■ Overview of President Clinton's Health Care Reform Proposal

As the nation prepares for massive restructuring of the health care system, numerous interest groups have provided input on the basic design of the health care proposal created by President Clinton's Health Care Reform Task Force. Last fall, the Task Force completed its mission and delivered its proposals to President Clinton. On October 27, 1993, President Clinton submitted his proposal for health care reform to Congress, where it now awaits congressional action.

President Clinton's proposal, known as the Health Security Act of 1993, was introduced as legislation on November 20, 1993: the bill became Resolution 3600 in the U. S. House of Representatives (H.R. 3600) and Resolution 1757 in the U.S. Senate (S.R. 1757).

Although the plan will undergo many changes as it wends its way through the political process, the following outline of the plan, based on information provided by the SNM/ACNP government relations office, covers the main provisions of the proposal as it was originally submitted to Congress.

Health alliances will be organized by the states, which will receive bids from organizations offering to provide health care services. Each state will determine which plans will be approved to market their services to residents of that state. There will be several health maintenance organizations (HMOs) and preferred provider organizations (PPOs) and one or more fee-for-service plans in each area. Alliances will have to offer eligible enrollees at least one fee-for-service plan. Individual states will also have the option of instituting a single-payer system in which there would be only one health plan rather than developing a multiple-payer managed competition system.

The economic incentives will steer many patients toward the managed care systems—the HMOs and PPOs. The system will implement cost savings by capping increases in annual premiums. An overrun in expenditures by any health care plan in a given year would have to be compensated for by decreasing the fees paid to the providers of the plan the following year.

> "When it's all said and done, it's pretty simple to me. Insurance ought to mean what it used to mean: You pay a fair price for security, and when you get sick, health care is always there, no matter what."

The health care plans will have latitude in treating patients and will apportion expenditures within the limits of the funds they receive from enrollees. Each health plan will be required to have adequate arrangements with providers to assure the provision of all services covered by the comprehensive benefit package promised to enrollees. While treatment guidelines will be developed over time, initially, the health care plans will determine which diagnostic or therapeutic treatments are necessary on a case-by-case basis. Each plan will disclose to the public the protocols it uses to control costs.

Provider fees will be negotiated between providers and health care plans in each state and will be equal or nearly equal for every plan approved by a state's purchasing alliance. Physicians will have a limited exemption from the anti-trust laws in order to permit negotiations between their representatives and the health care plans.

Patients will have the right to utilize a physician outside of the system in which they enroll; they may even use a physician who is not enrolled in any system. If they opt to use physicans or facilities outside their own plan, patients will pay a minimum coinsurance of 20%, and alliances may set the coinsurance premium higher.

All employers will be required to pay 80% of the cost of insurance for their employees. Everyone, whether or not employed, will be required to join the system and pay for coverage with the exceptions noted below. The government will pay subsidies for low-wage workers and the unemployed who have no other income source. Retirees who are not yet eligible for Medicare will be included in the program, but corporations that had previously covered early retirees will be taxed for about one-half of the cost of insuring these individuals.

Medicare will continue in its present format. Medicare beneficiaries will have the option of shifting to managed care systems but will not be required to do so. Also, medicare beneficiaries will continue to have full control over selection of their providers.

> "Our approach protects the quality of care and people's choices. It builds on what works today in the private sector to expand employer-based coverage to guarantee private insurance for every American."

The premiums paid by individuals will be the same for every resident in an alliance area, regardless of age or health status. The government estimates that this will raise costs for about 40% of the population. However, the premium increase will be offset, at least partially, by a reduction in uncovered expenses.

Since almost everyone will be insured, there will be very little uncompensated care. The government expects that this will reduce inflationary pressures on private hospitals because

the hospitals will no longer have to shift costs for uninsured patients onto insured patients, and with fewer insurance carriers, paperwork and billing costs will be reduced.

The U.S. Agency for Health Care Policy and Research (AHCPR) will be directed to develop guidelines for health care providers that suggest effective and appropriate methods for the clinical management of disease and disorders. The research will focus on those diseases, disorders, and health conditions with high treatment costs, wide variations in treatment, or a high level of uncertainty as to the appropriate treatment. The AHCPR is expected to work closely with members of medical specialties during this research project.

Every health care network will be required to gather and publish data on clinical outcomes and on patient satisfaction. This data does not currently exist, although a few states have gathered preliminary data. The government will create a new agency, the National Quality Management Council, whose mandate will be to develop national measures of quality performance, including access, appropriateness, and outcomes.

For those who wish to familiarize themselves further with President Clinton's health care reform proposal, copies of the Health Security Act of 1993 are available for sale from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. (202) 783-3238. A good overview of the health care proposal is provided in a book published by the Commerce Clearing House (1).

