to Smoke in the Federal Workplace*.

To address your request, we posed the following question:

How can the President promote smoking cessation through an Executive Order in a way that will result in the greatest public health impact, in the most cost-effective manner?

On the following pages, we provide a draft Executive Order addressing smoking cessation and some background information to support that Executive Order. In summary, the proposed Executive Order would include the following components:

1. Federal Employees -- Mandate that health plans bidding under the Federal Employees Health Benefit Program provide effective smoking cessation treatments* for all Federal employees.
2. Department of Defense Personnel -- Order that DOD health care programs provide effective smoking cessation treatments* for all DOD personnel.
3. U.S. Veterans -- Order that the Department of Veterans Affairs provide effective smoking cessation treatments* to all veterans.
4. Medicaid Beneficiaries -- Order the Health Care Financing Administration to review barriers to effective smoking cessation treatments* for Medicaid Beneficiaries and provide specific recommendations to remove those barriers.
5. Tax Treatment of Tobacco Use Cessation -- Order the IRS to review their regulations and interpretations regarding taxation of tobacco cessation treatments to identify and remove barriers to such treatments.

* FDA-Approved Pharmacotherapies and AHCPR-Endorsed Cessation Programs

Rationale for a Presidential Executive Order Addressing Smoking Cessation:

Smoking exacts an enormous toll on our society. It is responsible for 20% of all deaths in America (more than 400,000 deaths each year), an extraordinarily burden of illness, and more than 50 billion dollars in direct health care costs (about 10% of all health care costs) each year. Reducing tobacco use through successful smoking cessation will benefit the health and economic well-being of all Americans.

Among the 50 million adult smokers in the United States today, approximately 70% now state that they would like to quit and almost 20 million try to quit each year. Unfortunately, more than 9 out of 10 smokers who attempt to quit do so on their own, and less than 5% of these individuals are successful in achieving their goal. Clearly, smokers who want to quit should be encouraged to use the most effective cessation treatments available. Such treatments increase quit rates by 2-4 times, compared to self-quitting.

Over the last decade, enormous progress has been made in identifying smoking cessation treatments (both pharmacotherapy and counseling) that markedly increase quit rates above the discouraging percentages achieved by patients who try to quit on their own. These helpful treatments have been reviewed and endorsed by the U.S. Food and Drug Administration (FDA) and the Agency for Health Care Policy and Research (AHCPR). Among the most important public health challenges facing American society today is that of providing effective treatments to all American smokers wanting to quit.

A significant barrier to the use of effective treatments is inadequate insurance coverage. Recent surveys have documented that only about half of insurance plans in the United States provide coverage for either smoking cessation pharmacotherapy or counseling. Fewer still provide enrollees with the effective treatments documented by the FDA and AHCPR. An Executive Order that mandates such insurance coverage for key populations (e.g., Federal employees, veterans) would serve as a model for the insurance industry and establish a new standard of care that will improve health and reduce the health care costs of all Americans.

Parameters of Smoking Cessation Coverage

In order to mandate smoking cessation treatment coverage (for Federal employees or veterans, for example), parameters regarding the type and costs of the treatment are essential. Such parameters are needed for insurers to estimate the potential cost implications of such treatments. Additionally, some smoking cessation treatments are *ineffective*, and without rational, evidence-based parameters, resources might be spent inappropriately.

Fortunately, research evidence has clearly identified effective smoking cessation treatments. This evidence have been compiled by the U.S. Food and Drug Administration and the Agency for Health Care Policy and Research. Any Executive Order should specifically reference the criteria and findings of these federal agencies.

Specifically, only those treatments that fulfill either of the following two criteria should be deemed “effective treatments” and be made eligible for coverage mandated by an Executive Order:

- A. FDA-Approved Pharmacotherapies. The U.S. Food and Drug Administration has identified five separate agents as safe and effective aids for smoking cessation . These agents are nicotine gum, the nicotine patch, nicotine nasal spray, the nicotine inhaler, and bupropion SR (Zyban). All of these agents should be listed as eligible for coverage under an Executive Order that mandates coverage for effective smoking cessation treatments.
- B. AHCPR-Endorsed Cessation Programs: Through a systematic review of more than 3,000 scientific articles published since 1975, the AHCPR Smoking Cessation Guideline Panel identified a series of effective smoking cessation counseling treatments and programs. Specifically, the AHCPR Guideline endorsed brief counseling provided by a clinician as a regular part of health care delivery. Some other more intensive treatments were also endorsed. However, the Panel identified a series of treatments that were *not endorsed* (e.g., acupuncture, hypnosis).

Making coverage of treatments contingent upon AHCPR Guideline endorsement and FDA-approval will insure that patients are not subjected to ineffective treatments and will avoid financial abuse of this expansion of coverage.

In addition to type of treatment, language regarding mandated coverage must stipulate clear boundaries regarding the frequency and costs of treatment. This information is required to estimate the potential cost of expanded coverage that might be incurred by managed care organizations and other payers. Using available data, we believe the following are reasonable and fair parameters for limiting coverage of smoking cessation treatments:

Patients may engage in a covered smoking cessation treatment (pharmacotherapy and/or counseling) no more than one time per year and no more than three times per lifetime. The cost of such a covered treatment will not exceed \$400/treatment (1998 dollars).

The above treatment parameters are designed to *maximize successful smoking cessation* and are based on two research findings. First, research has now documented that the average smoker requires three to five cessation attempts before successfully quitting. As a result, three treatments in a lifetime is consistent with the therapy required to successfully treat this chronic disease. Second, the selection of \$400 per treatment is based upon the average cost of AHCPR-endorsed counseling and pharmacotherapy (1998 dollars) necessary to increase the likelihood of successful smoking cessation. These two key provisions (\$400/treatment, three covered treatments/lifetime) are greater than the smoking cessation coverage provisions currently available to most federal employees as part of their health insurance plans (\$100/treatment, one treatment/lifetime). This increase in coverage will markedly enhance the likelihood that federal employees will successfully quit smoking.

Finally, we urge you to consider one additional possibility:

Include coverage for smoking cessation treatments (both pharmacotherapy and counseling) as part of the proposed “Patient’s Bill of Rights”

As was recently documented in the Journal of the American Medical Association, tobacco cessation treatment is the single most cost-effective preventive intervention available for adults in the United States today. These effective tobacco cessation treatments include **pharmacotherapies** approved by the FDA and **counseling** outlined in the AHCPR Smoking Cessation Clinical Practice Guideline #18.

Currently, only about half of Managed Care Organizations in the United States pay for effective smoking cessation treatments. These treatments typically cost \$300 to \$400. This is paradoxical given that virtually all health insurance plans pay for the very expensive outcomes of smoking -- heart attacks, strokes, cancer, and lung disease. By highlighting the most effective preventive intervention as part of a “Patient’s Bill of Rights,” the President can make a powerful public health statement.

To support the proposed Executive Order, we have included the following attachments:

1. Draft Executive Order: Increasing Access to Effective Tobacco Cessation Treatment
2. Justification for Federal Employee Tobacco Cessation Health Benefit
3. Justification for Medicaid Beneficiary Tobacco Health Benefit
4. Current Medicaid Regulations Regarding Tobacco Cessation Treatment with Recommendation for Repeal
5. Current IRS Regulations Regarding Tobacco Cessation Treatment
6. Model Executive Order Used (Dated August 9, 1997)

1. EXECUTIVE ORDER: INCREASING ACCESS TO EFFECTIVE TOBACCO CESSATION TREATMENT

By the authority vested in me as President by the Constitution and the laws of the United States of America and to increase access to effective tobacco cessation treatments (both pharmacotherapy and counseling) for federal employees, Department of Defense personnel, Veterans, and Medicaid beneficiaries, and to encourage access for the general public, it is hereby ordered as follows:

Section 1. Federal Employees. It is the policy of the executive branch to increase access to effective tobacco cessation treatments (both pharmacotherapies and counseling) for federal employees through the Federal Employees Health Benefit Program. All health plans bidding under the Federal Employees Health Benefit Program must provide access to FDA-approved pharmacotherapies for cessation and evidence-based tobacco use cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692). The Secretary of Health and Human Services shall develop a program to educate federal employees about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 2. Department of Defense Personnel. It is the policy of the executive branch to increase access to effective tobacco cessation treatments for Department of Defense personnel. The Department of Defense accordingly shall make available to all personnel through the existing health care programs FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692). The Secretary of Defense shall develop a program to educate all Department of Defense personnel about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 3. U.S. Veterans. It is the policy of the executive branch to facilitate access to effective tobacco cessation treatments for all veterans. The Department of Veterans Affairs shall make available FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692) available to all veterans through the DVA health care programs. The Secretary of Veterans Affairs shall develop a program to educate veterans about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 4. Medicaid Beneficiaries. It is the policy of the executive branch to encourage access to effective tobacco cessation treatments for the Medicaid population. To improve the health of smokers within the Medicaid population and lower the medical cost burden associated with tobacco use, the Medicaid program should provide access to FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation programs (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692).

To promote this policy, the Health Care Financing Administration shall conduct a study of the availability of tobacco use cessation treatments under state Medicaid programs, identify the existing barriers to such coverage, and provide recommendations (1) for making FDA-approved pharmacotherapies for cessation and other evidence-based cessation treatments (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692) available to the Medicaid population, and (2) for informing the Medicaid population about the hazards of tobacco use the availability of effective tobacco cessation treatments.

Section 5. Public Education. It is the policy of the executive branch to encourage tobacco cessation. To promote this policy, the Secretary of Health and Human Services shall develop a public information and education program to encourage tobacco cessation among the general population emphasizing effective tobacco cessation treatments.

Section 6. Tax Treatment of Tobacco Use Cessation. It is the policy of the executive branch to remove barriers to health care coverage of tobacco cessation pharmacotherapies and counseling caused by the tax treatment of such treatments. Accordingly, the Internal Revenue Service shall (1) review their regulations and interpretations regarding the tax treatment of tobacco cessation treatments (both pharmacotherapies and counseling), particularly under Section 213 of the Internal Revenue Code, (2) identify current barriers to health care coverage of such pharmacotherapies and counseling, and (3) provide recommendations for promptly removing those barriers.

2. JUSTIFICATION FOR FEDERAL EMPLOYEES TOBACCO CESSATION HEALTH BENEFIT

The Federal Employees Health Benefits Program (FEHB) is paradoxical in its coverage of smoking cessation treatments -- despite overwhelming evidence that tobacco use constitutes a major threat to public health, and despite the Federal Governments' increased interest in reducing tobacco use, effective smoking cessation benefits are not guaranteed to Federal employees.

A signal feature of the FEHB is patient choice. Thus, health plans available to federal employees vary in their coverage of smoking cessation services. Many explicitly exclude all tobacco cessation treatments from coverage. Those plans that do cover smoking cessation tend to limit coverage to \$100/treatment, cover only prescription drugs, and to restrict cessation benefits to a single course of treatment per lifetime. Even in these instances, federal employees often become eligible for coverage only after the satisfaction of a calendar-year deductible.

As the world's largest employer-sponsored health insurance program, affecting over 9 million federal employees, retirees, and their families, the FEHB is in a unique position to set an appropriate standard of care for smoking cessation. It is likely that an FEHB guarantee of flexible access to effective, multicomponent cessation interventions to its beneficiaries would be adopted by other employers. This sort of ripple effect could dramatically improve the health of working Americans and produce tremendous long-term savings in health care costs that extend well into the next century. Of course, these cessation treatments will only be provided to smokers motivated to quit and desiring such treatments.

Guaranteed access to effective smoking cessation treatments for FEHB beneficiaries might take several forms, but achieving the optimal combination of health promotion and medical care savings will require two specific components. First, the services covered must be *proven effective*. Only pharmacotherapies and devices approved by the FDA and counseling programs conforming to AHCPR guidelines should be covered. Restricting coverage to these proven therapies will encourage their use, thereby optimizing overall cessation rates, and prevent wasteful spending on ineffective programs. Second, coverage must provide for *flexible* and *repeatable* treatment. Not all smokers benefit equally from a given intervention, and smokers differ in terms of which interventions they find appealing and/or acceptable. A coverage policy that does not provide smokers with a choice of treatments runs the risk of deterring as many smokers as it encourages. Additionally, studies indicate that most smokers make several serious attempts at quitting before they achieve long-term abstinence. Access to *repeatable* treatment, therefore, has the greatest potential to reduce smoking prevalence and the adverse impacts of smoking.

Understanding the need to indicate limits to such repeatable treatment, we have proposed the following:

Patients may engage in a covered smoking cessation treatment (pharmacotherapy and/or counseling) no more than one time per year and no more than three times per lifetime. The cost of such a covered treatment will not exceed \$400/treatment (1998 dollars).

3. JUSTIFICATION FOR MEDICAID BENEFICIARY TOBACCO CESSATION HEALTH BENEFIT

Cigarette smoking exacts an enormous toll on all segments of our society, one that is evident in terms of both burdensome health care costs and excess morbidity and mortality. However, Medicaid recipients represent a subgroup of our society that is particularly vulnerable to the health consequences of smoking. For instance, a study by the Center on Addiction and Substance Abuse at Columbia University found that over 42% of Medicaid recipients smoke, as compared to 25% of the general population. The same study estimated that tobacco-related illness accounts for over \$8 billion in Medicaid costs each year. Nearly 10% of all Medicaid hospital days are attributable to smoking.

