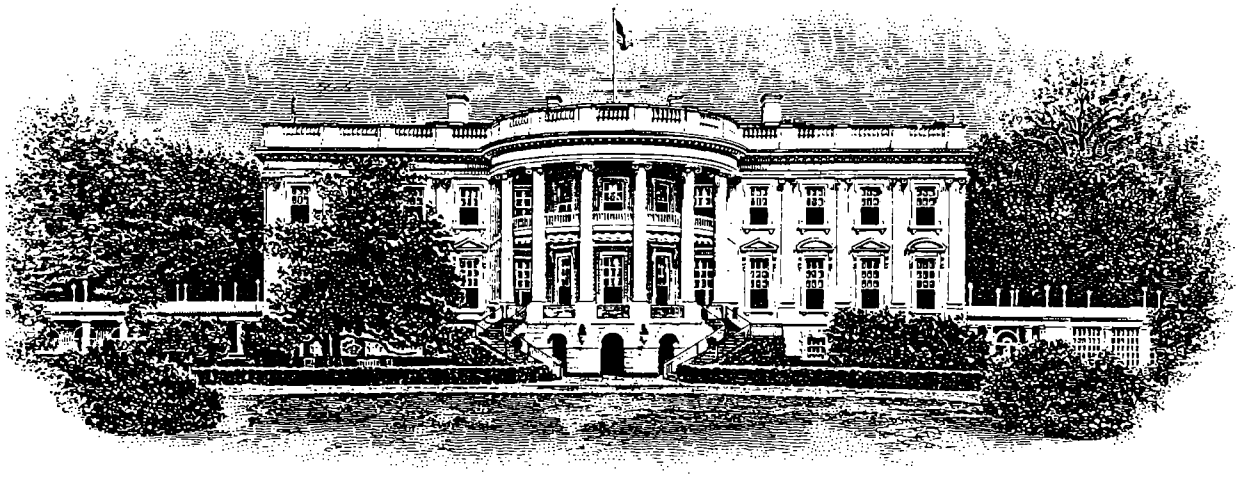
DEVORAH

PRIVACY

The White House



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THE WHITE HOUSE

WASHINGTON

October 28, 1999

STATEMENT ON MEDICAL PRIVACY REGULATION

DATE:	October 29, 1999
LOCATION:	Oval Office
BRIEFING TIME:	8:30am – 8:45am
EVENT TIME:	8:45am – 9:05am
FROM:	Bruce Reed, Mary Beth Cahill, Chris Jennings

I. PURPOSE

To unveil a new regulation ensuring privacy protections for medical information stored or transmitted electronically, and to urge the Congress to enact broader privacy protections without further delay.

II. BACKGROUND

Today you will unveil a landmark set of privacy protections for medical information stored or transmitted electronically. This new regulation, which you are proposing due to Congress's failure to act, underscores the Administration's commitment to safeguarding the security of personal health information. However, you will note that because your regulatory authority is limited, comprehensive federal legislation is urgently needed, and you will urge Congress to enact broader privacy protections without further delay.

The new regulation that you and HHS Secretary Shalala are announcing today would apply to all health plans and many health care providers, as well as to health care clearinghouses such as billing companies. It would 1) limit the non-consensual use and release of private health information; 2) inform consumers about their right to access their records and to know who else has accessed them; 3) restrict the disclosure of protected health information to the minimum necessary; 4) establish new disclosure requirements for researchers and others seeking access to health records; and 5) establish new criminal and civil sanctions for the improper use or disclosure of such information.

UNVEILING NEW SAFEGUARDS FOR SENSITIVE HEALTH INFORMATION. The new regulation being unveiled today is designed to give consumers more control over their health information; set boundaries on the use and release of health records and ensure their security; establish accountability for inappropriate use and release; and balance public responsibility with privacy protections. This new regulation would:

GIVE CONSUMERS CONTROL OVER THEIR HEALTH INFORMATION

- **Limit the release of private health information without consent.** This rule would establish a new Federal requirement that doctors, hospitals, health plans, and other covered entities could not -- without a patient's written consent -- release identifiable health information for purposes unrelated to treatment, payment for services, or priorities like public health. Under the current regime, such data is often released to marketing firms, financial institutions, and employers, without knowledge or consent, and is then used in direct marketing campaigns, in loan eligibility decisions, and for promotion and other purposes. In fact, a recent University of Illinois survey indicated that 35 percent of Fortune 500 companies check health records before they hire or promote.

- **Inform consumers how their health information is being used.** This new regulation will require health plans and providers to publish a notice to patients about how their information is being used and to whom it is being disclosed. It will also give each individual patient a right to a "disclosure history," listing the entities that have received information for purposes unrelated to treatment or payment.

- **Give patients access to their own health file and the right to request amendments or make corrections.** The regulation will give patients the right to see and copy their own records as well as the right to request correction of potentially harmful errors in their health files. These access and amendment rights are a core part of any regime to protect individual privacy. Without them, a person with an improper diagnosis in his or her medical file or payment record could be denied health insurance and left no redress.

