Testimony of Dr. John D. Clough
on behalf of the Cleveland Clinic Foundation

Before the Senate Committee on Health, Education, Labor and Pensions Hearing on Medical Privacy

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Good morning. I am Dr. John D. Clough, Director of Health Affairs for the Cleveland Clinic Foundation. I am also a practicing rheumatologist.

The Cleveland Clinic Foundation strongly supports meaningful federal privacy protections for identifiable patient information. The privacy rule is intended to give patients the first-ever federal protection of their identifiable health information. We believe the recently proposed modifications would make major and necessary improvements to the final rule that will help achieve privacy goals without erecting barriers to high quality and timely health care for patients.

What has been missed in much of the reporting and debate about the modifications is that they retain, and actually strengthen, the most important new protections for patients. For the first time, federal standards prohibit the use and disclosure of patient information for purposes other than treatment, payment, and health care operations without patient authorization. Thus, disclosing a patient's name and diagnosis to a newspaper, a bank, an employer, a marketer, without the prior, specific, written authorization of the patient is prohibited. The rule also gives patients new rights under federal law to receive notice of their rights, to be informed as to how their information can and cannot be used, and to access their own medical record.

In spite of the fact that the proposed modifications keep intact these protections and actually strengthened many of them, virtually all of the attention of late has focused on the "prior consent" requirement. This morning I will focus on the modification to the consent provision, as well as an important modification that the Department is considering with respect to how patient information is "de-identified."

Consent

We strongly support the proposed modification which would make it optional, rather than required, for providers to obtained a signed, written consent form before using or disclosing identifiable information for treatment, payment, and health care operations.

First: This modification would remove barriers to timely patient access to care created by the requirement in the final rule, while retaining and even strengthening strong patient privacy protections.

The following are a few of the many examples from the Cleveland Clinic's vantage point of how the requirement, without the proposed modifications, would create significant barriers to patient access to care.

- The Cleveland Clinic and other hospitals routinely receive information about a patient from referring physicians and use this information to schedule and prepare for procedures prior to the patient presenting themselves at the hospital. Prior consent would have to be obtained before any use of the patient's information for treatment. Thus, we could not use information to schedule

procedures or begin intake procedures until we had such consents.

- This would be problem enough for the Cleveland Clinic, where 1.6 million visits are on an outpatient basis each year. But, the disruption and delay for patients should be viewed in the totality of their care from beginning to end.

- For the patient, the consent requirement would mean multiple trips to sign a new consent form before receiving care at every point. It would mean signing one consent form before visiting their physician, another before referral to a specialist, another before getting an MRI, one more before scheduling surgery at the hospital, another for the ambulance ride to the nursing home, another before sending someone to pick up a prescription, and on and on.

- Other inevitable problems included patients being unable to discuss their care over the telephone with physicians, nurses and others covering for their colleagues during non-business hours because these providers may not have a signed consent form. Also, nurses staffing telephone call centers would be prohibited from advising patients in many cases because there is not opportunity to obtain prior written consent from the patient.

The proposed modification eliminates these barriers to care without eliminating privacy protections. It is the *written notice*, not the consent form, that is the means by which patients are informed of their rights and how and with whom their information may and may not be used. The modification retains and strengthens the notice requirement in the final rule by requiring that providers give patients the notice and obtain an acknowledgment that the patient has received it.

Second: The suggestion by some that the Department make exceptions for every problem that arises as a result of the consent requirement, as opposed to fixing the underlying problem, is unworkable.

The Department cannot possibly anticipate every problem that could arise, as dozens have become apparent since issuance of the final rule a year and a half ago. More will arise after the rule takes effect. Because the Health Insurance Portability and Accountability Act (HIPAA) allows modifications to the privacy rule only once each year to address such problems, patients would have to suffer through disruptions and delays in care for over a year before such problems could be fixed.

Third: Some have claimed that many states already have similar consent requirements. In fact, today NO state has a similarly broad prohibition on use and disclosure of information for treatment, payment and health care operations without prior consent.

One state – Maine – did attempt such a broad prior consent requirement in 1999. The Maine law was suspended in an emergency session of the legislature after only 12 days

because of severe disruptions in patient care.

Fourth: The modification making consent optional is a workable *compromise* of two diametrically opposed approaches taken in the Clinton proposed regulation, and the Clinton final regulation.

In November 1999, the Clinton administration's proposed privacy regulation not only rejected the idea of mandating that providers obtain consent, it went so far as to *prohibit* them from obtaining it. In doing so, the Clinton administration argued that "(s)uch authorizations could not provide meaningful privacy protections or individual control and could in fact cultivate in individuals erroneous understandings of their rights and protections." In addition, they maintained that separate authorization for routine referrals "could impair care.

Many physician and other groups objected to the prohibition on obtaining consent. In response, the administration went to the other extreme and mandated prior consent in the final rule. The recently-announced modifications strike the right balance between these two extremes. Providers may obtain consent if they wish to do so. However, a provider will not have to delay treatment.

Fifth: Even advocates for the most stringent privacy regulations testified last year that the prior consent requirement was "meaningless" and "coerced" because if the patient refused to sign the consent, the provider could deny treatment. If the patient refuses to sign, there are many situations in which laws, regulations, practice guidelines, and our code of ethics requires physicians to treat the patient. The physician following the code of ethics would then be in violation of the privacy regulation and subject to civil and even criminal penalties.

Sixth: Various press articles have suggested that physicians do not support the modification to the consent provision. It is important for members of Congress to know that many, if not most, physician organizations support the modification. In an April 10 letter to Congress which is attached to my statement, organizations representing family physicians, surgeons, cardiologists, OB/GYNs, and others -- over 400,000 physicians in all -- expressed support for making consent optional.

Research and "De-identification" of Patient Information

The modifications proposed by the Department with respect to research make several key improvements that will eliminate unnecessary barriers to the conduct of life-saving research, while maintaining important protections for patient confidentiality. In particular, the modifications simplify, for patients and researchers, the procedures and paperwork involved.

However, one additional revision to the privacy regulation is needed. We believe the regulations should permit a limited set of data which has been "facially de-identified" to

be disclosed for research purposes. The Department is considering such a revision, but has invited further comment before making a final decision to make the change.

The stringency of the final rule's requirements for de-identifying information prompts concerns that the standard would render data useless for much research. Under the final rule, some 18 characteristics would need to be removed from data to render it "de-identified." Most of the characteristics make sense, such as names and addresses, which could directly identify an individual. However, some do not. For example, zip codes, admission and discharge dates, date of death, and age do not directly identify an individual. However, such information is often critical to conducting research. Epidemiological studies routinely use hospital admission and discharge dates, date of death to track and understand diseases. Such studies have taken on new importance with the threat of bioterrorism. Hospitals need to be able to share de-identified information for such purposes, as well as for improving the quality of care for patients, and improving community health services. Under the final rule, sharing this information is not permitted.

There may be no other issue that has so united those in health care; the change is supported by virtually every corner of the health care community. This includes groups ranging from the Association of American Medical Colleges, the American Medical Association, state hospital associations, patient and consumer groups. Attached to my statement are two letters from these groups.

Mr. Chairman, that concludes my statement. Thank you, again, for giving me this opportunity to testify this morning. I will be happy to answer your questions.