Joan Hiam
Executive Editor, *JNMT*

Reference

1. CCH Business Law Editors. *Highlights of President Clinton's health care proposal.* Chicago, IL: Commerce Clearing House; November 1993.

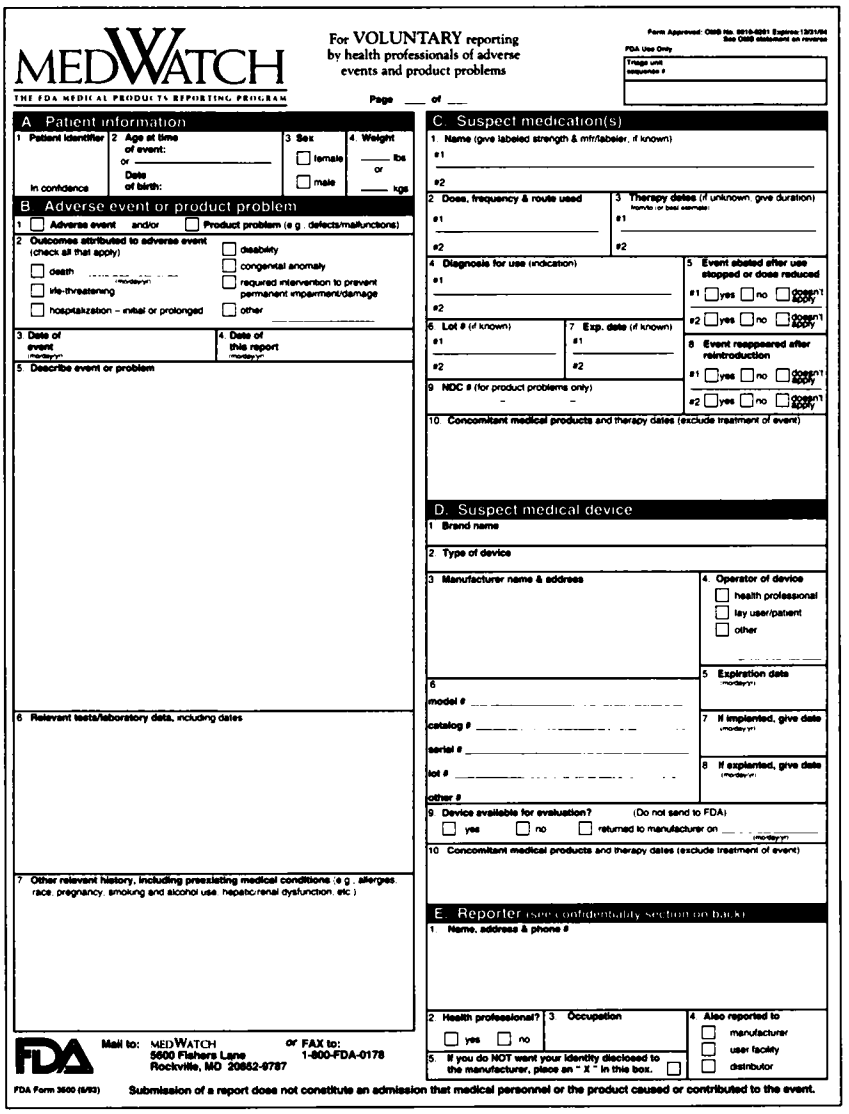
Boxed quotes are from President Clinton's State of the Union address delivered to Congress on January 25, 1994.

■ New FDA Program Encourages Reports of Adverse Medical Events and Product Defects or Malfunctions

In June 1993, the U.S. Food and Drug Administration (FDA) introduced MedWatch, a new medical products reporting program. The program seeks to facilitate, and thus encourage, the reporting of adverse medical events and product defects or malfunctions. The FDA hopes that this program will "embed the reporting of serious adverse events and product problems into the culture of professional practice."

One of the hallmarks of the new program is the simplicity of the reporting form (Fig. 1): the new form combines multi-page older forms and can be used to report either suspect devices or adverse events. Filing a report is voluntary, and the person reporting the event can request that his or her name be kept confidential, i.e., not disclosed to either the product manufacturer or the public. The patient's name is always kept confidential (Fig. 2).