These human and economic costs have not gone unnoticed. Indeed, 40 states have sued the tobacco industry to recover Medicaid costs related to smoking. Whatever the merits or eventual resolution of this litigation, it is clear that attaining the broader goal of protecting the health of Medicaid beneficiaries who smoke requires some mechanism for providing them access to smoking cessation therapies of proven effectiveness. In short, smoking-related illness and its associated costs will not be meaningfully reduced until smoking behavior itself is modified.

Currently, fewer than half of the states provide coverage for smoking cessation products in their Medicaid programs. This neglect of smoking cessation is codified in federal law, which allows states to exclude FDA-approved smoking cessation therapies from coverage under Medicaid (42 U.S.C. § 1396r-8(d)(2)). Other drugs covered under the same discretionary exclusion provision include agents for treating cold symptoms and for stimulating cosmetic hair regrowth. Federal law is silent with respect to coverage of counseling programs and other behavioral support for smoking cessation, and thus states vary with respect to coverage of these services.

The federal government has committed significant resources to determining which smoking cessation treatments are most effective. For instance, The Agency for Health Care Policy and Research commissioned an expert panel to review the entire scientific literature on smoking interventions and to offer recommendations about which are the most effective. A study published by the same group of experts demonstrated that, among preventive services, smoking cessation is second only infant immunization in terms of cost-effectiveness. Of course, many other agencies within the federal government, including the Food and Drug Administration and many divisions of the Department of Health and Human Services, have also evaluated cessation treatments. Clearly, the federal government considers smoking cessation to be a major health care priority for the U.S.. The absence of federal legislation mandating coverage for smoking cessation treatments for recipients of medical assistance under Title XIX is paradoxical.

While changing the current Medicaid policy regarding smoking cessation treatment access may require legislation, an Executive Order could promote such access.

4. **CURRENT MEDICAID REGULATIONS REGARDING TOBACCO CESSATION TREATMENT WITH RECOMMENDATION FOR REPEAL**

Current federal law allows states to exclude FDA-approved smoking cessation treatments from coverage under Medicaid. (42 U.S.C. § 1396r-8(d)(2)). Ironically, although 40 states have sued the tobacco industry to recover Medicaid costs related to smoking, less than half the states provide coverage for smoking cessation products in their Medicaid programs. Many of the states that do not provide Medicaid coverage for smoking cessation therapies directly or indirectly rely on the discretionary exclusion provision currently in the federal law. This statutory provision should be repealed so Medicaid recipients can have access to FDA-approved smoking cessation therapies.

Proposed Legislative Language:

Section 2:

(1) In general: Section 1927(d)(2) (42 U.S.C. § 1396r-8(d)(2)) is amended by striking subparagraph ‘(E)’; redesignate subparagraphs ‘(F)’, ‘(G)’, ‘(H)’, and ‘(I)’ as ‘(E)’, ‘(F)’, ‘(G)’, and ‘(I)’ respectively.

1927(d) Limitation on Coverage of Drugs:

‘(2) List of drugs subject to restriction: The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

‘(A) Agents when used for anorexia, weight loss, or weight gain.

‘(B) Agents when used to promote fertility.

‘(C) Agents when used for cosmetic hair regrowth.

‘(D) Agents when used for the symptomatic relief of cough and colds.

~~*‘(E) Agents when used to promote smoking cessation.*~~

‘(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

‘(G) Nonprescription drugs.

‘(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

‘(I) Barbiturates.

‘(J) Benzodiazepines.’

5. CURRENT IRS REGULATIONS REGARDING TOBACCO CESSATION TREATMENT

An expense is reimbursable under a health FSA only if it is a medical expense as defined in Code Sec. 213. Prop. Treas. Reg. Sec. 1.125-2, Q&A 7(b)(4). To be a medical expense under Code Sec. 213, an expense must be for “medical care.” Code Sec. 213(a); Treas. Reg. Sec. 1.213-1(a)(3).

- To qualify as an expense for “medical care,” an expense must be for goods or services proximately related to the diagnosis, cure, mitigation, treatment or prevention of a particular “disease.” Code Sec. 213(d)(1); Treas. Reg. Sec. 1.213-1(e); Stringham v. Commissioner, 12 T.C. 580, 584 (1949); Daniels v. Commissioner, 41 T.C. 324 (1965). Typically, a facts and circumstances inquiry is necessary to determine whether a particular expense meets this standard. See Stringham, 12 T.C. at 584; IRS Pub. 502 (Rev. Nov. 1996) at 13.
- Expenses related to a “drug” are subject to the general requirement that they be for “medical care,” Code Sec. 213(b). In addition, the “drug” must be a prescription drug or insulin, Code Sec. 213(d)(3), and it must be legally procured under federal law. Treas. Reg. Sec. 1.213-2; Rev. Rul. 97-9, 1997-9 I.R.B. I(Feb13, 1997) (noting that expense for prescription marijuana, which was legal under state law, are not deductible because marijuana is not legal under federal law).
- The IRS does not currently recognize smoking as a “disease.” GCM 37115 (May 10, 1997). Consequently, expenses for smoking cessation programs of any kind are not deductible for taxpayers who simply wish to stop smoking to improve their general health. Id.; see Rev. Rul. 79-162, 1979-1 C.B. 116 (Jan. 1979) (no deduction or nine-week smoking cessation program taken at physician’s suggestion because only taken “for the purpose of improving [taxpayer’s] health”); PLR 7906009 (Aug. 10, 1978) (no deduction for smoking cessation program recommended by doctor to alleviate “cigarette hacks” and reduce the possibility of developing serious respiratory problems because “Medical experts haven’t recognized smoking as disease therefore treatments weren’t for purpose of curing or mitigating specific illness or disease”); see also PLR 8919009 (Feb. 6, 1989 (“Attendance at classes or participation in programs given on a health-related topic are excluded from the definition of “medical care” if they are merely beneficial to the general health of the individual and not related to a specific condition.”)).
- The IRS does recognize, however, that smoking has been linked to several diseases, including lung cancer or respiratory disorders. GCM 37115. Expenses related to smoking cessation programs for smokers who have these disease “might well be” deductible, particularly if the smoker had been advised to enter the smoking cessation program by a doctor. Id.
- The IRS has also noted that “if medical authorities should ever classify smoking itself as a disease or addiction, [the IRS] believe(s) the expense incurred [or a smoking cessation program] would probably qualify as a deduction for medical care.” GCM 37115; see also Note, “Deducting the Cost of Smoking Cessation Programs Under Internal Revenue Code Section 213,” 81 U.Mich.L. Rev. 237 (Nov. 1982).

6. MODEL EXECUTIVE ORDER - AUGUST 9, 1997

THE WHITE HOUSE,
Office of the Press Secretary

For Immediate Release
EXECUTIVE ORDER

August 9, 1997

PROTECTING FEDERAL EMPLOYEES AND THE PUBLIC FROM EXPOSURE TO TOBACCO SMOKE IN THE FEDERAL WORKPLACE

By the authority vested in me as President by the Constitution and the laws of the United States of America and in order to protect Federal Government employees and members of the public from exposure to tobacco smoke in the Federal workplace, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the executive branch to establish a smoke-free environment for Federal employees and members of the public visiting or using Federal facilities. The smoking of tobacco products is thus prohibited in all interior space owned, rented, or leased by the executive branch of the Federal Government, and in any outdoor areas under executive branch control in front of air intake ducts.

Sec.2. Exceptions. The general policy established by this order is subject to the following exceptions:

(a) The order does not apply in designated smoking areas that are enclosed and exhausted directly to the outside and away from air intake ducts, and are maintained under negative pressure (with respect to surrounding spaces) sufficient to contain tobacco smoke within the designated area. Agency officials shall not require workers to enter such areas during business hours while smoking is ongoing.

(b) The order does not extend to any residential accommodation for persons voluntarily or involuntarily residing, on a temporary or long-term basis, in a building owned, leased, or rented by the Federal Government.

(c) The order does not extend to those portions of federally owned buildings leased, rented, or otherwise provided in their entirety to nonfederal parties.

(d) The order does not extend to places of employment in the private sector or in other nonfederal governmental units that serve as the permanent or intermittent duty station of one or more Federal employees.

(e) The head of any agency may establish limited and narrow exceptions that are necessary to accomplish agency missions. Such exception shall be in writing, approved by the agency head, and to the fullest extent possible provide protection of nonsmokers from exposure to environmental tobacco smoke. Authority to establish such exceptions may not be delegated.

Sec. 3. Other Locations. The heads of agencies shall evaluate the need to restrict smoking at doorways and

in courtyards under executive branch control in order to protect workers and visitors from environmental tobacco, and may restrict smoking in these areas in light of this evaluation.

Sec. 4. Smoking Cessation Programs. The heads of agencies are encouraged to use existing authority to establish programs designed to help employees stop smoking.

Sec. 5. Responsibility for Implementation. The heads of agencies are responsible for implementing and ensuring compliance with the provisions of this order. "Agency" as used in this order means an Executive agency, as defined in 5 U.S.C. 105, and includes any employing unit or authority of the Federal Government, other than those of the legislative and judicial branches. Independent agencies are encouraged to comply with the provisions of this order.

Sec. 6. Phase-In of Implementation. Implementation of the policy set forth in this order shall be achieved no later than 1 year after the date of this order. This 1 year phase-in period is designed to establish a fixed by reasonable time for implementing this policy. Agency heads are directed during this period to inform all employees and visitors to executive branch facilities about the requirements of this order, inform their employees of the health risks of exposure to environmental tobacco smoke, and undertake related activities as necessary.

Sec. 7. Consistency with Other Laws. The provisions of this order shall be implemented consistent with applicable laws, including the Federal Service Labor-Management Relations Act (5 U.S.C. 7171 et seq.) And the National Labor Relations Act (29 U.S.C. 151 et seq.) Provisions of existing collective bargaining agreements shall be honored and agencies shall consult with labor representative about the implementation of this order. Nothing herein shall be constructed to impair or alter the powers and duties of Federal agencies established under law. Nothing herein shall be constructed to replace any agency policy in writing and consistent with the terms of this order. Agencies shall review their current policy to confirm that agency policy comports with this order and policy found not in compliance shall be revised to comply with the terms of this order.

Sec. 8. Cause of Action. This order does not create any right to administrative or judicial review, or any other right or benefit, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person or affect in any way the liability of the executive branch under the Federal Tort Claims Act.

Sec. 9. Construction. Nothing in this order shall limit an agency head from establishing more protective policies on smoking in the Federal workplace for employees and members of the public visiting or using Federal facilities.

WILLIAM J. CLINTON

THE WHITE HOUSE
August 9, 1997.



MEMORANDUM

TO: Jerry Mande

FROM: Michael C. Fiore, M.D., M.P.H. MF

DATE: July 17, 1998

RE: Proposed Executive Order Addressing Smoking Cessation

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CENTER FOR TOBACCO RESEARCH AND INTERVENTION

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Rationale for a Presidential Executive Order Addressing Smoking Cessation:

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Finally, we urge you to consider one additional possibility:

Include coverage for smoking cessation treatments (both pharmacotherapy and counseling as part of the proposed “Patient’s Bill of Rights”

As was recently documented in the Journal of the American Medical Association, tobacco cessation treatment is the single most cost-effective preventive intervention available for adults in the United States today. These effective tobacco cessation treatments include **pharmacotherapies** approved by the FDA and **counseling** outlined in the AHCPR Smoking Cessation Clinical Practice Guideline #18.

Currently, only about half of Managed Care Organizations in the United States pay for effective smoking cessation treatments. These treatments typically cost \$300 to \$400. This is paradoxical given that virtually all health insurance plans pay for the very expensive outcomes of smoking -- heart attacks, strokes, cancer, and lung disease. By highlighting the most effective preventive intervention as part of a "Patient's Bill of Rights," the President can make a powerful public health statement.

To support the proposed Executive Order, we have included the following attachments:

1. Draft Executive Order
2. Justification for Federal Employee Tobacco Cessation Health Benefit
3. Justification for Medicaid Beneficiary Tobacco Health Benefit
4. Current Medicaid Regulations Regarding Tobacco Cessation Treatment with Recommendation for Repeal
5. Current IRS Regulations Regarding Tobacco Cessation Treatment
6. Model Executive Order Used (Dated August 9, 1997)

1. EXECUTIVE ORDER -- INCREASING ACCESS TO TOBACCO CESSATION TREATMENT

By the authority vested in me as President by the Constitution and the laws of the United States of America and to increase access to effective tobacco cessation treatments (both pharmacotherapy and counseling) for federal employees, Department of Defense personnel, Veterans, and Medicaid beneficiaries, and to encourage access for the general public, it is hereby ordered as follows:

Section 1. Federal Employees. It is the policy of the executive branch to increase access to effective tobacco cessation treatments (both pharmacotherapies and counseling) for federal employees through the Federal Employees Health Benefit Program. All health plans bidding under the Federal Employees Health Benefit Program must provide access to FDA-approved pharmacotherapies for cessation and evidence-based tobacco use cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692). The Secretary of Health and Human Services shall develop a program to educate federal employees about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 2. Department of Defense Personnel. It is the policy of the executive branch to increase access to effective tobacco cessation treatments for Department of Defense personnel. The Department of Defense accordingly shall make available to all personnel through the existing health care programs FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692). The Secretary of Defense shall develop a program to educate all Department of Defense personnel about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 3. U.S. Veterans. It is the policy of the executive branch to facilitate access to effective tobacco cessation treatments for all veterans. The Department of Veterans Affairs shall make available FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692) available to all veterans through the DVA health care programs. The Secretary of Veterans Affairs shall develop a program to educate veterans about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 4. Medicaid Beneficiaries. It is the policy of the executive branch to encourage access to effective tobacco cessation treatments for the Medicaid population. To improve the health of smokers within the Medicaid population and lower the medical cost burden associated with tobacco use, the Medicaid program should provide access to FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation programs (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692).

