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RULES ON PRIVACY OF PATIENT DATA STIR HOT DEBATE

HEALTH GROUPS OBJECT

Clinton's Plan Is Criticized as Costly and Inadequate for Protecting Records

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By ROBERT PEAR

WASHINGTON, Oct. 29 — President Clinton kicked off an intense debate today on how to protect the privacy of medical records in an era when doctors can test their patients for genetic defects and send the information around the world with the click of a computer mouse.

In unveiling new rules to safeguard such information, Mr. Clinton said, "These standards represent an unprecedented step toward putting Americans back in control of their own medical records."

But doctors said the rules were inadequate and could actually erode some protections that patients now have. Several physician groups said they had been invited to today's White House ceremony, but stayed away because in many cases the proposal does not require that patients give consent before their records are shared, only that they be notified. Such a rule, they said, does not give patients enough control over the use and disclosure of their medical records.

The Administration estimated that compliance would cost the health-care industry $3.8 billion over five years, but the insurance industry says the costs could be 10 times that amount. With both sides saying they support the goals of the standards, a central point in the debate will be: What is privacy worth in dollars and cents?

Health insurance plans object, in particular, to a provision that would make them responsible for privacy lapses by companies that collaborate in the care of a patient. For example, an H.M.O. that sends a patient to a pharmacy could be liable if the pharmacy improperly uses the patient's records.

Under the proposed rules, patients would gain a new Federal right to inspect, copy and suggest corrections in medical records that have been kept or transmitted electronically.

Federal officials estimated that it would cost doctors, hospitals and health maintenance organizations more than $400 million to issue notices informing patients of their privacy rights, as required by the rules. In addition, the officials predicted, thousands of patients will try to correct their medical records, and it will cost the health-care industry more than $2 billion to deal with these requests over the next five years.

The rules would permit the use and disclosure of medical information without a patient's consent for treatment, payment and a wide range of loosely defined "health-care operations," including many common business practices of H.M.O.'s.

Dr. Donald J. Palmisano, a trustee of the American Medical Association, said, "The A.M.A. believes that mere notice of a health plan's intended use is inadequate."

Many doctors contend that health plans and insurance companies should have to obtain consent from patients before using information from their files to monitor the patients' compliance with recommendations for medical treatment and testing. Too often, the doctors say, H.M.O.'s interfere in the doctor-patient relationship by suggesting a cheaper drug or a different course of treatment.

The Clinton Administration would allow health plans to use personal health information, without a patient's consent, for the following "health-care operations": assessing the quality of care and the performance of doctors and nurses; developing clinical guidelines; setting premiums for the renewal of insurance contracts, and investigating fraud.

Dr. Richard K. Harding, vice president of the American Psychiatric Association, said the proposed rules "give the Federal Good Housekeeping Seal of Approval to practices that could undermine privacy."

Many states allow patients to limit the use of some or all of the information in their medical files. In theory, the Federal rules do not override state laws that provide more protection for privacy.

But William B. Bruno, a lawyer for the psychiatric association, said, "Patients could lose some protections they now have. At present — because of state laws, court decisions and canons of medical ethics — many hospitals will not disclose medical records unless the patient gives consent. The Federal Government is now weighing in, saying that's not required. It's giving a green light for significant changes in current practice."

Administration officials insisted that the rules would create protections in areas where none now exist. Doctors, hospitals and H.M.O.'s would, for example, have to keep logs documenting who got access to patients' records for various purposes.

The rules would greatly expand the role of the Federal Government in regulating the practices of the health-care industry. It would set hundreds of detailed Federal standards, with civil and criminal penalties for violations.

Mary Nell Lehnhard, senior vice president of the Blue Cross and Blue Shield Association, described the rules as costly, complex and confusing.

"We believe that all patients should have the peace of mind that comes from knowing their personal records are secure, and we are outraged when breaches of this trust occur," Ms. Lehnhard said. "But why do we need 600 pages of regulations to protect medical records when the Bill of Rights takes only one page to provide Americans with all their basic rights? Why didn't the Administration just simply spell out what activities are illegal?"

Janlori Goldman, director of the health privacy project at Georgetown University, said, "This is a historic day. These regulations will be the first enforceable Federal rules protecting health privacy."

But, Ms. Goldman said, the proposal falls short because "there is no requirement that a judge or a magistrate approve or deny access to medical records sought by law enforcement agencies."

Under the rules, most health-care providers would have to designate "privacy officials" to develop privacy policies and procedures. This rule would apply even to a small office with three doctors, who could designate the office manager as privacy coordinator. Providers would also have to designate a "contact person" to handle patients' complaints about violations of privacy.