David Kessler, MD, commissioner of the FDA, wrote an article on MEDWatch, published in the *Journal of the*


MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

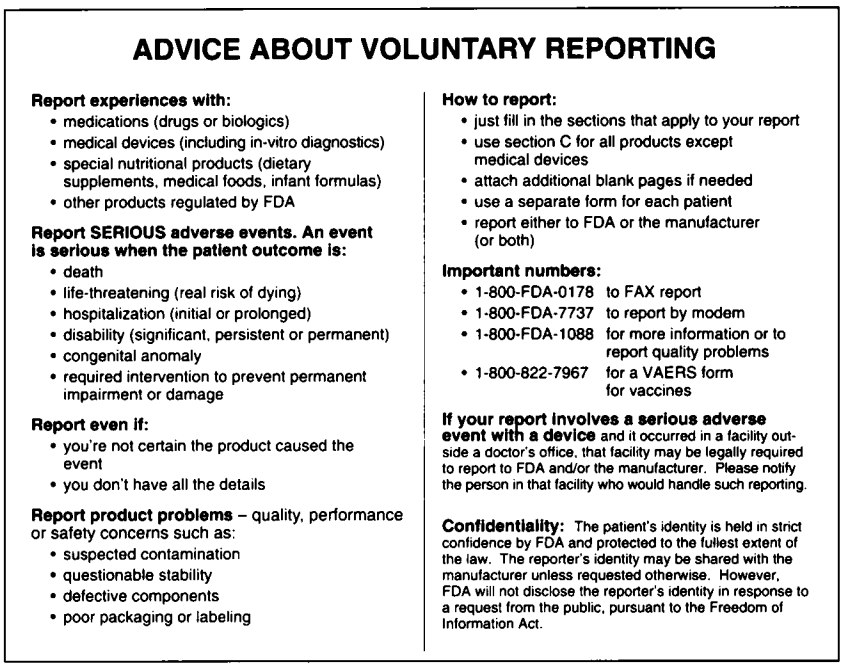
A. Patient information
B. Adverse event or product problem
C. Suspect medication(s)
D. Suspect medical device
E. Reporter

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FIG. 1. MEDWatch voluntary reporting form for medical adverse events or suspected problems with medical devices.



ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:
- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:
- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:
- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:
- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:
- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:
- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FIG. 2. Back side of MEDWatch reporting form.

American Medical Association, that introduced the MEDWatch program to the medical community (1). In this article, Dr. Kessler states that "reports from health professionals of adverse events or product quality problems are essential to ensure the safety of drugs, biologicals, medical devices, and other products regulated by the FDA." He notes that reporting adverse events and product problems is not an "ingrained practice" in the U.S., as it is in other countries, but expresses his belief that the "new system encourages health care professionals to regard reporting as a fundamental professional and public health responsibility."

The FDA expects that use of the new forms will decrease the amount of time it takes the FDA to follow up on reported problems and alert the medical community to the cause of a given product problem or adverse event.

The FDA has provided a 24-hour phone number for medical providers to request MEDWatch forms, request information about the program, or report quality problems: (800) FDA-1088. The fax number to report problems is (800) FDA-0178. Forms can also be requested by writing the FDA at MEDWatch, 5600 Fishers Lane, Rockville, MD 20852.

Joan Hiam
Executive Editor, *JNMT*

Reference

1. Kessler DA. Introducing MEDWatch: a new approach to reporting medication and device adverse effects and product problems. *JAMA* 1993;269:2765-2768.

■ News Briefs

NAFTA Supersedes U.S.-Canada Free Trade Agreement

The U.S.-Canada Free Trade Agreement (FTA), which became operational January 1, 1989, includes a schedule of professions. Specialties listed on this schedule are deemed qualifying professions, which allows listed professionals to work in either Canada or the United States subject to certain limitations. The SNM Technologist Section and the Canadian Association of Medical Radiation Technologists (CAMRT) have been trying to get an amendment passed that would add nuclear medicine technology to the schedule of professions.

Initially, the Canadian government tabled the issue because it felt that the Canadian provinces would resist the amendment. However, in the summer of 1993, Canadian government officials were assured by the provincial governments that the provinces would not stand in the way of passage of the amendment. The Canadian Working Group has signaled its approval of the amendment and is now waiting for a response from the American Working Group.

Meanwhile, passage of the North American Free Trade Agreement (NAFTA) means that provisions of the FTA will be superseded by NAFTA regulations. According to the U.S. Immigration and Naturalization Service, NAFTA has supplanted the FTA, effective January 1, 1994, but the schedule of professions will probably remain intact. Thus, work will continue to add nuclear medicine technology to the schedule of professions.

Passage of NAFTA has also raised concerns among medical professionals that state certification and licensing requirements might be circumvented. To address these concerns, a coalition of health professional organizations wrote to Mickey Kantor, U.S. trade representative, outlining its concerns. Mr. Kantor responded with a letter in which he stated that "the NAFTA does not permit Mexican or Canadian health care professionals—or any professional service providers—to circumvent state licensing and certification procedures." He further noted that "the federal government will not exert any pressure on state licensing authorities to adopt common education, accreditation, certification, or other measures....If the relevant professional licensing bodies deem it appropriate to agree on common procedures, then the NAFTA Commission will review these recommendations with an aim to expanding commitments between the three governments under the NAFTA to include them. If the licensing bodies believe it unwise to develop com-

mon procedures or criteria, no negotiations toward this end will take place."