To promote this policy, the Health Care Financing Administration shall conduct a study of the availability of tobacco use cessation treatments under state Medicaid programs, identify the existing barriers to such coverage, and provide recommendations (1) for making FDA-approved pharmacotherapies for cessation and other evidence-based cessation treatments (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692) available to the Medicaid population, and (2) for informing the Medicaid population about the hazards of tobacco use the availability of effective tobacco cessation treatments.

Section 5. Public Education. It is the policy of the executive branch to encourage tobacco cessation. To promote this policy, the Secretary of Health and Human Services shall develop a public information and education program to encourage tobacco cessation among the general population emphasizing effective tobacco cessation treatments.

Section 6. Tax Treatment of Tobacco Use Cessation. It is the policy of the executive branch to remove barriers to health care coverage of tobacco cessation pharmacotherapies and counseling caused by the tax treatment of such treatments. Accordingly, the Internal Revenue Service shall (1) review their regulations and interpretations regarding the tax treatment of tobacco cessation treatments (both pharmacotherapies and counseling), particularly under Section 213 of the Internal Revenue Code, (2) identify current barriers to health care coverage of such pharmacotherapies and counseling, and (3) provide recommendations for promptly removing those barriers.

2. JUSTIFICATION FOR FEDERAL EMPLOYEES TOBACCO CESSATION HEALTH BENEFIT

The Federal Employees Health Benefits Program (FEHB) is paradoxical in its coverage of smoking cessation treatments -- despite overwhelming evidence that tobacco use constitutes a major threat to public health, and despite the Federal Governments' increased interest in reducing tobacco use, no explicit smoking cessation benefits are guaranteed to Federal employees.

A signal feature of the FEHB is patient choice. Thus, health plans available to federal employees vary in their coverage of smoking cessation services. Many explicitly exclude all tobacco cessation treatments from coverage. Those plans that do cover smoking cessation tend to cover only prescription drugs, and to restrict cessation benefits to a single course of treatment per lifetime. Even in these instances, federal employees often become eligible for coverage only after the satisfaction of a calendar-year deductible.

As the world's largest employer-sponsored health insurance program, affecting over 9 million federal employees, retirees, and their families, the FEHB is in a unique position to set an appropriate standard of care for smoking cessation. It is likely that an FEHB guarantee of flexible access to effective, multicomponent cessation interventions to its beneficiaries would be adopted by other employers. This sort of ripple effect could dramatically improve the health of working Americans and produce tremendous long-term savings in health care costs that extend well into the next century. Of course, these cessation treatments will only be provided to smokers motivated to quit and desiring such treatments.

Guaranteed access to smoking cessation treatments for FEHB beneficiaries might take several forms, but achieving the optimal combination of health promotion and medical care savings will require two specific components. First, the services covered must be *proven effective*. Only pharmacotherapies and devices approved by the FDA and counseling programs conforming to AHCPR guidelines should be covered. Restricting coverage to these proven therapies will encourage their use, thereby optimizing overall cessation rates, and prevent wasteful spending on ineffective programs. Second, coverage must provide for *flexible* and *repeatable* treatment. Not all smokers benefit equally from a given intervention, and smokers differ in terms of which interventions they find appealing and/or acceptable. A coverage policy that does not provide smokers with a choice of treatments runs the risk of deterring as many smokers as it encourages. Additionally, studies indicate that most smokers make several serious attempts at quitting before they achieve long-term abstinence. Access to *repeatable* treatment, therefore, has the greatest potential to reduce smoking prevalence and the adverse impacts of smoking.

Understanding the need to indicate limits to such repeatable treatment, we have proposed the following:

Patients may engage in a covered smoking cessation treatment (pharmacotherapy and/or counseling) no more than one time per year and no more than three times per lifetime. The cost of such a covered treatment will not exceed \$400/treatment (1998 dollars).

3. JUSTIFICATION FOR MEDICAID BENEFICIARY TOBACCO CESSATION HEALTH BENEFIT

Cigarette smoking exacts an enormous toll on all segments of our society, one that is evident in terms of both burdensome health care costs and excess morbidity and mortality. However, Medicaid recipients represent a subgroup of our society that is particularly vulnerable to the health consequences of smoking. For instance, a study by the Center on Addiction and Substance Abuse, at Columbia University found that over 42% of Medicaid recipients smoke, as compared to 25% of the general population. The same study estimated that tobacco-related illness accounts for over \$8 billion in Medicaid costs each year. Nearly 10% of all Medicaid hospital days are attributable to smoking.

These human and economic costs have not gone unnoticed. Indeed, 40 states have sued the tobacco industry to recover Medicaid costs related to smoking. Whatever the merits or eventual resolution of this litigation, it is clear that attaining the broader goal of protecting the health of Medicaid beneficiaries who smoke requires some mechanism for providing them access to smoking cessation therapies of proven effectiveness. In short, smoking-related illness and its associated costs will not be meaningfully reduced until smoking behavior itself is modified.

Currently, fewer than half of the states provide coverage for smoking cessation products in their Medicaid programs. This neglect of smoking cessation is codified in federal law, which allows states to exclude FDA-approved smoking cessation therapies from coverage under Medicaid (42 U.S.C. § 1396r-8(d)(2)). Other drugs covered under the same discretionary exclusion provision include agents for treating cold symptoms and for stimulating cosmetic hair regrowth. Federal law is silent with respect to coverage of counseling programs and other behavioral support for smoking cessation, and thus states vary with respect to coverage of these services.

The federal government has committed significant resources to determining which smoking cessation treatments are most effective. For instance, The Agency for Health Care Policy and Research commissioned an expert panel to review the entire scientific literature on smoking interventions and to offer recommendations about which are the most effective. A study published by the same group of experts demonstrated that, among preventive services, smoking cessation is second only infant immunization in terms of cost-effectiveness. Of course, many other agencies within the federal government, including the Food and Drug Administration and many divisions of the Department of Health and Human Services, have also evaluated cessation treatments. Clearly, the federal government considers smoking cessation to be a major health care priority for the U.S.. The absence of federal legislation mandating coverage for smoking cessation treatments for recipients of medical assistance under Title XIX is paradoxical.

While changing the current Medicaid policy regarding smoking cessation treatment access may require legislation, an Executive Order could promote such access.

4. **CURRENT MEDICAID REGULATIONS REGARDING TOBACCO CESSATION TREATMENT WITH RECOMMENDATION FOR REPEAL**

Current federal law allows states to exclude FDA-approved smoking cessation treatments from coverage under Medicaid. (42 U.S.C. § 1396r-8(d)(2)). Ironically, although 40 states have sued the tobacco industry to recover Medicaid costs related to smoking, less than half the states provide coverage for smoking cessation products in their Medicaid programs. Many of the states that do not provide Medicaid coverage for smoking cessation therapies directly or indirectly rely on the discretionary exclusion provision currently in the federal law. This statutory provision should be repealed so Medicaid recipients can have access to FDA-approved smoking cessation therapies.

Proposed Legislative Language:

Section 2:

(1) In general: Section 1927(d)(2) (42 U.S.C. § 1396r-8(d)(2)) is amended by striking subparagraph ‘(E)’; redesignate subparagraphs ‘(F)’, ‘(G)’, ‘(H)’, and ‘(I)’ as ‘(E)’, ‘(F)’, ‘(G)’, and ‘(I)’ respectively.

1927(d) Limitation on Coverage of Drugs:

‘(2) List of drugs subject to restriction: The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

‘(A) Agents when used for anorexia, weight loss, or weight gain.

‘(B) Agents when used to promote fertility.

‘(C) Agents when used for cosmetic hair regrowth.

‘(D) Agents when used for the symptomatic relief of cough and colds.

~~*‘(E) Agents when used to promote smoking cessation.*~~

‘(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

‘(G) Nonprescription drugs.

‘(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

‘(I) Barbiturates.

‘(J) Benzodiazepines.’

6. MODEL EXECUTIVE ORDER - AUGUST 9, 1997

THE WHITE HOUSE,
Office of the Press Secretary

For Immediate Release
EXECUTIVE ORDER

August 9, 1997

PROTECTING FEDERAL EMPLOYEES AND THE PUBLIC FROM EXPOSURE TO TOBACCO SMOKE IN THE FEDERAL WORKPLACE

By the authority vested in me as President by the Constitution and the laws of the United States of America and in order to protect Federal Government employees and members of the public from exposure to tobacco smoke in the Federal workplace, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the executive branch to establish a smoke-free environment for Federal employees and members of the public visiting or using Federal facilities. The smoking of tobacco products is thus prohibited in all interior space owned, rented, or leased by the executive branch of the Federal Government, and in any outdoor areas under executive branch control in front of air intake ducts.

Sec.2. Exceptions. The general policy established by this order is subject to the following exceptions:

(a) The order does not apply in designated smoking areas that are enclosed and exhausted directly to the outside and away from air intake ducts, and are maintained under negative pressure (with respect to surrounding spaces) sufficient to contain tobacco smoke within the designated area. Agency officials shall not require workers to enter such areas during business hours while smoking is ongoing.

(b) The order does not extend to any residential accommodation for persons voluntarily or involuntarily residing, on a temporary or long-term basis, in a building owned, leased, or rented by the Federal Government.

(c) The order does not extend to those portions of federally owned buildings leased, rented, or otherwise provided in their entirety to nonfederal parties.

(d) The order does not extend to places of employment in the private sector or in other nonfederal governmental units that serve as the permanent or intermittent duty station of one or more Federal employees.

(e) The head of any agency may establish limited and narrow exceptions that are necessary to accomplish agency missions. Such exception shall be in writing, approved by the agency head, and to the fullest extent possible provide protection of nonsmokers from exposure to environmental tobacco smoke. Authority to establish such exceptions may not be delegated.

Sec. 3. Other Locations. The heads of agencies shall evaluate the need to restrict smoking at doorways and in courtyards under executive branch control in order to protect workers and visitors from environmental tobacco, and may restrict smoking in these areas in light of this evaluation.

Sec. 4. Smoking Cessation Programs. The heads of agencies are encouraged to use existing authority to establish programs designed to help employees stop smoking.

Sec. 5. Responsibility for Implementation. The heads of agencies are responsible for implementing and ensuring compliance with the provisions of this order. "Agency" as used in this order means an Executive agency, as defined in 5 U.S.C. 105, and includes any employing unit or authority of the Federal Government, other than those of the legislative and judicial branches. Independent agencies are encouraged to comply with the provisions of this order.

Sec. 6. Phase-In of Implementation. Implementation of the policy set forth in this order shall be achieved no later than 1 year after the date of this order. This 1 year phase-in period is designed to establish a fixed by reasonable time for implementing this policy. Agency heads are directed during this period to inform all employees and visitors to executive branch facilities about the requirements of this order, inform their employees of the health risks of exposure to environmental tobacco smoke, and undertake related activities as necessary.

Sec. 7. Consistency with Other Laws. The provisions of this order shall be implemented consistent with applicable laws, including the Federal Service Labor-Management Relations Act (5 U.S.C. 7171 et seq.) And the National Labor Relations Act (29 U.S.C. 151 et seq.) Provisions of existing collective bargaining agreements shall be honored and agencies shall consult with labor representative about the implementation of this order. Nothing herein shall be constructed to impair or alter the powers and duties of Federal agencies established under law. Nothing herein shall be constructed to replace any agency policy in writing and consistent with the terms of this order. Agencies shall review their current policy to confirm that agency policy comports with this order and policy found not in compliance shall be revised to comply with the terms of this order.

Sec. 8. Cause of Action. This order does not create any right to administrative or judicial review, or any other right or benefit, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person or affect in any way the liability of the executive branch under the Federal Tort Claims Act.

Sec. 9. Construction. Nothing in this order shall limit an agency head from establishing more protective policies on smoking in the Federal workplace for employees and members of the public visiting or using Federal facilities.

WILLIAM J. CLINTON

THE WHITE HOUSE
August 9, 1997.

INTERAGENCY ADVISORY GROUP

UNITED STATES
OFFICE OF PERSONNEL MANAGEMENT
WASHINGTON, DC 20415

Secretariat
1900 E St., NW

OCT - 1 1997

MEMORANDUM FOR DIRECTORS OF PERSONNEL

FROM: STEVEN R. COHEN
ACTING ASSOCIATE DIRECTOR
HUMAN RESOURCES SYSTEMS SERVICE



SUBJECT: Smoking Cessation Guidance

On August 9, 1997, the President issued Executive Order 13058 establishing a smoke-free environment for Federal employees and members of the public visiting or using Federal facilities. In Section 4 of the Executive Order, the President encouraged agencies "to use existing authority to establish programs designed to help employees stop smoking." A copy of the Executive Order is attached.

The purpose of this letter is to remind agencies of existing authority to utilize appropriated funds for such programs and to provide information to assist in establishing and/or locating programs designed to help employees stop smoking.

A decision by the Comptroller General of the United States (B-231543 dated February 3, 1989) held that under 5 USC §7901, Federal agencies have the authority to utilize appropriated funds to pay the costs incurred by employees participating in agency-authorized smoking cessation programs. The decision held that because smoking is a major contributing cause of illnesses such as cancer, coronary disease and emphysema, smoking cessation programs are "preventive" in nature and authorized under 5 USC §7901(c)(4). This authority can also include payment for nicotine replacement therapy (use of the nicotine patch or nicotine gum) when purchased as part of an agency's smoking cessation program.