Mr. Clinton and Donna E. Shalala, the Secretary of Health and Human Services, expansively interpreted their authority. The rules make doctors, H.M.O.'s and insurance compa-

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The New York Times
SATURDAY, OCTOBER 30, 1999

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Associated Press

President Clinton offered rules yesterday that he said would put "Americans back in control of their own medical records." He also met with the health secretary, Donna E. Shalala, at the White House.

nies responsible for any violation of a patient's privacy by their "business partners."

Kristin A. Bass, director of legislative affairs at the American Association of Health Plans, a trade group, said that an H.M.O. would have little power over a drug store that improperly sold information about the patient to a drug manufacturer.

"They would hold us responsible for the pharmacy's misbehavior," Ms. Bass said.

Insurance plans could also be held accountable for the misuse of medical records by their other "business partners," including lawyers, auditors, billing firms and consultants.

Under the rules, health-care providers and health plans would have to get a patient's consent for certain types of disclosures — if, for example, the information was to be used in marketing.

Doctors and insurers could not insist that people surrender their privacy rights as a condition of obtaining treatment or insurance. In other words, they could not coerce patients into giving consent.

The Administration acknowledged that the rules would create substantial costs for health-care providers and health plans. But, it said, the rules are necessary because computer technology makes it possible to "breach the security and privacy of health information on a scale that was previously inconceivable."

In addition, doctors have many new clues to their patients' destiny. Scientists have developed more than 450 genetic tests that may help identify people with an increased risk of developing breast cancer, prostate cancer and other diseases.

In a preface to the rules, the Administration said they would have "major social benefits" that could not be quantified. Privacy concerns now discourage people from being tested for certain types of cancer and for some sexually transmitted diseases, the Administration said. The new rules will allay these concerns, so more people will receive effective treatments, it said.

A person who violated the rules could be required to pay a civil penalty of $25,000. The rules authorize tougher penalties for criminal violations: a $50,000 fine and one year in prison for willful violations; a $250,000 fine and 10 years in prison if the offender tried to use or sell data for "commercial advantage, personal gain or malicious harm."

The public will have two months to comment on the proposals, which are to be published in the Federal Register on Nov. 3. The Secretary of Health and Human Services is supposed to issue final rules, with the force of law, by Feb. 21, 2000.

Mr. Clinton said he was acting because Congress failed to meet its goal of adopting comprehensive privacy standards by Aug. 21.

"I am taking this action today because Congress has failed to act and because, a few years ago, Congress explicitly gave me the authority to step in if they were unable to deal with this issue," he said.

The New York Times

SATURDAY, OCTOBER 30, 1999

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

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THE DIRECTOR

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October 31, 1999

MEMORANDUM FOR THE PRESIDENT

FROM: Jacob J. Lew

SUBJECT: Wye River Agreement and the Budget – INFORMATIONAL

Before you begin your trip to Oslo, I wanted to give you an update on Congressional action on your Wye River funding request.

You requested $1.9 billion to help the parties to the Wye River agreement achieve peace. This included $1.2 billion for Israel, $400 million for the Palestinians, and $300 million for Jordan spread over three fiscal years (FY 1999 to FY 2001). To date, Congress has not acted on the bulk of your request in support of the peace accords, only appropriating $100 million for Jordan earlier this year, as part of a FY 1999 supplemental.

There is considerable desire both within the Administration and among many in Congress to provide Wye funding as part of final budget negotiations. We have been pressing very hard that this funding be resolved along with other foreign policy issues since there is a real risk that while Wye would be funded, many other priorities (including debt relief for Africa and Latin America) would be left behind. As you know, there is strong outside pressure for Wye funding, while it is primarily your leadership that keeps the other issues on the table.

Congressional Republicans are considering a plan which would fund Wye and provide only modest increases for other foreign policy priorities by changing the timing of disbursements to Israel for one year. Assistance payments are currently disbursed immediately upon enactment. By making periodic payments, as we do with assistance to other countries, Congress could create additional room for FY 2000 spending without dipping into the Social Security surplus. Through this mechanism, the Congress could provide full funding for Wye and modest increases in other areas.

Israel has sent conflicting signals on this proposal, trying not to get caught between Congress and the Administration on the larger budget battle. Israel would clearly oppose any permanent change in disbursement and would prefer not to modify the highly favorable terms even for one year, as such a change could easily become a precedent. On the other hand, they do not want to send any signals that would undermine efforts to fund Wye this year.

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In the House, this proposal is viewed as a serious threat to unity within the Democratic caucus, since Wye funding may be resolved with inadequate funding for Africa and Latin America. John Podesta and I spoke with House Minority Leader Gephardt on Friday about this and plan to meet with a number of Members representing the Jewish, Black, and Hispanic caucuses to try to maintain unity behind keeping all foreign policy priorities together as we move through the final budget negotiations. There may be a request for you to meet with these groups when you return.

