

MEMO

To: Interested Parties

From: Jim Pyles

Date: April 4, 2003

Re: Lawsuit to Enjoin Elimination of Right of Consent

This is to provide a brief summary of the lawsuit we have been developing to enjoin elimination of the right of consent for the use and disclosure of health information under the Health Information Privacy Rule which has a final compliance date of April 14, 2003. 67 Fed. Reg. 53,182 (August 14, 2002)

The suit will seek to invalidate and enjoin the amendments to the Health Information Privacy Rule issued on August 14, 2002 that repealed the provisions in the original Privacy Rule that guaranteed all Americans the right to not have their identifiable health information used or disclosed for routine purposes (treatment, payment or health care operations) without their consent.

The grounds for the relief will be as follows:

1. HHS violated the rulemaking requirements of the **Administrative Procedure Act** by failing to provide an adequate basis for reversing their original interpretation of HIPAA that the right of consent is essential for medical privacy and quality health care.
2. HHS exceeded that authority granted by Congress under **HIPAA** to set forth the privacy rights that individuals should have with respect to their identifiable health information when HHS granted blanket "regulatory permission" to thousands of covered entities and their business associates to use and disclose that information without consent and regardless of the individual's wishes.
3. HHS violated the intent of Congress under **HIPAA** to provide greater privacy protections as it was facilitating the computerization of medical records. The Privacy Rule provides for the widespread use and disclosure of identifiable health information but the Security Standards necessary to protect the privacy of this information in the hands of covered entities do not go into effect for two years and the Enforcement regulations necessary to ensure compliance with HIPAA standards have not even been proposed.
4. HHS has violated the right to privacy of personal information under the **Fifth Amendment to the U.S. Constitution** by depriving individuals of the power to exercise their privacy rights with respect to their health information and by granting "regulatory permission" for third parties to use and disclose that information against the individuals' wishes. The violation

of the right to medical privacy is further evident by HHS' failure to require adequate security measures to be in place before the disclosures authorized under the Privacy Rule occur.

5. HHS has violated the right to private conversation protected under the First Amendment to the U.S. Constitution (the right to not speak publicly). The amended Privacy Rule authorizes the disclosure of information that is the subject of private conversations between patients and practitioners which is likely to have a "chilling" effect on the physician-patient and therapist-patient relationship.

We anticipate that the complaint will be filed in Federal District Court for the District of Columbia or Federal District Court for the Eastern District of Pennsylvania.

The reasons why the lawsuit should be filed:

1. Recognition of a right to medical privacy at either the federal or state level depends on whether individuals have a "reasonable expectation" of privacy. If health information can be used and disclosed without consent and over the individual's objections, even purely as a matter of federal policy, a right of medical privacy is unlikely to be recognized at any level.
2. States are likely to begin to conform their statutory health privacy laws to the federal law with the support of providers who will subscribe to the short sighted view that this will ease their administrative burdens.
3. We have sought to have legislation introduced to restore the right of consent, and it appears that two such bipartisan bills will be introduced soon. It is doubtful, however, that these bills could be enacted into law soon enough prevent serious damage to the public's right to privacy and trust in the health delivery system.
4. A challenge to the rulemaking process that led to HHS' adoption of the amended Rule limits the court's review to the rulemaking record which contains extensive findings that "privacy is a fundamental right" and is "necessary to secure effective, high quality health care". The record also shows that HHS failed to address any of these findings in reversing its position.
5. Each day that these regulations are in effect the privacy of identifiable health information is being lost. While the Privacy Rule contains special protections for "psychotherapy notes", those protections are uncertain and vague. The interpretation of the "minimum necessary" limitation on the use and disclosure of mental health information under the Rule varies so broadly as to cast serious doubt on its effectiveness.
6. The Privacy Rule applies retroactively to permit the use and disclosure of health information for patients even though they have not sought further health services, so it is unclear that practitioners would have the opportunity to protect the privacy of their patients' health information even if they were so inclined.

It has been said that the right to privacy is “the right to be let alone”. That right is clearly jeopardized by the Privacy Rule.

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