SET BOUNDARIES ON MEDICAL RECORD USE AND RELEASE

- **Restrict the amount of information used and disclosed to the "minimum necessary."** Currently, health care providers and plans can often release a patient's entire health record even if an employer or other entity needs only particular information. This new regulation would restrict the information that is used and disclosed to the minimum amount of information necessary.

ENSURE THE SECURITY OF PERSONAL HEALTH INFORMATION

- **Require the establishment of privacy-conscious business practices.** Sensitive information is often stored where it can be easily accessed. Earlier this year, for example, a major medical center inadvertently stored several thousand patient records on a public Internet site for two months. The regulation you will announce today will require health plans and providers to establish internal procedures to protect the privacy of health records. They include: training employees about privacy considerations in the workplace; receiving complaints from patients on privacy issues; designating a "privacy officer" to

assist patients with complaints and employees with questions; and ensuring that appropriate safeguards are in place for the protection of health information.

BALANCE PUBLIC RESPONSIBILITY WITH PRIVACY PROTECTIONS

- **Require that information be disclosed only for research conducted responsibly.** Since health care research is an important public priority, under this rule researchers may obtain identifiable health information without prior consent if they certify to a provider or plan that an "institutional review board" or "privacy board" has reviewed the research protocol and determined that the research would meet certain privacy protection criteria.

ESTABLISH ACCOUNTABILITY FOR MEDICAL RECORD USE AND RELEASE

- **Create new criminal and civil penalties for improper use or disclosure of information.** Currently, there is often no legal basis to prosecute individuals who inappropriately disclose private medical information. This rule creates new criminal penalties for intentional disclosure -- up to $50,000 and up to a year in prison. Disclosure with an intent to *sell* the data will be punishable with a fine of up to $250,000 and up to 10 years in prison. The regulation also establishes new civil penalties of $100 per person for unintentional disclosures and other violations (up to $25,000 per person per year).

NOW CONGRESS MUST ENACT COMPREHENSIVE LEGISLATION. The important new protections you will unveil today are a critical first step -- a step you are taking because Congress has failed to act in the three-year timeframe it gave itself in 1996. But your administrative authority is limited by statute and there remains an urgent need for comprehensive Federal privacy protections. Today's regulation, for instance, does not cover all paper records. It does not directly regulate many entities, including employers, other insurers, or public health agencies -- thus allowing for unlimited reuse of information by such entities. Federal legislation is also needed to fortify the penalties and to create a private right of action so that citizens can hold health plans and providers directly accountable for inappropriate and harmful disclosures of information. That is why today you will call on Congress to finish the job and enact the comprehensive protections that the American people want and need.

III. PARTICIPANTS

Briefing Participants:
Secretary Donna Shalala
Bruce Reed
Loretta Ucelli
Mary Beth Cahill
Chris Jennings
Lowell Weiss

Event Participants:
Janlori Goldman, Director, Health Privacy Project
Zoe Hudson, Policy Director, Health Privacy Project
Judy Lichtman, President, National Partnership for Women and Families
Sara Collins, Manager, Federal Government Relations, National Multiple Sclerosis Society
Jeffrey Crowley, Deputy Executive Director, National Association of People with AIDS, and Chair, Privacy Working Group, Consortium for Citizens with Disabilities
Mary Davidson, Executive Director, Alliance of Genetic Support Groups
Christine Koyanagi, Policy Director, Brazelon Center for Mental Health
Rebecca Patton, Treasurer, Board of Directors, American Nurses Association
Chai Feldblum, Professor of Law, Georgetown University Law School; Director of Federal Legislation Clinic; and Counsel to the Consortium of Citizens with Disabilities Privacy Working Groups
Adrienne Hahn, Director, Consumers Union
Marcia Nielsen-McPherson, Director, Legislative Relations, AFL/CIO
Ronald Weich, ACLU

Program Participants:
YOU
Secretary Donna Shalala

IV. PRESS PLAN

Pool Press.

V. SEQUENCE OF EVENTS

- **YOU** will greet representatives from consumer, women, and provider advocacy organizations.
- Secretary Donna Shalala will make brief remarks and introduce **YOU**.
- **YOU** will make remarks.

VI. REMARKS

To be provided by speechwriting.

DRAFT: THE NEED FOR MEDICAL RECORDS PRIVACY PROTECTIONS

MOST AMERICANS BELIEVE THAT THEIR MEDICAL RECORDS ARE UNSAFE

One in five American adults believe that a health care provider, insurance plan, government agency, or employer has improperly disclosed personal medical information. Half of these people say that this disclosure has resulted in personal embarrassment or harm. (Princeton Survey Research Associates, January 1999)

Two thirds of American adults say that they do not trust health plans to maintain confidentiality all or most of the time. (Princeton Survey Research Associates, January 1999)

This lack of confidence in the health care system can lead to poor quality or inappropriate care. One in six American adults say they have done something out of the ordinary to keep personal medical information confidential, including: going to another doctor; paying out of pocket for services; not seeking care; giving inaccurate or incomplete information on a medical history; and asking a physician not to write down the health problem or record a less serious or embarrassing condition. (Princeton Survey Research Associates, January 1999)

Eighty-two percent of people were concerned about their privacy, up from 64 percent in 1978. Nearly 60 percent of people have at some point "refused to give information to a business or company" because of privacy concerns, up from 40 percent in 1990. (Louis Harris and Associates, 1995)

EXAMPLES OF MEDICAL RECORDS PRIVACY VIOLATIONS

Sharing private prescription and other medical records for marketing purposes.