Attached are: (1) the Executive Order; and (2) guidelines on establishing programs designed to help employees stop smoking. Agencies may also contact OPM's Employee Health Services Policy Center at (202) 606-2920 for assistance in establishing and/or locating programs.

Attachments - 2

Federal Register

Vol. 62, No. 156

Wednesday, August 13, 1997

Presidential Documents

Title 3—

Executive Order 13058 of August 9, 1997

The President

Protecting Federal Employees and the Public From Exposure to Tobacco Smoke in the Federal Workplace

By the authority vested in me as President by the Constitution and the laws of the United States of America and in order to protect Federal Government employees and members of the public from exposure to tobacco smoke in the Federal workplace, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the executive branch to establish a smoke-free environment for Federal employees and members of the public visiting or using Federal facilities. The smoking of tobacco products is thus prohibited in all interior space owned, rented, or leased by the executive branch of the Federal Government, and in any outdoor areas under executive branch control in front of air intake ducts.

Sec. 2. Exceptions. The general policy established by this order is subject to the following exceptions: (a) The order does not apply in designated smoking areas that are enclosed and exhausted directly to the outside and away from air intake ducts, and are maintained under negative pressure (with respect to surrounding spaces) sufficient to contain tobacco smoke within the designated area. Agency officials shall not require workers to enter such areas during business hours while smoking is ongoing.

(b) The order does not extend to any residential accommodation for persons voluntarily or involuntarily residing, on a temporary or long-term basis, in a building owned, leased, or rented by the Federal Government.

(c) The order does not extend to those portions of federally owned buildings leased, rented, or otherwise provided in their entirety to nonfederal parties.

(d) The order does not extend to places of employment in the private sector or in other nonfederal governmental units that serve as the permanent or intermittent duty station of one or more Federal employees.

(e) The head of any agency may establish limited and narrow exceptions that are necessary to accomplish agency missions. Such exception shall be in writing, approved by the agency head, and to the fullest extent possible provide protection of nonsmokers from exposure to environmental tobacco smoke. Authority to establish such exceptions may not be delegated.

Sec. 3. Other Locations. The heads of agencies shall evaluate the need to restrict smoking at doorways and in courtyards under executive branch control in order to protect workers and visitors from environmental tobacco smoke, and may restrict smoking in these areas in light of this evaluation.

Sec. 4. Smoking Cessation Programs. The heads of agencies are encouraged to use existing authority to establish programs designed to help employees stop smoking.

Sec. 5. Responsibility for Implementation. The heads of agencies are responsible for implementing and ensuring compliance with the provisions of this order. "Agency" as used in this order means an Executive agency, as defined in 5 U.S.C. 105, and includes any employing unit or authority of the Federal Government, other than those of the legislative and judicial branches. Independent agencies are encouraged to comply with the provisions of this order.

Sec. 6. Phase-In of Implementation. Implementation of the policy set forth in this order shall be achieved no later than 1 year after the date of this

order. This 1 year phase-in period is designed to establish a fixed but reasonable time for implementing this policy. Agency heads are directed during this period to inform all employees and visitors to executive branch facilities about the requirements of this order, inform their employees of the health risks of exposure to environmental tobacco smoke, and undertake related activities as necessary.

Sec. 7. Consistency with Other Laws. The provisions of this order shall be implemented consistent with applicable law, including the Federal Service Labor-Management Relations Act (5 U.S.C. 7101 *et seq.*) and the National Labor Relations Act (29 U.S.C. 151 *et seq.*) Provisions of existing collective bargaining agreements shall be honored and agencies shall consult with employee labor representatives about the implementation of this order. Nothing herein shall be construed to impair or alter the powers and duties of Federal agencies established under law. Nothing herein shall be construed to replace any agency policy currently in effect, if such policy is legally established, in writing, and consistent with the terms of this order. Agencies shall review their current policy to confirm that agency policy comports with this order, and policy found not in compliance shall be revised to comply with the terms of this order.

Sec. 8. Cause of Action. This order does not create any right to administrative or judicial review, or any other right or benefit, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person or affect in any way the liability of the executive branch under the Federal Tort Claims Act.

Sec. 9. Construction. Nothing in this order shall limit an agency head from establishing more protective policies on smoking in the Federal workplace for employees and members of the public visiting or using Federal facilities.



THE WHITE HOUSE,
August 9, 1997.

Smoking Cessation Programs

Guidance on Establishing Programs Designed to Help Employees Stop Smoking

I. FUNDING SMOKING CESSATION PROGRAMS

INTRODUCTION

The U.S. Office of Personnel Management supports and encourages agency authorized programs aimed at health promotion and disease prevention, including smoking cessation programs. According to reports issued by the Surgeon General, smoking is the chief avoidable cause of death in our society. Programs designed to help employees stop smoking are in the best health interests of those Federal employees who smoke and those who do not smoke. These programs may also contribute to improved organizational performance and productivity.

The purpose of these guidelines is to assist agencies in the development of smoking cessation programs, including those which provide, as one element, pharmacologic therapy (such as a nicotine replacement therapy (NRT), i.e., the nicotine patch or nicotine gum).

USE OF APPROPRIATED FUNDS FOR SMOKING CESSATION PROGRAMS

A decision by the Comptroller General of the United States (B-231543 dated February 3, 1989) held that under 5 U.S.C. §7901, Federal agencies have the authority to utilize appropriated funds to pay the costs incurred by employees participating in agency-sponsored smoking cessation programs. The decision held that because smoking is a major contributing cause of illnesses such as cancer, coronary disease and emphysema, smoking cessation programs are "preventive" in nature and authorized under 5 USC §7901(c)(4).

Agencies may wish to develop their own in-house programs or contract with program providers (see section B, **A CHECKLIST FOR ASSESSING A GROUP CESSATION PROGRAM**). Such programs usually include: (1) educational materials; (2) classroom training; (3) individual and/or group counseling; and/or (4) pharmacologic therapy (such as nicotine replacement therapy).

NICOTINE PATCH/GUM AS PART OF AN AGENCY'S PROGRAM

As part of an agency's program, appropriated funds may be used to pay for the provision of pharmacologic treatment such as nicotine replacement therapy. With regard to paying the costs of over-the-counter nicotine replacement therapy (such as the nicotine patch or nicotine gum), the following guidance is provided to assist program administrators:

Agency Purchase: Agencies that desire to provide their employees with over-the-counter nicotine replacement therapy (such as nicotine patches or nicotine gum), as part of an agency's smoking cessation program, should acquire those items in accordance with the regulatory and statutory provisions contained in the Federal Acquisition Regulation and all internal agency guidelines for the expenditure of appropriated funds. Agencies may also wish to contract with smoking cessation program providers which include, as part of their program, nicotine replacement therapy. Agencies may also purchase nicotine replacement therapy for employees who wish to quit smoking but who do not wish to attend formal classroom sessions sponsored by the agency. In this instance, agencies should offer employees on-site or telephone counseling services. Such counseling services, however, should not be made mandatory. Employees requesting agency purchase of the nicotine patch or nicotine gum in such circumstances should be considered as participating in the agency's smoking cessation program.

Employee Requests: When requesting the agency to purchase the nicotine patch or nicotine gum, which is to be purchased as part of an agency's program, employees should provide program administrators (e.g., health unit physician, nurse, or Employee Assistance Program counselor) with a written request. Such a request would be appropriate regardless of whether the employee is participating in an on-site classroom program or in a self-initiated process.

RELATIONSHIP TO HEALTH INSURANCE REIMBURSEMENTS

The following information is provided for the benefit of employees who elect to participate in smoking cessation programs other than agency-sponsored programs on-site. While agencies would not pay for the cost of registration for such programs, employees should be aware that they can seek insurance plan reimbursement (up to the amount covered in their health benefits plan). In these instances, however, employees may request agency purchase of pharmacologic treatment such as nicotine replacement therapy if such therapy were in addition to the program registration cost. These employees would be considered as participating in the agency's program.

Under the Federal Employee Health Benefits programs, a number of insurance plans cover some costs associated with smoking cessation. Federal employees need to refer to their plan brochure for specific coverage information. Generally, fee-for-service (FFS) plans cover up to \$100 towards the cost of enrollment in one smoking cessation program per member per lifetime after the calendar year deductible has been met. Many FFS plans also cover the cost of smoking cessation drugs that require a prescription; some cover the cost of non-prescription drugs as part of the \$100 lifetime benefit to aid in smoking cessation. **NOTE:** although some drugs for smoking cessation are over-the-counter products, others require a prescription.

Benefits in HMOs vary greatly; the Prescription Drugs Benefits section of each plan's brochure specifies whether drugs to aid in smoking cessation are covered or excluded. **Generally, members must contact their HMO to find out whether classes are offered for smoking**

cessation and whether they require any payment by the member. Following is a summary of coverage **currently** available under fee-for-service plans:

Alliance - After the \$300 non-PPO calendar year deductible has been met, the Plan pays up to \$100 for enrollment in one smoking cessation program per member per lifetime.

APWU - After satisfaction of the \$250 calendar year deductible, the Plan will pay up to \$100 for enrollment in one smoking cessation program per member per lifetime.

BC/BS Service Benefit Plan - After satisfaction of the calendar year deductible, the Plan will pay 100% of billed charges up to a maximum payment of \$100 for enrollment in one smoking cessation per member per lifetime. Services may be rendered by any covered provider or by a smoking cessation clinic. Drugs that require a prescription are covered under prescription drug benefits.

GEHA - After satisfaction of the calendar year deductible, up to \$100 for enrollment in one smoking cessation program per member per lifetime. Drugs to aid in smoking cessation are covered under this benefit subject to the calendar year deductible and subject to the \$100 lifetime maximum. You must purchase these drugs and file the receipt from the pharmacy including the name of the drug, patient's name, date and amount of purchase with the GEHA claim office. Prescription drugs for smoking cessation are excluded from the prescription drug benefit.

NALC - After satisfaction of the calendar year deductible, the Plan will pay up to \$100 for enrollment in one smoking cessation program per member per lifetime. Related prescription drugs are covered under Prescription Drug Benefits.

Postmasters - After satisfaction of the calendar year deductible, the Plan will pay up to \$100 for enrollment in one smoking cessation program, including any related prescription drugs, per member per lifetime. Smoking cessation drugs and medications, including nicotine patches, are not available under any other Plan provisions. Benefits will be paid directly to the enrollee upon submission of a completed claim form and bill.

Foreign Service Benefit Plan - After satisfaction of the calendar year deductible, the plan will pay up to \$100 for enrollment in one smoking cessation program per member per lifetime. A statement from the provider certifying completion of the program is required to obtain this benefit.

Panama Canal Area Benefit Plan - The Plan will pay up to \$100 for enrollment in one smoking cessation program per member per lifetime. This benefit will not be subject to the Outpatient benefit maximums (\$650/\$1,500 per calendar year). This benefit must be approved by the Plan prior to the member enrolling.

Rural Carrier Benefit Plan - The Plan will pay up to \$100 for enrollment in one smoking cessation program, including any related prescription drugs, per member per lifetime. Charges applied to satisfy the deductible are counted toward the benefit limit. Smoking cessation drugs and medications, including nicotine patches, are not available under any other Plan provisions.

SAMBA - after satisfaction of the calendar year deductible, the Plan will pay up to \$100 for enrollment in one smoking cessation program, including cost of any related prescription drugs, per member per lifetime.

Association - after satisfaction of the \$250 calendar year deductible, the plan will pay up to \$100 for enrollment in one smoking cessation program per person per lifetime. This benefit includes FDA-approved prescription drugs and medicines (including generic drugs) that are intended to aid in smoking cessation.

BACE - After satisfaction of the \$250 calendar year deductible, the plan will pay up to \$100 for enrollment in one smoking cessation program per member per lifetime.

SSEHA - After satisfaction of the \$200 CYD, the plan will pay up to \$100 for enrollment in one smoking cessation program per member per lifetime.

Mailhandlers - up to \$100 for enrollment in one smoking cessation program per member per lifetime. All claims will be paid directly to you. Prescription drugs for smoking cessation are paid under the Prescription Drug Benefit and their cost does not count toward the \$100 limit.

II. GUIDELINES FOR THE DEVELOPMENT OF EFFECTIVE AGENCY SMOKING CESSATION PROGRAMS

BACKGROUND: The leading agency in the area of smoking cessation is the Agency for Health Care Policy and Research (AHCPR) of the U.S. Department of Health and Human Services. The following recommendations were developed by the AHCPR as part of a “*Quick Reference Guide for Smoking Cessation Specialists*,” and can be used by agency planners in the development of their smoking cessation programs or in assessing the effectiveness of potential program providers. The *Quick Reference Guide for Smoking Cessation Specialists* resulted from the findings of a private-sector panel convened by AHCPR and the Centers for Disease Control and Prevention (CDC). The panel employed an explicit science-based methodology and expert clinical judgement to develop specific statements on smoking cessation. Whether agency-developed programs are administered internally (e.g., by a coordinated effort involving the agency’s Health Unit and the Employee Assistance Program Counselor) or externally (by contracting with a smoking cessation program provider), agencies are urged to follow these recommendations in the development of their programs:

A. PROGRAM DEVELOPMENT RECOMMENDATIONS

Assess the Smoker who has Entered a Program

Assess whether participants in smoking cessation programs are motivated to quit smoking using an intensive program. Specialists may also conduct other assessments that can provide information useful in counseling. For example, such assessments may reveal the presence of high stress levels caused by other issues in a smoker’s life or may reveal the presence of other psychological or medical conditions that will affect success in quitting.