If asked about this at Oslo, we recommend you say that this idea requires significant scrutiny. We need to consider both the long-term potential impact on Middle East assistance and on the larger budget. It seems all but certain that Wye funding will be included in a final budget agreement, but there is substantial risk with regard to other foreign policy funding priorities.

THE WHITE HOUSE

WASHINGTON

October 31, 1999

MR. PRESIDENT: 10-31-99

Jack wanted you to see this before your trip to Oslo.

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U.S. Moves To Require Disclosure Of Gene Tests

The New York Times
SATURDAY, OCTOBER 30, 1999

By SHERYL GAY STOLBERG

WASHINGTON, Oct. 29 — Concerned that investigators in gene therapy experiments are trying to keep information about patient deaths and serious side effects out of public view, members of a Federal oversight panel are planning to rewrite their rules to force greater disclosure.

The move by the Recombinant DNA Advisory Committee comes six weeks after the death of an 18-year-old Arizona man, Jesse Gelsinger, apparently the first person to die as a result of gene therapy. Researchers at the University of Pennsylvania, where the experiment was conducted, were quick to report the death and have spoken about it publicly.

At this point there is no evidence that any other patients have died as a direct result of receiving gene therapy. But the committee is concerned that some scientists and companies have not always been forthcoming with information about side effects experienced by gene therapy patients, or about patients who died from causes other than the therapy.

In one case, a researcher reported the death of a patient with advanced heart disease last year and asked that it be "kept confidential and not part of the public record." In another, a drug company, the Schering-Plough Corporation, has insisted that information about side effects be classified as a trade secret.

"Things that might be patentable are things that a company should rightfully hold as confidential," said the panel's chairwoman, Dr. Claudia Mickelson, biosafety officer at the Massachusetts Institute of Technology. "Adverse events, we do not feel, fall into that category, and so we are changing the language to be more explicit."

At issue, Dr. Mickelson and others say, is how much information scientists and companies should share with their competitors in what is still a novel, and relatively unsuccessful, scientific field. Typically, companies experimenting with drugs and therapies report solely to the Food and Drug Administration, and the information they generate is kept confidential until the drug is approved.

But gene therapy experiments are treated differently; they are submitted to both the F.D.A. and to the advisory committee, a group that was established in the early days of the research to foster public discussion. The committee, which reports to the director of the National Institutes of Health, no longer has authority to approve gene therapy experiments, but is authorized to review and publicly discuss experiments, except for proprietary information.

The question of just what is proprietary is a sticking point between the committee and at least one company, Schering-Plough. A spokesman for Schering-Plough, Robert Consalvo, says the company believes that information about the design of gene therapy experiments and patient safety data is proprietary and should be kept confidential.

"That is the same information that goes to the F.D.A. and remains confidential there," Mr. Consalvo said.

The committee greeted that suggestion with "a sufficient amount of outrage," said another member, Dr. Ruth Macklin, a professor of bioethics at Albert Einstein College of Medicine in the Bronx.

In addition, Dr. Macklin and others said, the committee is aware of deaths that have been reported to the F.D.A. but not to the panel. She said it was important that information about deaths be made public, even if they were not as a direct result of gene therapy, so that scientists and the public could learn from them.

The debate reached a boiling point at the committee's meeting in September, before Mr. Gelsinger died. At that time, the panel received information about Schering-Plough.

Also, to bolster their case that patient deaths were not being discussed publicly, staff members gave the committee a copy of a 16-month-old confidential letter from Dr. Ronald G. Crystal of New York Hospital-Cornell Medical Center. He wrote on May 14, 1998, to report on a patient with advanced heart disease who died during a gene therapy trial.

Although Dr. Crystal asked that the information be kept confidential at the time, he said today that he had since publicly discussed that death and others indirectly related to gene therapy at scientific meetings, and had reported on them in the medical literature. He noted that the letter advised members of the committee, known as the RAC, to call him with any questions. "There was no intention of holding this back from members of the RAC," he said.

Dr. LeRoy Walters, a bioethicist at Georgetown University who served as chairman of the committee until 1996, said that as far as he knew Dr. Crystal's letter represented the first time an investigator had asked that a death in a gene therapy trial not be publicly disclosed.

"The premise of the RAC review process from its inception was that all nonproprietary details about the protocol itself and all adverse events would be publicly reported," Dr. Walters said, "and in a timely way."

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Monday: Prayer 8:00 PM
Tuesday: Pastor Class 8:00 PM
Thursday: Noon Day Prayer
Friday: Evangisistic 8:00 PM