In recent years, drug manufacturers have accessed sensitive patient information from pharmacies and doctors to market their products directly to consumers.

An Orlando woman had her doctor perform some routine tests, and received a letter weeks later from a drug company touting a treatment for her high cholesterol. (*Orlando Sentinel*, November 30, 1997).

Under the proposed rule, doctors, hospitals, and other health care providers and plans would have to obtain patients' written consent before using information for marketing or releasing information to others for marketing. The patient would have to be told that the information is being exchanged for financial gain.

Using confidential medical records to sabotage reputations or cause malicious harm.

After news of a famous actress' recent surgery was leaked to the press, photos of her leaving the UCLA Medical Center appeared in papers with commentary about her health status. (Parade Magazine, May 10, 1998)

A New York Congresswoman's confidential medical records – including details of a bout with depression and a suicide attempt – were faxed from a New York hospital to a local newspaper and television station on the eve of her 1992 primary. She later testified on this in front of the Senate Judiciary Committee.

Under the proposed rule, none of these disclosures would be permissible absent written consent from the patient. In addition, under the rule facilities would have to have security procedures to limit access by unauthorized persons.

Inappropriate release of private medical records.

In *Doe vs. Septa*, a major drug store chain provided the Pennsylvania state transportation authority (SEPTA) information on the prescription drugs being taken by their employees. In disclosing to SEPTA that one of its employees was receiving AZT, the company in effect disclosed the employee's HIV status. (*Doe v. Septa*, WL 76, 2891 (3d Cir. 1995))

Under the proposed rule, the pharmacy would not be permitted to release any information to the employer absent consent.

A woman in California who suffered a work-related injury authorized her insurance company to release information pertaining to the injury. When she reviewed what the employer had received, it contained her entire medical record including records on recent fertility treatment and pregnancy loss. (*Sacramento Business Journal*, April 5, 1999)

Under the proposed rule, health care providers and plans would only be allowed to release the minimum amount of information necessary to the employer.

Using private medical records as a basis to deny promotions or employment.

According to a recent University of Illinois survey, 35 percent of Fortune 500 companies check medical records before they hire or promote.

The director of a work site health clinic operated by a large manufacturing company testified that he was frequently pressured to provide personal information about his patients to his supervisors. (Testimony by Jan Lori-Goldman in front of the House Subcommittee on Government Management, Information, and Technology of the Committee on Government Reform and Oversight, May 19, 1998)

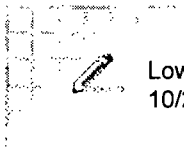
Under the proposed rule, health care plans and providers could not disclose patients' medical file to the employers for personnel purposes without written consent of the patient.

Careless design of system for handling sensitive medical information.

The Harvard Community Health Plan, a Boston-based HMO, admitted to maintaining detailed notes of psychotherapy sessions in computer records that were accessible by all clinical employees. (*Boston Globe,* March 7, 1995)

The University of Michigan Medical Center inadvertently posted several thousand patient records on a public Internet site for two months. Individuals searching the Internet for information about a provider were linked to patient records containing names, addresses, social security number, treatment for medical conditions and other data. (*Washington Business*, February 22, 1999).

Under the proposed rule, access to protected health information would be limited to those people who need it, and while some mental health information, like medications the patient is taking, is essential for other care, detailed psychotherapy notes are not.



Lowell A. Weiss
10/28/99 08:51:02 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: privacy remarks -- final

Draft 10/27/99 8:40pm
Lowell Weiss

PRESIDENT WILLIAM J. CLINTON
REMARKS UPON DEPARTURE
ON PRIVACY PROTECTIONS FOR MEDICAL RECORDS
THE WHITE HOUSE
October 29, 1999

Acknowledge: Sec. Shalala.

Good morning. Today, I am pleased to be joined here in the Oval Office by a diverse group of health care and consumer advocates to announce new actions to protect the sanctity of our medical records.

Every American has a right to know that his or her medical records are protected at all times from falling into the wrong hands. And yet, as more and more of our medical records are stored electronically, the threats to our privacy have greatly increased. And so has our sense of vulnerability.

To be sure, storing and transmitting medical records electronically is a remarkable application of information technology. Electronic records are not only cost-effective. They can save lives - by helping doctors make quicker and better-informed decisions, by helping to prevent dangerous drug interactions, by giving patients in rural areas the benefit of specialist care hundreds of miles away.