Use a Variety of Clinicians

Multiple types of clinicians should be used in intensive smoking cessation programs. One strategy would be to have a medical/health care clinician deliver messages about health risks and benefits, and nonmedical clinicians deliver psychological or behavioral interventions.

Ensure that the Program is Intensive Enough

Individual or group counseling programs are helpful. The AHCPR guidelines panel found a direct relationship between the intensity of treatment and the likelihood for success. Because of evidence of a strong dose-response relation, the program should include the following elements:

- Session length - at least 20-30 minutes in length.
- Number of sessions - at least 4-7 sessions
- Length in weeks - at least 2 weeks, but preferably up to 8 weeks.

Use a Variety of Program Formats

Either individual or group counseling should be used. Specialists may also use supplementary self-help materials.

Include Effective Counseling Techniques

Interventions should include problem solving/skill training content as well as clinician-delivered social support for quitting. For example, common elements of problem solving/skills-training treatments would be: (1) recognition of danger situations (e.g., being around other smokers, being under time pressure, getting into an argument, experiencing urges or negative moods, or drinking alcohol); (2) coping skills (e.g., learning to anticipate and avoid danger situations, learning cognitive strategies that will reduce negative moods, accomplishing lifestyle changes that reduce stress, improve quality of life, or produce pleasure); and (3) basic information (e.g., the nature/timecourse of withdrawal, the addictive nature of smoking, or the fact that any smoking (even a single puff) increases the likelihood of full relapse). Common elements of supportive smoking cessation treatments would be: (1) encourage the participant in the quit attempt; (2) communicate caring and concern; (3) encourage the participant to talk about the quitting process; and (4) provide basic information about smoking and successful quitting.

Provide Relapse Prevention Intervention

Most relapses occur soon after a person quits smoking, although some people relapse months or years after the quit date. Therefore, specialists should work to prevent long-term risks of relapse. These interventions can occur during treatment sessions or during followup contacts and should: (1) reinforce the employee's decision to quit; (2) review the benefits of quitting; and (3) assist in resolving any problems related to quitting.

Include Nicotine Replacement Therapy*

Except in special circumstances (i.e., in the presence of serious medical precautions), every smoker should be offered nicotine replacement therapy (NRT). The nicotine patch and nicotine gum are particularly useful in helping smokers quit. In the instance of relapse, a careful assessment should be made to determine if incorrect use of NRT contributed to the relapse, and employees should be encouraged to try again.

***NOTE:** According to AHCPR guidelines on smoking cessation programs, nicotine replacement therapy is one of the elements in a cessation program that is particularly effective. The guidelines state that either a nicotine patch or nicotine gum doubles the rate of quitting success in a cessation program.

Other treatments (findings of the AHCPR guidelines panel): (1) *Acupuncture* (there was relatively little evidence available regarding acupuncture and the existing evidence was inconclusive); (2) *hypnosis* (because the studies were of poor quality and their results were inconsistent, the evidence was insufficient to assess the effectiveness of hypnosis); (3) *Clonidine* (there is little support for the use of clonidine either as a primary or as an adjunctive pharmacologic treatment for smoking cessation); (4) *antidepressants* (because of a paucity of data, the panel drew no conclusions about antidepressant therapy for smoking cessation); (5) *anxiolytics/benzodiazepines* (because of a lack of data, no conclusion was drawn regarding the efficacy of anxiolytics in smoking cessation); and (6) *nicotine nasal sprays and nicotine inhalers* (although early studies appeared promising, there was limited data regarding the use of these products at the time the AHCPR guideline was produced, and no conclusions were drawn regarding the efficacy of these products).

B. A CHECKLIST FOR ASSESSING A GROUP CESSATION PROGRAM

NOTE: Providers should be carefully screened before contracting for their services or referring employees. The following checklist, provided by the Office on Smoking and Health of the U.S. Department of Health and Human Services, can be used for screening such services.

1. How long has the organization been in existence? How long has it been providing smoking cessation programs?
2. How many people have gone through the program?
3. Will the approach be appropriate for the employee?
 - a. What methods are used to help smokers quit?
 - b. How is maintaining abstinence from smoking addressed?
 - c. What resources are provided to help promote the program among agency employees and stimulate participation?
4. Have others been satisfied with the program?
 - a. Will they provide a list of clients, especially other Federal agencies?
 - b. Will they provide references so that satisfaction and success rates can be checked?
5. What are the qualifications of the instructors? What training have they received? What is their cessation counseling experience?
6. Are printed materials appropriate for the educational level of the employees? Are they attractive and motivational?
7. Will the structure of the program accommodate the needs of employees? That is, can they:
 - a. accommodate all shifts?
 - b. provide on-site and off-site programs?
 - c. structure flexible program formats?
 - d. provide audio or visual equipment?
8. Is the program provider willing to provide ongoing assistance and follow-up once the formal program ends?
9. Does the program incorporate participants' support systems? For example, peers and family members?
10. Does the program offer any form of guarantee? For example, can employees repeat the program for free or at a lower cost?
11. Can the program provider provide evidence of six-month and one-year success rates of previous clients? (A range of 20-40% success rate is realistic.) Remember: if it sounds too good to be true, it probably is.
12. How much does the program cost per employee? Are group discounts available?

III. RESOURCES AND INFORMATION ON SMOKING CESSATION PROGRAMS

FEDERAL GOVERNMENT ORGANIZATIONS

Agency for Health Care Policy and Research (AHCPR)
Public Health Service
2101 East Jefferson Street, Suite 501
Rockville, MD 20852
(301) 594-6662
<http://www.ahcpr.gov>
1-800-358-9295 (to request materials on all AHCPR Smoking Cessation Guidelines)

Office on Smoking and Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Mail Stop K-50, 4770 Buford Highway
Atlanta, GA 30341-3724
(770) 488-5705
<http://www.cdc.gov/tobacco>
1-800-CDC-1311

Real Property Policy Division
Office of Real Property
General Services Administration (GSA)
18th and F Streets, N.W., Rm. 6203
Washington, DC 20405
(202) 501-1737
<http://policyworks.gov/org/main/mp/pm r.htm>

Employee Health Services Policy Center
U.S. Office of Personnel Management
1900 E Street, N.W., Rm. 7425
Washington, DC 20415
(202) 606-2920

RESOURCES AVAILABLE

AHCPR is the lead agency charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services. AHCPR's broad programs of research, clinical guideline development, and technology assessment bring practical, science-based information to medical practitioners and to consumers and other health care purchasers.

The Federal focal point for activities on smoking and health. Serves as the national and world center for scientific and technical information. Produces the Surgeon General's annual report related to smoking and health, carries out a public education program, and a tobacco epidemiology program.

Responsible for regulations on smoking in GSA-controlled Federal buildings and facilities. Each Federal agency head is responsible for implementing and enforcing the GSA regulations and establishing designated smoking areas.

Responsible for Federal employee health and assistance-related personnel policy guidance and technical assistance.

Cancer Information Service (CIS)
National Cancer Institute (NCI)
31 Center Drive MSC2580
Building 31, Room 10A07
Bethesda, MD 20892-2580
1-800-4-CANCER (1-800-442-6237)
1-800-332-8615 - TTY
<http://cancernet.nci.nih.gov>

The Cancer Information Service provides information on cancer to patients and their families, health professionals, and the general public. The CIS is a resource for state and regional organizations by providing expertise in program planning, use of NCI materials, media relations, networking and coalition building.

OTHER ORGANIZATIONS

American Cancer Society (ACA)
National Headquarters
1599 Clifton Road, N.E.
Atlanta, GA 30329-4251
(404) 320-3333 or call the local number listed in the telephone directory.
<http://www.cancer.org>
Washington, DC Area:
1875 Conn. Ave., N.W., Suite 730
Washington, DC 20009
(202) 483-2600

The ACA is dedicated to eliminating cancer through research, education, advocacy and service. Offers the "Fresh Start" program designed to help participants stop smoking. Offers a variety of brochures, videos and other resources on smoking cessation.

American Heart Association (AHA)
National Center
7320 Greenville Avenue
Dallas, TX 75231
(214) 750-5300 or call the local number listed in the telephone directory
<http://www.amhrt.org/aha.html>
Washington DC Area:
5335 Wisconsin Ave., N.W.
Washington, DC 20015-2030
(202) 686-6888

AHA provides research support, public and professional education, and community programs in the fight against cardiovascular diseases and stroke. Offers The Heart At Work health promotion program, including a module on smoking cessation. The program can be implemented with program support provided by a local AHA representative.

American Lung Association (ALA)
Headquarters
1740 Broadway
New York, NY 10019
(212) 315-8700 or call the local number listed in the telephone directory.
<http://www.lungusa.org>
Washington, DC Area:
425 H Street, NW
Washington, DC 20005
(202) 682-LUNG

The ALA supports research and other efforts to better understand why smokers are addicted and how to help them. Offers a stop-smoking program (*Freedom From Smoking*) which gives ideas on how to quit. Also provides self-help options including guidebooks, videotapes and audiotapes.

**File Contains Data for
PostScript Printers Only**

**Center for Tobacco Research and Intervention
1300 University Avenue, Room 7278
Madison, WI 53706**

Telephone: (608) 262-8673

Fax: (608) 265-3102

FAX COVER SHEET

TO: Jerry Mande

DATE: July 17, 1998

FROM: Michael Fiore

PAGE 1 of 13

Jerry,

Attached is a cover memo followed by the draft Executive Order and rationale. I enjoyed working on this. I will give you a call next week on Tuesday to discuss the proposal as well as dates for a possible visit.

Have a good weekend.

Michael Fiore

**MEMORANDUM**

TO: Jerry Mande

FROM: Michael C. Fiore, M.D., M.P.H. *MF*

DATE: July 17, 1998

RE: Proposed Executive Order Addressing Smoking Cessation

Over the last week, my colleagues and I at the University of Wisconsin *Center for Tobacco Research and Intervention* have considered your request to draft an Executive Order addressing smoking cessation. To assist us in this endeavor, we used as a model the President's Executive Order dated August 9, 1997, *Protecting Federal Employees and the Public From Exposure to Smoke in the Federal Workplace*.

To address your request, we posed the following question:

How can the President promote smoking cessation through an Executive Order in a way that will result in the greatest public health impact, in the most cost-effective manner?

On the following pages, we provide a draft Executive Order addressing smoking cessation and some background information to support that Executive Order. In summary, the proposed Executive Order would include the following components:

1. Federal Employees -- Mandate that health plans bidding under the Federal Employees Health Benefit Program provide effective smoking cessation treatments (both pharmacotherapy and counseling) for all Federal employees.
2. Department of Defense Personnel -- Order that DOD health care programs provide effective smoking cessation treatments for all DOD personnel.
3. U.S. Veterans -- Order that the Department of Veterans Affairs provide effective smoking cessation treatments to all veterans.
4. Medicaid Beneficiaries -- Order the Health Care Financing Administration to review barriers to effective smoking cessation treatments for Medicaid Beneficiaries and provide specific recommendations to remove those barriers.
5. Tax Treatment of Tobacco Use Cessation -- Order the IRS to review their regulations and interpretations regarding taxation of tobacco cessation treatments to identify and remove barriers to such treatments.

CENTER FOR TOBACCO RESEARCH AND INTERVENTION

UNIVERSITY OF WISCONSIN MEDICAL SCHOOL

7278 Medical Sciences Center 1300 University Avenue Madison, WI 53706-1532

TEL: 608/262-8673 FAX: 608/265-3102

Rationale for a Presidential Executive Order Addressing Smoking Cessation:

Smoking exacts an enormous toll on our society. It is responsible for 20% of all deaths in America (more than 400,000 deaths each year), an extraordinarily burden of illness, and more than 50 billion dollars in direct health care costs (about 10% of all health care costs) each year. Reducing tobacco use through successful smoking cessation will benefit the health and economic well-being of all Americans.

Among the 50 million adult smokers in the United States today, approximately 70% now state that they would like to quit and almost 20 million try to quit each year. Unfortunately, more than 9 out of 10 smokers who attempt to quit do so on their own, and less than 5% of these individuals are successful in achieving their goal. Clearly, smokers who want to quit should be encouraged to use the most effective cessation treatments available. Such treatments increase quit rates by 2-4 times, compared to self-quitting.

Over the last decade, enormous progress has been made in identifying smoking cessation treatments (both pharmacotherapy and counseling) that markedly increase quit rates above the discouraging percentages achieved by patients who try to quit on their own. These helpful treatments have been reviewed and endorsed by the U.S. Food and Drug Administration (FDA) and the Agency for Health Care Policy and Research (AHCPR). Among the most important public health challenges facing American society today is that of providing effective treatments to all American smokers wanting to quit.

A significant barrier to the use of effective treatments is inadequate insurance coverage. Recent surveys have documented that only about half of insurance plans in the United States provide coverage for either smoking cessation pharmacotherapy or counseling. Fewer still provide enrollees with the effective treatments documented by the FDA and AHCPR. An Executive Order that mandates such insurance coverage for key populations (e.g., Federal employees, veterans) would serve as a model for the insurance industry and establish a new standard of care that will improve health and reduce the health care costs of all Americans.

Parameters of Smoking Cessation Coverage

In order to mandate smoking cessation treatment coverage (for Federal employees or veterans, for example), parameters regarding the type and costs of the treatment are essential. Such parameters are needed for insurers to estimate the potential cost implications of such treatments. Additionally, some smoking cessation treatments are *ineffective*, and without rational, evidence-based parameters, resources might be spent inappropriately.