Nuclear Medicine Week Preparations Under Way

Nuclear Medicine Week (NMW) will be celebrated from October 2-8 this year although nuclear medicine departments may celebrate any time between July and December and still be eligible for the Media Stars Contest. (The contest will be renamed later this year.) Nanci Burchell, CNMT, 1993-1994 chair of the SNM-TS NMW Subcommittee, notes that this year's theme, The Science of Nuclear Medicine, was picked to convey that nuclear medicine is more than technologists pushing buttons and injecting radioactive isotopes. She says that the NMW Subcommittee wants to recognize all the professionals involved in nuclear medicine and to use the week to educate the public and other health care professionals about the practice of nuclear medicine.

Ms. Burchell emphasizes that there are four objectives of Nuclear Medicine Week: to motivate members of the nuclear medicine community to promote the specialty of nuclear medicine; to market nuclear medicine to referring physicians and increase their awareness and use of nuclear medicine; to educate the general public about the benefits of nuclear medicine and to eliminate negative connotations associated with radiation; and to promote nuclear medicine as a viable and exciting careeer path for students.

Anyone with suggestions or questions about Nuclear Medicine Week may contact Ms. Burchell at (816) 234-3214 or (816) 842-7112 (fax).

FDA Allows Women to Participate in Early Phases of Drug Trials

The U.S. Food and Drug Administration (FDA) has published a new guideline that encourages those conducting clinical trials for new drugs to include women in the early phases of the studies, i.e., in Phase I and early Phase II studies. The new policy, which was published in the *Federal Register* in July 1993, seeks to incorporate the effects of a drug on women in the earliest trial data so that dosage amounts and methods of delivery in the later phases of the trials reflect the drug's effect on females as well as males.

The new FDA policy replaces a 1977 FDA guideline that specifically excluded women of childbearing potential from participating in the early phases of most drug trials. The new guideline also directs drug trial sponsors to conduct analyses using the databases from the early clinical trials to probe for any gender-based differences in the drug's effect. The FDA believes that decisions on whether to admit women to particular clinical trials should be made by institutional review boards, investigators, and potential trial participants. The FDA has noted that it will continue to review its guidelines on how best to minimize the danger of a woman becoming pregnant and exposing the fetus to potential harm during a clinical drug trial.

New Jersey Technologist Society Created

Nuclear medicine technologists in New Jersey have recently formed their own society: The Garden State Society of Nuclear Medicine Technology. The fledgling organization held its first meeting in October 1993 with 140 technologists attending. The new Society has formed a committee to foster its growth and focus its objectives as a society.

This committee has established the following objectives for the Garden State Society: provide continuing education for nuclear medicine technologists; provide an informational network where technologists and support personnel can share their knowledge and educational experiences and develop career opportunities; promote professionalism and pride among technologists; promote nuclear medicine to those in other medical specialties; and provide education to the public concerning nuclear medicine.

Any nuclear medicine technologist may join the Garden State Society for a $15 annual fee; vendors and others associated with nuclear medicine technology may join as associate members for $20 per year. Those who wish more information on the Garden State Society or wish to join should contact Pat Wells, CNMT, Overlook Hospital School of Nuclear Medicine Technology at (908) 522-2342.

Staff Changes in SNM/ACNP Government Relations Office

Kristen Morris, who had served as director of government relations in the SNM/ACNP government relations office since April 1990, resigned last fall to accept a position with the Health Industries Manufacturer's Association. Sandy Bilko, formerly the office specialist in reimbursement issues, is now the acting director of government relations. She will continue to handle reimbursement issues and healthcare while overseeing the entire office. Valerie Fedio, assistant director of government relations, remains in charge of technical issues and and issues pertaining to the FDA. David Nichols, legislative coordinator, will concentrate on low-level radioactive waste issues and questions relating to the following agencies: NRC, DOE, and EPA. Carolyn Getchell has joined the office as an administrative assistant.

Call for Book Authors

The Technologist Section is seeking authors to write chapters for clinical primers on the following subjects: cardiovascular imaging, gastrointestinal imaging, central nervous system imaging, and urinary tract imaging. Authors will receive honorariums based on their level of participation. If you would like to participate or would like more information on the project, please contact either John Childs, director of publications, SNM at (212) 889-0717 or Jim Wirrell, chairman of the SNM-TS Publications Committee at (317) 929-8088.