But as Sec. Shalala has just said, our electronic medical records are not protected under federal law. And the American people are worried. Two thirds of adults say that they do not trust that their medical records will be kept safe.

They have good reason to be concerned. Today, with the click of a mouse, personal health information can easily - and legally - be passed around without patients' consent ... to people who are not doctors ... for reasons that have nothing to do with patient care. A recent

survey showed that more than a third of all Fortune 500 companies check medical records before they hire or promote. One large employer in Pennsylvania had no trouble obtaining detailed information on the prescription drugs taken by its workers - easily discovering that an employee was HIV positive.

This is outrageous. Americans should never have to worry that their employers are looking at the medications they take or the ailments they've had. In 1999, Americans should never have to worry about the nightmare scenarios depicted in the book *1984*. I am determined to put an end to these violations of privacy. That is why I am honoring my State of the Union pledge and using the full authority of this office to create the first comprehensive national standards for protection of medical records.

The new standards I am proposing would apply to all electronic medical records - and to all health plans. They would greatly limit the release of private health information without consent. They would require health plans to inform patients about how medical information is used and to whom it is disclosed. They would give patients the right to see their own health files and request corrections. They would require health plans and providers to strengthen internal safeguards. They would create new criminal and civil penalties for improper use or disclosure of information. These standards represent an unprecedented step toward putting Americans back in control of their own medical records.

These standards were developed by Sec. Shalala and the Department of Health and Human Services. And over the next 60 days, HHS will take comment from the public before we put the final standards into effect. On behalf of America's families, I want to thank Sec. Shalala for her tireless work.

The reason I am taking executive action today is because, quite simply, the Congress failed to live up to its responsibility to act. On this crucial issue, as with so many others, the leadership of Congress has let the American people down. Member of Congress gave themselves three years to pass meaningful privacy protections - and gave our Administration authority to act if they did not. Two months ago, their deadline expired. After three full years, Congress was unable to pass a bill in either chamber.

But even as we put forward our plan today, there are still some protections that we can give our families only with the help of Congress. For example, only through legislation can we cover all paper records and all employers. So today, I say to the Congressional leaders: America's families are still waiting for you to help protect them from new abuses. You owe the American people the peace of mind of a comprehensive medical privacy law. Let's do this together. Let's make this a season of progress - and protection - for America's families.

# # #

Message Sent To:_____

Devorah R. Adler/OPD/EOP@EOP
Christopher C. Jennings/OPD/EOP@EOP
Sally Katzen/OMB/EOP@EOP
Peter P. Swire/OMB/EOP@EOP
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Michele Ballantyne/WHO/EOP@EOP
Terry Edmonds/WHO/EOP@EOP
Joshua S. Gottheimer/WHO/EOP@EOP
Loretta M. Ucelli/WHO/EOP@EOP

final DES remarks

I'm pleased to welcome all of you.

We've worked very hard to do what common sense – and common decency – says should have been done long ago.

That is to come up with reasonable rules for protecting the privacy of our health records.

I've spoken about this issue many times, and I usually bring my Blockbuster video card with me.

I hold it up and say: If you like watching a good Muppet movie, the federal government protects your right to keep that information private.

But if you have a history of breast cancer in your family, or if you've been prescribed anti-depressants; . . .

. . . there is no federal law telling health care professionals and payers what they can – and cannot – do with that information.

But thanks to the President's leadership – that changes today.

Imagine Derek Jeter of the Yankees refusing to go up to bat – and expecting his teammates to do all the work. Well that's about Congress has done.

But not the President.

He understands that Americans deserve health care that is real.

That is affordable.

That offers choices.

And that is there when you need it.

And he understands that this issue is important to every American.

That's why today's announcement builds on the President's solid record of protecting the health of American families, . . .

. . . by fighting for a Patient's Bill of Rights, . . .

. . . by fighting for children's health insurance.

. . . by fighting to expand biomedical research, . . .

. . .and by fighting for health care privacy.

Now, I'm very proud to introduce the President of the United States.

President Clinton . . .

THE WALL STREET JOURNAL INTERACTIVE EDITION
FROM THE ARCHIVES

PRINT

October 29, 1999

Clinton to Propose Protections For Medical-Records Privacy

By SHAILAGH MURRAY
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON -- President Clinton Friday will propose regulations to protect the **privacy** of medical records, a long-awaited move meant to restrict access to what can be the most intimate details of life.

The regulations would represent the first national standards for medical **privacy**, and while their scope is limited by statute, they provide far greater protections than the patchwork of existing state laws. If the rules are enacted, as expected, in February 2002, people will be able to see their medical records, correct mistakes and limit the use and further disclosure of information by their health plan or insurer.

"These proposed standards are an important step forward in protecting the **privacy** of some of our most personal information," Health and Human Services Secretary Donna Shalala said in remarks prepared for delivery this morning.