Fortunately, research evidence has clearly identified effective smoking cessation treatments. This evidence have been compiled by the U.S. Food and Drug Administration and the Agency for Health Care Policy and Research. Any Executive Order should specifically reference the criteria and findings of these federal agencies.

Specifically, only those treatments that fulfill either of the following two criteria should be deemed "effective treatments" and be made eligible for coverage mandated by an Executive Order:

- A. **FDA-Approved Pharmacotherapies.** The U.S. Food and Drug Administration has identified five separate agents as safe and effective aids for smoking cessation. These agents are nicotine gum, the nicotine patch, nicotine nasal spray, the nicotine inhaler, and bupropion SR (Zyban). All of these agents should be listed as eligible for coverage under an Executive Order that mandates coverage for effective smoking cessation treatments.
- B. **AHCPR-Endorsed Cessation Programs.** Through a systematic review of more than 3,000 scientific articles published since 1975, the AHCPR Smoking Cessation Guideline Panel identified a series of effective smoking cessation counseling treatments and programs. Specifically, the AHCPR Guideline endorsed as effective brief counseling provided by a clinician as a regular part of health care delivery. Some other more intensive treatments were also endorsed. However, the Panel identified a series of treatments that were *not endorsed* (e.g., acupuncture, hypnosis).

Making coverage of treatments contingent upon AHCPR Guideline endorsement and FDA-approval will insure that patients are not subjected to ineffective treatments and will avoid financial abuse of this expansion of coverage.

In addition to type of treatment, language regarding mandated coverage must stipulate clear boundaries regarding the frequency and costs of treatment. This information is required to estimate the potential cost of expanded coverage that might be incurred by managed care organizations and other payers. Using available data, we believe the following are reasonable and fair parameters for limiting coverage of smoking cessation treatments:

Patients may engage in a covered smoking cessation treatment (pharmacotherapy and/or counseling) no more than one time per year and no more than three times per lifetime. The cost of such a covered treatment will not exceed \$400/treatment (1998 dollars).

Finally, we urge you to consider one additional possibility:

Include coverage for smoking cessation treatments (both pharmacotherapy and counseling as part of the proposed "Patient's Bill of Rights")

As was recently documented in the Journal of the American Medical Association, tobacco cessation treatment is the single most cost-effective preventive intervention available for adults in the United States today. These effective tobacco cessation treatments include **pharmacotherapies** approved by the FDA and **counseling** outlined in the AHCPR Smoking Cessation Clinical Practice Guideline #18.

Currently, only about half of Managed Care Organizations in the United States pay for effective smoking cessation treatments. These treatments typically cost \$300 to \$400. This is paradoxical given that virtually all health insurance plans pay for the very expensive outcomes of smoking -- heart attacks, strokes, cancer, and lung disease. By highlighting the most effective preventive intervention as part of a "Patient's Bill of Rights," the President can make a powerful public health statement.

To support the proposed Executive Order, we have included the following attachments:

1. Draft Executive Order
2. Justification for Federal Employee Tobacco Cessation Health Benefit
3. Justification for Medicaid Beneficiary Tobacco Health Benefit
4. Current Medicaid Regulations Regarding Tobacco Cessation Treatment with Recommendation for Repeal
5. Current IRS Regulations Regarding Tobacco Cessation Treatment
6. Model Executive Order Used (Dated August 9, 1997)

1. EXECUTIVE ORDER -- INCREASING ACCESS TO TOBACCO CESSATION TREATMENT

By the authority vested in me as President by the Constitution and the laws of the United States of America and to increase access to effective tobacco cessation treatments (both pharmacotherapy and counseling) for federal employees, Department of Defense personnel, Veterans, and Medicaid beneficiaries, and to encourage access for the general public, it is hereby ordered as follows:

Section 1. Federal Employees. It is the policy of the executive branch to increase access to effective tobacco cessation treatments (both pharmacotherapies and counseling) for federal employees through the Federal Employees Health Benefit Program. All health plans bidding under the Federal Employees Health Benefit Program must provide access to FDA-approved pharmacotherapies for cessation and evidence-based tobacco use cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692). The Secretary of Health and Human Services shall develop a program to educate federal employees about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 2. Department of Defense Personnel. It is the policy of the executive branch to increase access to effective tobacco cessation treatments for Department of Defense personnel. The Department of Defense accordingly shall make available to all personnel through the existing health care programs FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692). The Secretary of Defense shall develop a program to educate all Department of Defense personnel about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 3. U.S. Veterans. It is the policy of the executive branch to facilitate access to effective tobacco cessation treatments for all veterans. The Department of Veterans Affairs shall make available FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation counseling (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692) available to all veterans through the DVA health care programs. The Secretary of Veterans Affairs shall develop a program to educate veterans about the hazards of tobacco use and the availability of tobacco cessation treatments.

Section 4. Medicaid Beneficiaries. It is the policy of the executive branch to encourage access to effective tobacco cessation treatments for the Medicaid population. To improve the health of smokers within the Medicaid population and lower the medical cost burden associated with tobacco use, the Medicaid program should provide access to FDA-approved pharmacotherapies for cessation and evidence-based tobacco cessation programs (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692).

To promote this policy, the Health Care Financing Administration shall conduct a study of the availability of tobacco use cessation treatments under state Medicaid programs, identify the existing barriers to such coverage, and provide recommendations (1) for making FDA-approved pharmacotherapies for cessation and other evidence-based cessation treatments (see AHCPR Smoking Cessation Clinical Practice Guideline #18, AHCPR Publication No. 96-0692) available to the Medicaid population, and (2) for informing the Medicaid population about the hazards of tobacco use the availability of effective tobacco cessation treatments.

Section 5. Public Education. It is the policy of the executive branch to encourage tobacco cessation. To promote this policy, the Secretary of Health and Human Services shall develop a public information and education program to encourage tobacco cessation among the general population emphasizing effective tobacco cessation treatments.

Section 6. Tax Treatment of Tobacco Use Cessation. It is the policy of the executive branch to remove barriers to health care coverage of tobacco cessation pharmacotherapies and counseling caused by the tax treatment of such treatments. Accordingly, the Internal Revenue Service shall (1) review their regulations and interpretations regarding the tax treatment of tobacco cessation treatments (both pharmacotherapies and counseling), particularly under Section 213 of the Internal Revenue Code, (2) identify current barriers to health care coverage of such pharmacotherapies and counseling, and (3) provide recommendations for promptly removing those barriers.

2. JUSTIFICATION FOR FEDERAL EMPLOYEES TOBACCO CESSATION HEALTH BENEFIT

The Federal Employees Health Benefits Program (FEHB) is paradoxical in its coverage of smoking cessation treatments -- despite overwhelming evidence that tobacco use constitutes a major threat to public health, and despite the Federal Governments' increased interest in reducing tobacco use, no explicit smoking cessation benefits are guaranteed to Federal employees.

A signal feature of the FEHB is patient choice. Thus, health plans available to federal employees vary in their coverage of smoking cessation services. Many explicitly exclude all tobacco cessation treatments from coverage. Those plans that do cover smoking cessation tend to cover only prescription drugs, and to restrict cessation benefits to a single course of treatment per lifetime. Even in these instances, federal employees often become eligible for coverage only after the satisfaction of a calendar-year deductible.

As the world's largest employer-sponsored health insurance program, affecting over 9 million federal employees, retirees, and their families, the FEHB is in a unique position to set an appropriate standard of care for smoking cessation. It is likely that an FEHB guarantee of flexible access to effective, multicomponent cessation interventions to its beneficiaries would be adopted by other employers. This sort of ripple effect could dramatically improve the health of working Americans and produce tremendous long-term savings in health care costs that extend well into the next century. Of course, these cessation treatments will only be provided to smokers motivated to quit and desiring such treatments.

Guaranteed access to smoking cessation treatments for FEHB beneficiaries might take several forms, but achieving the optimal combination of health promotion and medical care savings will require two specific components. First, the services covered must be *proven effective*. Only pharmacotherapies and devices approved by the FDA and counseling programs conforming to AHCPR guidelines should be covered. Restricting coverage to these proven therapies will encourage their use, thereby optimizing overall cessation rates, and prevent wasteful spending on ineffective programs. Second, coverage must provide for *flexible* and *repeatable* treatment. Not all smokers benefit equally from a given intervention, and smokers differ in terms of which interventions they find appealing and/or acceptable. A coverage policy that does not provide smokers with a choice of treatments runs the risk of deterring as many smokers as it encourages. Additionally, studies indicate that most smokers make several serious attempts at quitting before they achieve long-term abstinence. Access to *repeatable* treatment, therefore, has the greatest potential to reduce smoking prevalence and the adverse impacts of smoking.

Understanding the need to indicate limits to such repeatable treatment, we have proposed the following:

Patients may engage in a covered smoking cessation treatment (pharmacotherapy and/or counseling) no more than one time per year and no more than three times per lifetime. The cost of such a covered treatment will not exceed \$400/treatment (1998 dollars).

3. JUSTIFICATION FOR MEDICAID BENEFICIARY TOBACCO CESSATION HEALTH BENEFIT

Cigarette smoking exacts an enormous toll on all segments of our society, one that is evident in terms of both burdensome health care costs and excess morbidity and mortality. However, Medicaid recipients represent a subgroup of our society that is particularly vulnerable to the health consequences of smoking. For instance, a study by the Center on Addiction and Substance Abuse at Columbia University found that over 42% of Medicaid recipients smoke, as compared to 25% of the general population. The same study estimated that tobacco-related illness accounts for over \$8 billion in Medicaid costs each year. Nearly 10% of all Medicaid hospital days are attributable to smoking.

These human and economic costs have not gone unnoticed. Indeed, 40 states have sued the tobacco industry to recover Medicaid costs related to smoking. Whatever the merits or eventual resolution of this litigation, it is clear that attaining the broader goal of protecting the health of Medicaid beneficiaries who smoke requires some mechanism for providing them access to smoking cessation therapies of proven effectiveness. In short, smoking-related illness and its associated costs will not be meaningfully reduced until smoking behavior itself is modified.

Currently, fewer than half of the states provide coverage for smoking cessation products in their Medicaid programs. This neglect of smoking cessation is codified in federal law, which allows states to exclude FDA-approved smoking cessation therapies from coverage under Medicaid (42 U.S.C. § 1396r-8(d)(2)). Other drugs covered under the same discretionary exclusion provision include agents for treating cold symptoms and for stimulating cosmetic hair regrowth. Federal law is silent with respect to coverage of counseling programs and other behavioral support for smoking cessation, and thus states vary with respect to coverage of these services.

The federal government has committed significant resources to determining which smoking cessation treatments are most effective. For instance, The Agency for Health Care Policy and Research commissioned an expert panel to review the entire scientific literature on smoking interventions and to offer recommendations about which are the most effective. A study published by the same group of experts demonstrated that, among preventive services, smoking cessation is second only infant immunization in terms of cost-effectiveness. Of course, many other agencies within the federal government, including the Food and Drug Administration and many divisions of the Department of Health and Human Services, have also evaluated cessation treatments. Clearly, the federal government considers smoking cessation to be a major health care priority for the U.S.. The absence of federal legislation mandating coverage for smoking cessation treatments for recipients of medical assistance under Title XIX is paradoxical.

While changing the current Medicaid policy regarding smoking cessation treatment access may require legislation, an Executive Order could promote such access.

4. CURRENT MEDICAID REGULATIONS REGARDING TOBACCO CESSATION TREATMENT WITH RECOMMENDATION FOR REPEAL

Current federal law allows states to exclude FDA-approved smoking cessation treatments from coverage under Medicaid. (42 U.S.C. § 1396r-8(d)(2)). Ironically, although 40 states have sued the tobacco industry to recover Medicaid costs related to smoking, less than half the states provide coverage for smoking cessation products in their Medicaid programs. Many of the states that do not provide Medicaid coverage for smoking cessation therapies directly or indirectly rely on the discretionary exclusion provision currently in the federal law. This statutory provision should be repealed so Medicaid recipients can have access to FDA-approved smoking cessation therapies.

Proposed Legislative Language:

Section 2:

(1) In general: Section 1927(d)(2) (42 U.S.C. § 1396r-8(d)(2)) is amended by striking subparagraph '(E)'; redesignate subparagraphs '(F)', '(G)', '(H)', and '(I)' as '(E)', '(F)', '(G)', and '(I)' respectively.

1927(d) Limitation on Coverage of Drugs:

'(2) List of drugs subject to restriction: The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

'(A) Agents when used for anorexia, weight loss, or weight gain.

'(B) Agents when used to promote fertility.

'(C) Agents when used for cosmetic hair regrowth.

'(D) Agents when used for the symptomatic relief of cough and colds.

~~*'(E) Agents when used to promote smoking cessation.*~~

'(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

'(G) Nonprescription drugs.

'(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

'(I) Barbiturates.

'(J) Benzodiazepines.'

5. CURRENT IRS REGULATIONS REGARDING TOBACCO CESSATION TREATMENT

An expense is reimbursable under a health FSA only if it is a medical expense as defined in Code Sec. 213. Prop. Treas. Reg. Sec. 1.125-2, Q&A 7(b)(4). To be a medical expense under Code Sec. 213, an expense must be for "medical care." Code Sec. 213(a); Treas. Reg. Sec. 1.213-1(a)(3).