Entities covered under the proposed regulations are health plans, insurance companies, health-care clearinghouses, and, to a limited degree, employers who offer self-funded plans. The protections would extend to all documents that are or ever have been transmitted electronically. Information could be used without authorization only for payment, treatment or minor administrative activities.

Health plans and insurers would be compelled to notify patients of how their records will be used, and would be required to draw the minimum data necessary for whatever task they are performing --

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Corrections

disclosing, for example, a single test result as opposed to an entire patient history.

But there are significant gaps in the regulations. They don't cover paper records that have never been electronically transmitted. Nor do they restrict lawyers, auditors, consultants, third-party administrators and the legions of other individuals who come into contact with medical information. However, they do bar the disclosure of diagnostic and treatment information to banks or credit-card companies as part of the payment process, a major concern due to the credit-rating implications. Insurance and health plans are meant to require business partners to abide by the regulations, although these third parties aren't directly covered.

The regulations don't provide much enforcement teeth: Civil penalties are capped at $25,000 a person, a year, although criminal charges can be brought if protected information is intentionally abused.

On the thorny issue of law-enforcement access, the administration has retreated from its earlier proposal, which was to preserve the status quo of unfettered access by local, state and federal agents. Now, an officer would have to seek the minimum of an administrative subpoena, which is issued internally by law-enforcement agencies. **Privacy** advocates had hoped for a warrant requirement, forcing agents to take their requests before a judge. Under the regulations, officers can seek a warrant, but they don't have to.

"Faced with a Chinese menu of options," says Janlori Goldman of Georgetown University's Health **Privacy** Project, "why wouldn't they go for the easiest thing?"

Ms. Goldman hopes to see the standard tightened in the final regulations, which must be issued by Feb. 21. In the meantime, the public and all interested parties will have a chance to comment. HHS officials are certain to hear an earful from health plans and insurers, which have expressed concerns about added costs.

Congress has tried for two years to pass a medical-privacy law but failed to meet its own deadline of Aug. 21. That compelled HHS to act, if only in this limited fashion. The move Friday "really does not allow the level of **privacy** protection we would all like," an administration official conceded, adding that he hoped Congress would eventually pass a more comprehensive law.

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CHRIS JENNINGS' SCHEDULE

8:15 White House Mess
Sally Katzen, Gary Claxton

8:30 Briefing in Oval
Medical Records Privacy

8:45 Departure Statement
Oval

9:05 Press Briefing on Privacy
Briefing Room

11:00 Meeting with Bruce and Sarah
Prescription Drugs

11:00 Meeting with ADA
John Podesta, Dan Mendelson
John's office

12:30 Lunch with Teresa

October 29, 1999

Clinton Proposing Medical Privacy

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 1:32 a.m. EDT

By The Associated Press

WASHINGTON (AP) -- Picking up where Congress failed, President Clinton is proposing regulations to keep electronic medical records from the prying eyes of employers, marketing firms and others who often see patients' most sensitive information without their consent.

``I will use the full authority of this office to create the first comprehensive national standards for the protection of medical records,'' Clinton said in a prepared statement.

``The new rules I'm proposing would apply to all electronic medical records and to all health plans. It represents an unprecedented step toward putting Americans back in control of their own medical records,'' the president said in advance of a formal announcement scheduled for today.

The proposed regulations, administration officials said, would restrict the use and release of private health information transmitted or maintained by computers. Congress debated the issue for years, but failed to meet a self-imposed Aug. 21 deadline for legislating new protections.

Existing laws protecting medical privacy vary widely from state to state. Currently, there are no federal guarantees that private information won't be passed to employers, sold to pharmaceutical companies or talked about in insurance company offices.

The administration will publish the proposal next week for review. It has until February 2000 to issue a final proposal, with the rules to take effect in 2002.

The new federal rules would go beyond the weaker protections of some states, but would not override those with more restrictive laws.

The rules would apply only to electronic information, including computer records that have been copied to paper.

Only congressional action can protect the large amount of medical information that has existed only on paper, said Sen. Christopher Dodd, D-Conn., who wrote a bipartisan privacy bill before the August deadline.

``I can only hope that the administration's action will light a fire under Congress, so that we can deal with this critically important issue in a serious, bipartisan and comprehensive way,'' he said in a prepared statement.

Under the proposal, doctors, hospitals or health plans would not release a patient's information for purposes unrelated to treatment and payment without written consent. Private information can now be released to financial institutions, direct marketing firms and others without a patient's knowledge or consent.

When required to release medical information, health organizations would have to limit the disclosure to the minimum necessary for each case instead of a patient's entire record. For example, when paying for medical services, no treatment information would be sent to banks or credit card companies.

The proposal would create new civil and criminal penalties for improperly disclosing patient information. Intentionally releasing information would be punishable by a fine of up to $50,000 and one year in jail. Someone trying to sell information could face a $250,000 fine and 10 years in prison.

Patients also would be given the right to see and copy their medical records and to request corrections of any errors.

Under the new rules, law enforcement organizations would be prohibited from obtaining medical records without legal authorization like a warrant or court order. This retreats from the administration's previous position of allowing law enforcement unfettered access to health records.