- To qualify as an expense for "medical care," an expense must be for goods or services proximately related to the diagnosis, cure, mitigation, treatment or prevention of a particular "disease." Code Sec. 213(d)(1); Treas. Reg. Sec. 1.213-1(e); Stringham v. Commissioner, 12 T.C. 580, 584 (1949); Daniels v. Commissioner, 41 T.C. 324 (1965). Typically, a facts and circumstances inquiry is necessary to determine whether a particular expense meets this standard. See Stringham, 12 T.C. at 584; IRS Pub. 502 (Rev. Nov. 1996) at 13.
- Expenses related to a "drug" are subject to the general requirement that they be for "medical care," Code Sec. 213(b). In addition, the "drug" must be a prescription drug or insulin, Code Sec. 213(d)(3), and it must be legally procured under federal law. Treas. Reg. Sec. 1.213-2; Rev. Rul. 97-9, 1997-9 I.R.B. 1 (Feb 13, 1997) (noting that expense for prescription marijuana, which was legal under state law, are not deductible because marijuana is not legal under federal law).
- The IRS does not currently recognize smoking as a "disease." GCM 37115 (May 10, 1997). Consequently, expenses for smoking cessation programs of any kind are not deductible for taxpayers who simply wish to stop smoking to improve their general health. Id.; see Rev. Rul. 79-162, 1979-1 C.B. 116 (Jan. 1979) (no deduction or nine-week smoking cessation program taken at physician's suggestion because only taken "for the purpose of improving [taxpayer's] health"); PLR 7906009 (Aug. 10, 1978) (no deduction for smoking cessation program recommended by doctor to alleviate "cigarette hacks" and reduce the possibility of developing serious respiratory problems because "Medical experts haven't recognized smoking as disease therefore treatments weren't for purpose of curing or mitigating specific illness or disease"); see also PLR 8919009 (Feb. 6, 1989 ("Attendance at classes or participation in programs given on a health-related topic are excluded from the definition of "medical care" if they are merely beneficial to the general health of the individual and not related to a specific condition.")).
- The IRS does recognize, however, that smoking has been linked to several diseases, including lung cancer or respiratory disorders. GCM 37115. Expenses related to smoking cessation programs for smokers who have these disease "might well be" deductible, particularly if the smoker had been advised to enter the smoking cessation program by a doctor. Id.
- The IRS has also noted that "if medical authorities should ever classify smoking itself as a disease or addiction, [the IRS] believe(s) the expense incurred [or a smoking cessation program] would probably qualify as a deduction for medical care." GCM 37115; see also Note, "Deducting the Cost of Smoking Cessation Programs Under Internal Revenue Code Section 213," 81 U.Mich.L. Rev. 237 (Nov. 1982).

6. MODEL EXECUTIVE ORDER - AUGUST 9, 1997

**THE WHITE HOUSE,
Office of the Press Secretary**

**For Immediate Release
EXECUTIVE ORDER**

August 9, 1997

PROTECTING FEDERAL EMPLOYEES AND THE PUBLIC FROM EXPOSURE TO TOBACCO SMOKE IN THE FEDERAL WORKPLACE

By the authority vested in me as President by the Constitution and the laws of the United States of America and in order to protect Federal Government employees and members of the public from exposure to tobacco smoke in the Federal workplace, it is hereby ordered as follows:

Section 1. Policy. It is the policy of the executive branch to establish a smoke-free environment for Federal employees and members of the public visiting or using Federal facilities. The smoking of tobacco products is thus prohibited in all interior space owned, rented, or leased by the executive branch of the Federal Government, and in any outdoor areas under executive branch control in front of air intake ducts.

Sec.2. Exceptions. The general policy established by this order is subject to the following exceptions:

(a) The order does not apply in designated smoking areas that are enclosed and exhausted directly to the outside and away from air intake ducts, and are maintained under negative pressure (with respect to surrounding spaces) sufficient to contain tobacco smoke within the designated area. Agency officials shall not require workers to enter such areas during business hours while smoking is ongoing.

(b) The order does not extend to any residential accommodation for persons voluntarily or involuntarily residing, on a temporary or long-term basis, in a building owned, leased, or rented by the Federal Government.

(c) The order does not extend to those portions of federally owned buildings leased, rented, or otherwise provided in their entirety to nonfederal parties.

(d) The order does not extend to places of employment in the private sector or in other nonfederal governmental units that serve as the permanent or intermittent duty station of one or more Federal employees.

(e) The head of any agency may establish limited and narrow exceptions that are necessary to accomplish agency missions. Such exception shall be in writing, approved by the agency head, and to the fullest extent possible provide protection of nonsmokers from exposure to environmental tobacco smoke. Authority to establish such exceptions may not be delegated.

Sec. 3. Other Locations. The heads of agencies shall evaluate the need to restrict smoking at doorways and in courtyards under executive branch control in order to protect workers and visitors from environmental tobacco, and may restrict smoking in these areas in light of this evaluation.

Sec. 4. Smoking Cessation Programs. The heads of agencies are encouraged to use existing authority to establish programs designed to help employees stop smoking.

Sec. 5. Responsibility for Implementation. The heads of agencies are responsible for implementing and ensuring compliance with the provisions of this order. "Agency" as used in this order means an Executive agency, as defined in 5 U.S.C. 105, and includes any employing unit or authority of the Federal Government, other than those of the legislative and judicial branches. Independent agencies are encouraged to comply with the provisions of this order.

Sec. 6. Phase-In of Implementation. Implementation of the policy set forth in this order shall be achieved no later than 1 year after the date of this order. This 1 year phase-in period is designed to establish a fixed by reasonable time for implementing this policy. Agency heads are directed during this period to inform all employees and visitors to executive branch facilities about the requirements of this order, inform their employees of the health risks of exposure to environmental tobacco smoke, and undertake related activities as necessary.

Sec. 7. Consistency with Other Laws. The provisions of this order shall be implemented consistent with applicable laws, including the Federal Service Labor-Management Relations Act (5 U.S.C. 7171 et seq.) And the National Labor Relations Act (29 U.S.C. 151 et seq.) Provisions of existing collective bargaining agreements shall be honored and agencies shall consult with labor representative about the implementation of this order. Nothing herein shall be constructed to impair or alter the powers and duties of Federal agencies established under law. Nothing herein shall be constructed to replace any agency policy in writing and consistent with the terms of this order. Agencies shall review their current policy to confirm that agency policy comports with this order and policy found not in compliance shall be revised to comply with the terms of this order.

Sec. 8. Cause of Action. This order does not create any right to administrative or judicial review, or any other right or benefit, substantive or procedural, enforceable by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person or affect in any way the liability of the executive branch under the Federal Tort Claims Act.

Sec. 9. Construction. Nothing in this order shall limit an agency head from establishing more protective policies on smoking in the Federal workplace for employees and members of the public visiting or using Federal facilities.

WILLIAM J. CLINTON

THE WHITE HOUSE
August 9, 1997.

Agenda

Smoking Cessation Options for Federal Employees

- Overview of smoking cessation benefits currently available under the Federal Employees Health Benefits (FEHB) program and the employee health services program
- FEHB Contract Cycle --CY 1999 and CY 2000
- Possible Alternative Actions and Forms of Coverage
 - Expanded use in the FEHB program of Agency for Health Care Policy and Research (AHCPR) cessation clinical practice guidelines
 - FEHB program cost-sharing (e.g., adjust deductibles or copayments)
 - FEHB program design and content
 - counseling
 - medication
 - other services
 - Health services outreach for federal employees

Name	Agency	Phone	Fax
Cynthia Rice	WH DPC	456-2846	456-7431
Cynthia Dailard	WH DPC	456-7871	456-5581
Jerry Mande	WA	456-6018	456-6027
Gracey Long	OPM	606-1638	606-0967
Steve Cohen	OPM	606-1918	606-1443
FRANK TITUS	OPM	606 0770	606-4640
Dan Green	OPM	606-3818	606-0208
Carol Johnson	OMB	395-4644	395-5738
Lairdes Lamela	OMB	395-7819	395-5648
Frank Seidl	OMB	395-5146	395-5648
Richard Turnman	OMB	395- 4926	395-5648



Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

August 18, 1998

Nicotine Dependence Center
507-266-1930
800-344-5984

Mr. Jerry Mande
Room 436
OE OB
Washington, DC 20502

Dear Jerry:

It was a pleasure speaking with you and learning about the plans in Washington. As I mentioned, there is a person within the Navy who has been very interested in developing intervention programs and has been instrumental in providing these kind of services. Her name is Nancy Von Tersch, and she can be reached at 1257 Smokey Mountain Trail, Chesapeake, Virginia 23320-8187; home: (757) 548-2380, work: (757) 363-5605. In addition, Dr. Anne Joseph at the Minneapolis V.A. has been very involved in the smoke-free policies throughout the V.A. system, but also has been involved in developing intervention programs that could be implemented throughout the V.A. Her address is General Internal Medicine (111-0), V.A. Medical Center, One Veterans Drive, Minneapolis, MN 55417.

I have attached a cost outcome study that we performed in which we compare the cost-effectiveness of various medical interventions in Table 3. If Medicare has the ability to administratively begin to include these services, I think a strong case can be made given the relative cost-effectiveness of smoking interventions compared to a whole range of other now covered interventions.

I hope this is helpful. I look forward to hearing from you again. I would be more than happy to discuss the documents with the people who are putting together the ad campaigns and help in any way I can there.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard D. Hurt".

Richard D. Hurt, M.D.

RDH:aab
Enclosures

Table 3.—Cost-Effectiveness of Various Medical Interventions*

Intervention	Cost-effectiveness (dollars per year of life gained)
<i>Primary prevention</i>	
Phenylketonuria screening ¹⁷	7,000
Breast cancer screening ¹⁸	26,800
Cervical cancer screening by Papanicolaou smear (every 4 yr vs annually) ¹⁹	10,000 to >1,000,000
<i>Secondary prevention</i>	
Smoking-cessation programs	
Current study†	1,094 to 6,828
Brief advice ²⁰	705 to 2,058
For pregnant women ²¹	2,934
Nicotine gum + advice ¹³	4,113 to 9,473
Pneumonia vaccine in elderly patients ¹⁷	1,500
Treating moderate hypertension (diastolic BP >110 mm Hg) ²²	11,300
Treating mild hypertension (diastolic BP 90-110 mm Hg) ²²	24,408
Estrogen replacement therapy ¹⁷	23,500
Dialysis ¹⁷	37,000
Monotherapy for mild to moderate hypertension ²³	
By propranolol (β -adrenergic blocker)	10,900
By captopril (angiotensin-converting enzyme inhibitor)	72,100
Treating hypercholesterolemia‡ with cholestyramine ²⁴	36,000 to >1,000,000
Streptokinase therapy (for suspected MI or patients ≥ 65 yr old) ²⁵	55,000
Zidovudine therapy (for asymptomatic patients with HIV infection) ²⁶	6,553 to 70,526
<i>Tertiary prevention</i>	
CABG (patients with left and main vessel disease, severe angina) ²⁷	4,329
Kidney transplantation ²⁷	9,756
Heart transplantation ²⁷	16,239

*BP = blood pressure; CABG = coronary artery bypass grafting; HIV = human immunodeficiency virus; MI = myocardial infarction.

†Based on diverse cessation and relapse rates and discount rates (0%, 3%, and 5%) for benefits (see Table 2).

‡Cholesterol level ≥ 265 mg/dL.

Comparison of the dollars spent per year of life gained with treatment at the NDC and the treatment of other common medical problems is revealing. The costs for smoking interventions are relatively low in comparison with those of other medical interventions (Table 3), especially when the duration of medical interventions is considered.^{28,29} Whereas other medical interventions may be needed for a lifetime (as in hypertension), smoking cessation—if successful—is relatively short. Even if a smoker needs to participate in the smoking-cessation intervention several times, the cost for this treatment intervention ceases to exist once abstinence has been attained and maintained, yet the product consumption cost savings continue.

Despite the impressive nature of our results, they probably understate the true cost savings and benefits associated with smoking cessation. We have not included any tobacco product cost savings associated with smoking cessation, nor have we derived estimates of the direct medical-care cost or savings experienced by persons who stop smoking. Furthermore, neither health status gains nor quality-of-life changes

were “shadow-priced” and expressed in economic terms.^{30,31} Unfortunately, we could not adjust our cost-effectiveness results for quality-of-life years because we did not include an assessment of quality of life in this study.

Perhaps our study overstates the cost savings by not including costs patients might incur for other health-care visits at which smoking cessation was discussed or interventions provided or for care resulting from use of medications to stop smoking (for example, treating side effects) or as a consequence of stopping smoking. Related to this factor, a limitation of our study is that it does not address costs avoided for diagnoses and treatment of smoking-related diseases (such as lung cancer, chronic obstructive pulmonary disease, or coronary artery disease) nor those possibly incurred by successful cessation-related sequelae, such as major depression and ulcerative colitis. Further research would be needed to address these complicated issues.

Although our study sample consists primarily of patients being seen at the Mayo Clinic for medical care and may thus differ from other study cohorts, our results are somewhat

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Cost-Effectiveness of Treating Nicotine Dependence: The Mayo Clinic Experience

IVANA T. CROGHAN, PH.D., KENNETH P. OFFORD, M.S., ROGER W. EVANS, PH.D., SILKE SCHMIDT, B.S.,
LEIGH C. GOMEZ-DAHL, B.S., DARRELL R. SCHROEDER, M.S., CHRISTI A. PATTEN, PH.D., AND
RICHARD D. HURT, M.D.

- **Objective:** To estimate the cost-effectiveness of treating nicotine dependence, expressed as cost per net year of life gained by smoking cessation.

- **Design:** A cost-effectiveness analysis was conducted of a cohort of consecutive adult patients treated for nicotine dependence from April 1988 through December 1992 at the Mayo Clinic Nicotine Dependence Center (NDC).