The plan would require health care providers to send patients a notice describing how they use electronic medical information and advise patients in advance of any changes.

Health maintenance organizations would also have to establish internal procedures to protect patient records, including limiting access to information and training employees to keep patient information private during their routine operations.

Regarding teen-agers who seek medical care on their own, the plan follows the lead of existing state laws. When a state allows a minor to obtain health care without notifying a parent or getting their consent, the minor's rights would be protected under the proposed plan. If a state requires a parent to be involved, then the privacy rights would apply to the parent, not the minor.

During congressional debate, Democrats led by Massachusetts Sen.

Edward Kennedy pushed to allow teens to keep their records private, even from their parents and even when it involves abortion.

After Congress failed to meet the Aug. 21 deadline it set three years earlier, the 1996 law required the Department of Health and Human Services to write regulations on medical privacy.

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Friday, October 29, 1999 | Print this story

Clinton to Seek Rules on Medical Record Privacy

Health: Regulations would limit sharing of electronic information. The patient's consent would be required.

By ALISSA J. RUBIN, Times Staff Writer

WASHINGTON--President Clinton today will propose far-reaching regulations that place strict limits on the dissemination and use of consumers' medical records.

The proposed regulations would be the first federal standards designed to protect individuals' health information. The rules would cover electronic records held by doctors, hospitals, pharmacies and managed care organizations, among others, and would require a patient's consent before information could be released, and then only for purposes related to treatment and payment.

"I will use the full authority of this office to create the first comprehensive national standards for protection of medical records," Clinton said in a text prepared for delivery today. "The new rule . . . represents an unprecedented step toward putting Americans back in control of their own medical records."

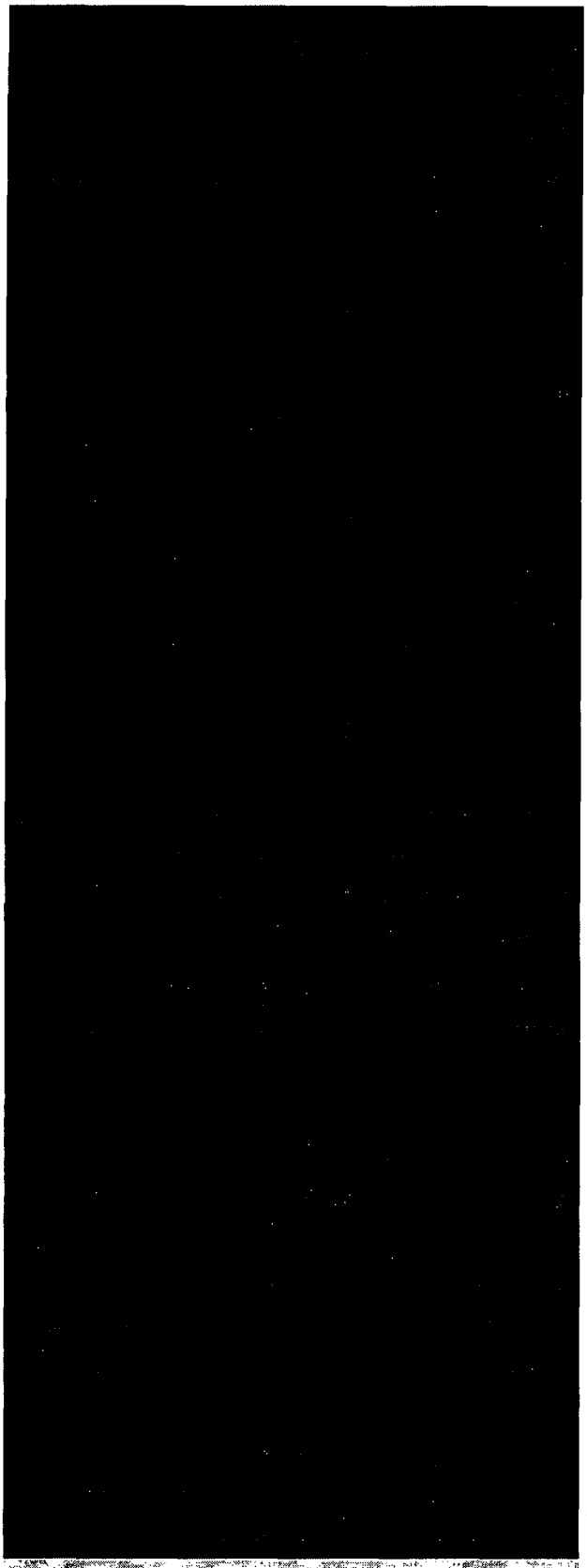
The need for such rules stems from the technological revolution in the health care system, which has resulted in the sharing by doctors, pharmacies and hospitals of an ever-increasing amount of electronic information. The sharing has been done in part to meet demands of insurers and managed care organizations for more information before they will pay claims.

Consumers rarely know when their medical records have been shared. In surveys, 20% of consumers reported that their medical records were disclosed inappropriately, and half of those said their cases resulted in harm or embarrassment, according to administration officials. Health care privacy laws in the states are a patchwork, with some states, including California, having strong protections, especially for information related to sexually transmitted diseases and psychiatric care. But few states have broad rules to protect all health information and not all states enforce their laws.

Under the proposed regulations, insurers, billing companies and health care providers would be permitted to share medical records only for treatment, payment or health care operations such as quality assurance. That means records could not be sold or shared with consultants or others except for those purposes.

Currently, for instance, when a consumer uses a credit card to pay a medical bill, the company issuing the card can give the information legally to a bank considering whether to grant the consumer a loan. Similarly, individual health information can be released to firms marketing drugs or medical devices and for a host of other purposes unrelated to the individual's medical treatment or payment.

Under the new rules, consumers would have to be notified by their health providers about how medical information would be used and to whom it would be released. If the provider or insurer wanted to release information for purposes other than



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treatment or payment, they would have to obtain consumers' permission. Consumers would have the right to request histories of information disclosed.

And for the first time, consumers would have an explicit right to examine their medical files, copy them and request additions or corrections.

A 1996 law required the administration to issue the new rules, since Congress had failed to pass legislation on the subject.

The final regulations will be published in February and health care providers and managed care organizations would have two years to comply.

Under the 1996 law, the new rules cannot cover records kept on paper. While the number of computer records grows daily, most records are still on paper. The balance is expected to change within a couple of years.

The administration appears to have made the rules as broad as possible. They would apply to "any information that is maintained or transmitted electronically, even if subsequently it is stored on paper," said an administration official.

The 1996 law made no mention of the many intermediaries used by providers and insurers, such as lawyers and consultants. To reach those players, the administration has proposed requiring that providers and insurers have contractual agreements with their partners to limit disclosure to treatment, payment or operations--the same ground rules that must be followed by the providers themselves.

For providers, insurers and claims managers, the regulations set out an array of stringent new rules for handling consumers' health care data, which providers predict will add billions of dollars to the cost of health care. A recent study by the Blue Cross and Blue Shield Assn. found that similar confidentiality requirements would add $43 billion to health care bills over the next five years.

"We don't think anybody looked at potential expenses or interference with physician communication," said Bill Pierce, a spokesman for the Blue Cross and Blue Shield Assn., adding that the group strongly supports the confidentiality of records.

A core tenet of the proposed regulations is that providers and insurers may release only the minimum amount of information necessary for claims payment and treatment. Currently, for instance, an employer requesting information from a provider because of a work-related injury might be sent the worker's entire medical record, an administration official said. That would no longer be possible under the proposal.

A 1996 survey by researchers at the University of Illinois found that 35% of Fortune 500 companies used individual medical information to make job-related decisions.

To ensure that the strict limits are followed, health plans and providers would have to put in place internal controls, including training employees about medical confidentiality and designating an employee to act as privacy point person, charged with monitoring and setting up privacy and confidentiality protocols.

"The privacy of Americans is protected in their bank transactions, their credit card statements and even their video rentals," according to remarks prepared for delivery today by Donna Shalala, secretary of Health and Human Services, the lead agency overseeing the regulations.

"These proposed standards are an important step forward in protecting the privacy of some of our most personal information," the statement said.

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President to Detai lPatient Privacy Rules

Policy Restricts Who Can Access Online Records

By Amy Goldstein
Washington Post Staff Writer
Friday, October 29, 1999; Page A01

President Clinton today will unveil the first federal protections to safeguard the confidentiality of Americans' medical records, restricting the conditions under which doctors, hospitals and health plans can divulge patients' medical information without their consent.

Under broad new rules the administration has worked on for years, the federal government would ensure patients the right to peer into their own medical records, determine who else has looked at them and pursue criminal action against anyone who misuses their medical history.

Unless people give permission for other uses, the policy allows health care records to be shared primarily to help treat patients and pay their medical bills, and is designed to prevent the release of such sensitive information to marketing firms, financial institutions and an individual's employer. It also would permit the release of information for activities that promote the public's health and for a somewhat vague category allowing their disclosure if a health care organization deemed it necessary for "business operations."

The policy is emerging at a time when the proliferation of electronic records has allowed medical information to be used in ways that would have been unimaginable even a few years ago, provoking widespread public anxiety about the security of information that once remained a secret between patients and their personal doctors. Companies that manage pharmacy benefits, for example, routinely inspect what drugs patients take and call their doctors to recommend alternatives.

The rules that Clinton will put forth mark the first time the government has developed a concrete standard after a lengthy tug of war between the administration and Capitol Hill over how far the federal government should reach in reining in the use of medical records. Mindful of the promise and peril of the new era of medical information, Congress three years ago gave the administration the power to develop a policy, unless lawmakers passed a medical privacy law by August 1999. Congress missed its self-imposed deadline.