- **Material and Methods:** The study cohort consisted of 5,544 patients (50.8% female; mean age, 47.8 years) with a mean baseline smoking rate of 25.4 cigarettes per day. After an initial consultation, a nonphysician counselor developed an individual nicotine dependence treatment plan, which could include follow-up counseling, nicotine replacement therapy (patches or gum), group therapy, or an inpatient program. A relapse-prevention program included telephone calls and a series of letters to the patient. We computed the years of life gained for each person specific to age, gender, smoking rate at entry, and 6-month smoking status by using published mortality rates for current and former cigarette smokers. The 6-month smoking status was assumed to be applicable at 1 year. For subsequent determinations, we modeled by computer simulation the year-by-year (to age 100) smoking status by using published relapse and late cessation rates.

Coupled with treatment costs, this information allowed the expression of cost per net year of life gained by stopping smoking. Net years of life gained, discounted 0, 3, and 5%, were computed with use of cessation and relapse rates expected for patients not seen in the NDC. Treatment costs were based on 1993 rates for the intervention services but did not include any tobacco product cost savings associated with smoking cessation.

- **Results:** The 1-year smoking-cessation rate was 22.2%. With all NDC patients included, the estimated net years of life gained, with use of a 5% rate of discount for benefits, was 0.058, and the corresponding cost was \$6,828 per net year of life gained.

- **Conclusion:** In comparison with the cost-effectiveness of other medical services, the cost of \$6,828 per net year of life gained by treatment of nicotine dependence is relatively inexpensive. Such cost-outcome data are important as economic considerations are applied for optimal allocation of limited health-care resources. Nonphysician health-care professionals can assume a key role in the provision of cost-effective nicotine dependence intervention.

(*Mayo Clin Proc* 1997;72:917-924)

NDC = Nicotine Dependence Center

BACKGROUND

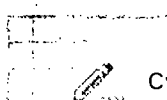
In the United States, cigarette smoking is responsible for at least 19% of all deaths,¹ many of which can be prevented. Using the Coronary Heart Disease Policy Model (a computer simulation model of coronary artery disease in the United

States), one study has determined that an average 35-year-old smoker can gain 1.2 to 2.8 years of life by stopping smoking.² Furthermore, a US government report estimated that between 1964 and 1985, approximately 750,000 smoking-related deaths were avoided or postponed as a result of decisions to stop smoking or not to start.³ Annually in the United States, 17 million smokers attempt to stop smoking on their own, of whom 7.6% are successful.⁴

The costs associated with this entirely preventable behavior are equally striking. In 1989, the US combined nonproduct costs of smoking exceeded \$65 billion.^{5,6} Nonproduct costs include direct costs such as medical ser-

From the Nicotine Research Center (I.T.C., K.P.O., C.A.P., R.D.H.), Department of Health Sciences Research (K.P.O., R.W.E., S.S., L.C.G.-D., D.R.S.), and Division of Community Internal Medicine (R.D.H.), Mayo Clinic Rochester, Rochester, Minnesota.

Address reprint requests to Dr. R. D. Hurt, Division of Community Internal Medicine, Mayo Clinic Rochester, 200 First Street SW, Rochester, MN 55905.

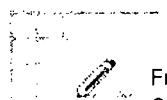


Cynthia Dailard
08/04/98 11:12:58 AM

Record Type: Record

To: Cynthia A. Rice/OPD/EOP, Jerold R. Mande/OSTP/EOP
cc:
Subject: Additional Information on FEHB/Smoking Cessation

----- Forwarded by Cynthia Dailard/OPD/EOP on 08/04/98 11:13 AM -----



Frank J. Seidl III
08/03/98 07:04:07 PM

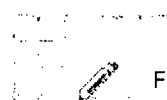
Record Type: Record

To: Cynthia Dailard/OPD/EOP
cc:
Subject: Additional Information on FEHB/Smoking Cessation

Attached is the material on FEHB/Cessation that we were talking about last Friday.

In addition, do you have a time yet for the Michael Fiore session on Wednesday? We have some people in OMB that are interested in attending. Thanks.

----- Forwarded by Frank J. Seidl III/OMB/EOP on 08/03/98 07:00 PM -----



Frank J. Seidl III
07/31/98 01:59:05 PM

Record Type: Record

To: Joshua Gotbaum/OMB/EOP@EOP, Daniel N. Mendelson/OMB/EOP@EOP
cc: See the distribution list at the bottom of this message
Subject: Additional Information on FEHB/Smoking Cessation

(This e-mail has been coordinated with the Personnel, Postal and EXOP branch.)

On July 17th, OPM briefed OMB and DPC about smoking cessation benefits under its FEHB programs. At the meeting, OPM said that fee-for-service plans under the FEHB currently offer a \$100 per person lifetime benefit for smoking cessation, subject to a calendar-year deductible. Both OMB and DPC were interested in the extent to which these cessation benefits are currently used by FEHB participants, since that information would be helpful in considering expanded options for Federal employees and other groups.

OPM has now provided the additional data on the use of cessation benefits in the fee-for service plans (scanned file attached). The data clearly has some limitations, in that Blue Cross/Blue Shield was unable to identify how many enrollees and family members used the benefit and how much was spent.



FEHB2.wp

At the same time, OPM was able to gather some basic data on the use of smoking cessation benefits from four other fee-for-service plans -- Mail Handlers, GEHA, Letter Carriers, and American Postal Workers. The table below incorporates some of the OPM data and adds information on the average cessation benefit per user in 1997.

**Smoking Cessation Expenditures in
Four Fee-For-Service Plans**

	<u>1997 Benefit (\$ in thous.)</u>	<u># Using Benefit</u>	<u>Aver. Benefit Per User</u>
Mail Handlers (MHBP)	\$72.7	2224	\$33
GEHA	19.0	337	56
Letter Carriers (NALC)	7.4	188	39
Postal Workers (APWU)	<u>2.5</u>	<u>50</u>	<u>50</u>
Total/Average	\$101.6	2799	\$36

What Portion of Smokers in the Four Plans Received Cessation Benefits? We can make a rough approximation of the percentage of smokers receiving cessation benefits during 1997.

Number of enrollees in the four plans above: 914,000

Number of total covered persons in the four plans --
number of enrollees times factor of 2.5: 2,300,000

Number of covered persons aged 18 and over (assume
74% based on 1996 census data): 1,700,000

Number of covered persons aged 18 and over who are
smokers (assume population average of 25%): 425,000

Number of covered persons receiving cessation benefits
under four FEHB plans in 1997: 2,799
(or 0.7%)

Based on this admittedly limited data, it is fair to say that only a tiny portion of smokers in these four plans received benefits in 1997, and even if one were to take account of cumulative cessation benefits over five or ten years, the percentage of smokers receiving benefits would still be small -- probably in the 5% range.

The Size of the Cessation Benefit. The average reimbursement for cessation products and services under the four plans in 1997 was only \$36. OPM does not have data on the total cost of cessation products/services used by FEHB enrollees. Comprehensive programs such as the Group Health Cooperative in Washington State have been estimated to cost \$150-200. Other sources have suggested that costs of programs may approach \$400, and might be needed three times during a lifetime.

Relevance of OPM Data to Development of Non-legislative Cessation Options. OPM's data tells us that only a small fraction of smokers in fee-for-service plans obtained reimbursement for a modest level of cessation products/services. More data should be gathered before an expansion or modification of the benefit is proposed. In addition, to increase smoking cessation rates among Federal employees, further work is needed to:

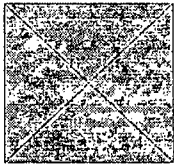
- determine why the current benefit appears to be used so infrequently;
 - determine the extent to which the benefit level, in fact, affects cessation;
 - identify the cessation strategies that have proven most successful;
 - focus on approaches that draw out smokers who are currently unlikely to quit; and
- determine which cessation strategies are most cost-effective e.g., is waiving co-payments (the approach taken by the Group Health Cooperative in Washington State) as cost-effective as an initiative to have more active cessation efforts in individual Federal agencies?

Message Copied To:

Richard J. Turman/OMB/EOP@EOP
Barry T. Clendenin/OMB/EOP@EOP
Bruce D. Long/OMB/EOP@EOP
Lisa B. Fairhall/OMB/EOP@EOP
Carol S. Johnson/OMB/EOP@EOP
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Marc Garufi/OMB/EOP@EOP
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Victoria A. Wachino/OMB/EOP@EOP
Gina C. Mooers/OMB/EOP@EOP

07/27/98 MON 16:03 FAX 202 606 0208

OPM/INS.PRG



United States

Office of Personnel Management

Washington, D.C. 20415-0001

In Reply Refer To:

Your Reference:

Smoking Cessation Programs Within the FEHB Fee-for-Service Plans

Plan	Enrollment	# Used Benefit in 97	Amount Spent in 97	Ttl. # at max	# reaching max in 1997
BCBS	1.8 million			156 (in last 3 yrs.)	48
MHBP	452 thousand	2,224	\$72,688		790
GEHA	250 thousand	337	\$19,000	2303	137
NALC	115 thousand	188	\$7,387		39
APWU	97 thousand	50	\$2,522		14

Other Information:

Total covered lives (including family members) approximates 2.5 times the number enrolled.

Blue Cross Blue Shield (BCBS) - has no information on drugs for smoking cessation. They have no policy guidance on the benefit; they 'just pay it if submitted by a licensed provider.'

Mail Handlers Benefit Plan (MHBP) - No additional information received.

Government Employees Hospital Association (GEHA) - Does not record type of expenses submitted. Covers prescription and nonprescription smoking cessation drugs, patches educational material, acupuncture and hypnosis. 4,421 individuals currently

enrolled

have smoking cessation benefits accumulated (\$345K through July 1998).

Females

account for 56% of benefits used.

National Association of Letter Carriers (NALC) - Unable to determine from their records the type of service received.

American Postal Workers' Union (APWU) - Charges in 1997 totaled \$4,647; of that amount, \$2,522 was covered and paid. Benefit subject to medical/surgical deductible

but not coinsurance. Physician referrals are not required; the patient may self-refer. Benefit includes patches, "Catapres" or Nicoreete or any other similar smoking cessation aid and may be used for both prescription and non-prescription

deterrents.

Prescription drugs processed through prescription drug vendor will be paid under

the

drug benefit, not the smoking cessation benefit.

Compi

by:

Da

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202-6

dagreen~o

gov

07/27/98 MON 16:02 FAX 202 606 0208



United States
Office of
Personnel Management

Washington, D.C. 20415-0001

In Reply Refer To:

Your Address:

Smoking Cessation Programs Within the FEHB Fee-for-Service Plans

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Compiled by:
Dan Green
202-606-3818
dagreen@opm.gov

July 22, 1998

NOTE TO: Jerry Mande

Per our discussion yesterday, I am enclosing five copies of the AHCPR-sponsored Smoking Cessation Guideline and one copy each of the related products. Descriptions of the products are as follows:

Smoking Cessation Clinical Practice Guideline - This Guideline contains strategies and recommendations designed to assist clinicians, smoking cessation specialists, and health care administrators/insurers/purchasers in identifying tobacco users and supporting and delivering effective smoking cessation interventions.

You Can Quit Smoking - This consumer guide tells how to improve chances of quitting smoking and overcoming the addiction to nicotine. It also explains how best to work with health care providers in this effort. Issues of relapse, weight gain, and referral information are included. The guide also is available in Spanish, Chinese, Vietnamese, Tagalog, Korean, Cambodian, and Laotian.

Smoking Cessation Two-Three Tools Kit - Designed to aid the clinician in cessation interventions with easy-to-read, one pagers to address and distribute to specific patient populations and issues such as Pregnant Women, First-Time Quitters, Multiple Quit Attempts, and Elective Surgery.

Helping Smokers Quit: A Guide for Primary Care Clinicians - This pocket guide highlights Guideline recommendations and steps all clinicians should follow during a cessation intervention.

Quick Reference Guide for Smoking Cessation Specialists - This guide highlights recommendations for smoking cessation specialists who are a vital resource in smoking cessation efforts, not only through their important contributions to cessation research but also through their critical role in service delivery -- especially in intensive cessation interventions.

Smoking Cessation: A Systems Approach - This guide is designed to provide health care administrators, insurers, managed care organizations, and purchasers with information needed to make smoking cessation a priority.

Since the release of our Guideline we have been actively working with various federal and private sector groups to encourage dissemination and implementation activity. One of those groups is the Veterans Administration. In October 1996 the Under Secretary of Health/ VA issued an extremely supportive letter to its medical facilities recommending the use of the Guideline as part of its efforts to help veterans quit smoking. As a followup the VA has asked us to assist them in developing a measurement tool to evaluate the level and effectiveness of Guideline implementation thus far.

To further promote smoking cessation within the federal sector, we have done or are assisting with the following:

- Provided cessation materials and input to the HHS Union-Management Partnership Council. In July, Secretary Shalala issued a memorandum to the Heads of OPDivs, and Regional Directors recommending steps to fully implement the smoke-free ban at federal buildings. Interventions mentioned in AHCPR's Guideline are included.
- Working with the Employee Health Services Branch, OPM, and will present at this year's National Conference on Federal Employee Assistance and Health Enhancement Programs.

- Contacting OPM's National Partnership Council, Office of Labor Management Relations.

As implementation of the Executive Order banning smoking in the federal workplace continues, making the AHCPR smoking cessation products more widely available to the federal workforce remains a high priority. We look forward to working with you.

A handwritten signature in black ink that reads "Chris Williams". The script is cursive and fluid, with the first name "Chris" and last name "Williams" clearly distinguishable.

Christine G. Williams