The protections the president will announce at a White House ceremony this morning come in the form of proposed regulations that will become law in February and will be enforced starting in 2002. The rules could be modified before becoming final, depending on the

comments that pour in during the next two months, but they do not require congressional approval.

On Capitol Hill, lawmakers proved unable to thread their way between lobbyists for greater medical privacy, on the one hand, and much of the medical industry, on the other. The industry has argued that restricting the use of records would be counterproductive, raising health care costs while thwarting the research that will bring about effective new treatments. The approach the administration will lay out today largely, but not entirely, sides with the privacy advocates.

In remarks prepared for this morning's ceremony, Clinton calls the strategy "an unprecedented step toward putting Americans back in control of their own medical records."

But administration officials, speaking on background yesterday, emphasized that they were frustrated because the 1996 law, which cleared the way for the administration's regulation, contained several significant restrictions on how far it could go. As a result, Clinton aides said they would prefer that Congress adopt a privacy law to address the areas that these regulations cannot.

The 1996 law, for example, allows the administration to regulate only electronic records, even though the majority of medical information remains in paper form, for now. The rules can apply to health insurers and providers of health care, but not to pharmaceutical companies and a variety of outside business that help process medical claims. And while permitting civil and criminal penalties for confidentiality violations, the administration cannot give individuals the power to file their own lawsuits against those who breach their privacy.

At a time when a growing number of states have adopted their own medical privacy laws, the regulation is intended as a minimum national standard, overriding weaker state statutes but not interfering with states that have taken a more aggressive approach.

The new federal rules say that medical information should be released, whenever possible, without patients' names attached and only in the smallest amounts needed for a specific purpose. White House documents say, for example, that an employer who needs to process an insurance claim for a work-related injury should not be given a patient's entire health record.

Similarly, unless patients give permission, all health care researchers who want access to identifiable information will have to go through an approval process similar to one that exists for federally funded research. And in a reversal of the administration's stance two years ago, law enforcement officials who want access to records will have to get permission first from a judge or administrative hearing office.

For the first time, patients would get a guarantee--currently available only in certain parts of the country--that they could inspect their own medical records and demand that mistakes be corrected. Health plans and those who provide care will have to tell patients what their policy is for disclosing medical information and, if patients ask, will be required to give them a list of every organization that has gotten their medical information.

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The new regulation that President Clinton and HHS Secretary Shalala are announcing today would apply to all health plans and many health care providers, as well as to health care clearinghouses such as billing companies. It would: 1) limit the non-consensual use and release of private health information; 2) inform consumers about their right to access their records and to know who else has accessed them; 3) restrict the disclosure of protected health information to the minimum necessary; 4) establish new disclosure requirements for researchers and others seeking access to health records; and 5) establish new criminal and civil sanctions for the improper use or disclosure of such information.

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- **Limit the release of private health information without consent.** This rule would establish a new Federal requirement that doctors, hospitals, health plans, and other covered entities could not -- without a patient's written consent -- release identifiable health information for purposes unrelated to treatment, payment for services, or priorities like public health. Under the current regime, such data is often released to marketing firms, financial institutions, and employers, without knowledge or consent, and is then

used in direct marketing campaigns, in loan eligibility decisions, and for promotion and other purposes. In fact, a recent University of Illinois survey indicated that 35 percent of Fortune 500 companies check health records before they hire or promote.

- **Inform consumers how their health information is being used.** This new regulation will require health plans and providers to publish a notice to patients about how their information is being used and to whom it is being disclosed. It will also give each individual patient a right to a "disclosure history," listing the entities that have received information for purposes unrelated to treatment or payment.

- **Give patients access to their own health file and the right to request amendments or make corrections.** The regulation will give patients the right to see and copy their own records as well as the right to request correction of potentially harmful errors in their health files. These access and amendment rights are a core part of any regime to protect individual privacy. Without them, a person with an improper diagnosis in his or her medical file or payment record could be denied health insurance and left no redress.

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- **Restrict the amount of information used and disclosed to the "minimum necessary."** Currently, health care providers and plans can often release a patient's entire health record even if an employer or other entity needs only particular information. This new regulation would restrict the information that is used and disclosed to the minimum amount of information necessary.

ENSURE THE SECURITY OF PERSONAL HEALTH INFORMATION

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- **Require that information be disclosed only for research conducted responsibly.** Since health care research is an important public priority, under this rule researchers may obtain identifiable health information without prior consent if they certify to a provider or plan that an "institutional review board" or "privacy board" has reviewed the research protocol and determined that the research would meet certain privacy protection criteria.

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- **Create new criminal and civil penalties for improper use or disclosure of information.** Currently, there is often no legal basis to prosecute individuals who inappropriately disclose private medical information. This rule creates new criminal penalties for intentional disclosure -- up to $50,000 and up to a year in prison. Disclosure with an intent to *sell* the data will be punishable with a fine of up to $250,000 and up to 10 years in prison. The regulation also establishes new civil penalties of $100 per person for unintentional disclosures and other violations (up to $25,000 per person per year).

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