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March 10, 2014 Via upload to regulations.gov

The Honorable Kathleen Sebelius, Secretary U.S. Department of Health and Human Services Attn: HIPAA Privacy Rule and NICS Hubert H. Humphrey Building 200 Independence Avenue, S.W., Room 509F Washington, D.C. 20201

Comments on Notice of Proposed Rulemaking on Health Subject:

Insurance Portability and Accountability Act (HIPAA) Privacy Rule

and the National Instant Criminal Background Check System

(NICS), 79 Fed. Reg. 784 (Jan. 7, 2014)

Dear Secretary Sebelius:

These comments are submitted in response to the above-referenced Department of Health and Human Services' Notice of Proposed Rulemaking of changes to the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule related to the operation of the National Instant Criminal Background Check System ("NICS").

HIPAA and the HIPAA Privacy Rule

The HIPAA Privacy Rule was promulgated to implement certain requirements of HIPAA, which was enacted in 1996. Pub. L. No. 104-191. The purpose of HIPAA and the HIPAA Privacy Rule was to have a uniform national system that restricted disclosure of individuals' health information to only what the individual authorized, or what was expressly authorized by law.

Indeed, one of the primary goals of the Privacy Rule was "to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being." See Summary of the HIPAA Privacy Rule.1

Supposedly, "[a] covered entity (generally, a health care provider) may not use or disclose protected health information, except either: (1) as the Privacy Rule permits or requires; or (2) as the individual who is the subject of the information ... authorizes in writing." *Id.* However, it now appears that virtually any use that the government desires has been either "permitted" or "required" by Regulation. What was intended to be a law **protecting** individual healthcare information has, by virtue of HHS regulations, been perverted to becoming a law **broadly authorizing disclosure of private healthcare information** -- primarily to the government -- without the patient's permission.

Even without this latest category of authorized disclosures, there exists an impressive list of exclusions from the HIPAA Privacy Rule. Indeed, it is difficult to assemble a comprehensive list of exemptions, as the exclusions appear to have swallowed up the Rule. *See* Summary of the Privacy Rule, pp. 6-9. Some of the exclusions are:

- Treatment, payment, health care operations
- Incidental Use and Disclosure
- 12 exemptions against non-disclosure that are related to what are collectively called "national priority purposes"
- Public Health Activities
- Victims of Abuse, Neglect or Domestic Violence
- Health Oversight Activities
- Judicial and Administrative Proceedings
- Law Enforcement Purposes --- including administrative subpoenas issued by a bureaucrat, and many requests for information by individual law enforcement personnel
- Serious Threat to Health or Safety
- Essential Government Functions --- including the proper execution of a military mission, conducting intelligence and national security activities, and providing protective services to the President
- Compliance with Workers' Compensation Law

By at least one report, enforcement of the Privacy Rule appears not to have been a priority to HHS, since in the first three years after its issuance, the federal government had not imposed a single civil fine, and had prosecuted just two criminal cases.²

² http://www.washingtonpost.com/wpyn/content/article/2006/06/04/AR2006060400672.html.

Moreover, health care providers generally require broad HIPAA waivers be signed by patients prior to treatment, allowing the disclosure of their records to persons of the health care provider's choosing. Failure to sign these broad waivers will generally result in a health care provider refusing to provide necessary treatment.

For all these reasons, what Congress supposedly enacted to protect privacy has come, perversely, to strip away from the American people such privacy as they may once have had. Certainly there is no privacy from confiscation of the most sensitive personal information which a person owns by the federal government, and very little privacy from State and local government and even many private parties.

When all the exemptions are fully understood, it seems that the only effect of the HIPAA Privacy Rule will be to prevent a patient's file being placed in a holder outside a treatment room, waiting for the physician to review it as he meets with a patient. This is not what Congress led the American people to believe was the purpose of HIPAA.

Proposed HHS Rules

The proposed regulations broaden even further the types of personal, private, sensitive, medical information which may be disclosed by health care providers to the federal government.

Federal law precludes individuals who have been "adjudicated as a mental defective or who has been committed to a mental institution" from owning or possessing a firearm. See 18 U.S.C. § 922(g)(4). In its regulations, the U.S. Department of Justice and ATF have expanded unreasonably that statutory definition, and now in a rulemaking concurrent with the instant HHS rulemaking, are seeking to expand it even further to include all manner of psychological conditions, however minor or temporary. 79 Fed. Reg. 774 (Jan. 7, 2014). Now, HHS is attempting to modify its regulations to facilitate ATF's unauthorized, overreaching regulation.

The NPRM acknowledges that, with respect to involuntary commitment or mental health adjudications that originate with a State entity, "there are ways in which the Privacy Rule permits the reporting to the NICS." 79 Fed. Reg. 787. However, it speculates that "concerns have been raised that the HIPAA Privacy Rule's restrictions on covered entities' disclosures of protected health information may be preventing certain States from reporting the relevant information to the NICS." *Id*.

HIPAA applies primarily to health care providers, not to the States. Currently, the States have the authority to decide what to report, or not report, to the NICS system. Insofar as the current rulemaking applies to the States, it is premised on the false notion that the States are not reporting to the NICS system due to HIPAA concerns. Insofar as the current rulemaking applies to entities other than the States, the purpose of the present rulemaking is to bypass the decisions of the States, and allow covered entities to report such actions to the NICS. It should be clear that HHS' assertion that "the rule would not have Federalism implications" is bogus. 79 Fed. Reg. 795.

Adverse Effect on Veterans

The HHS proposed regulations are likely to have an adverse effect on veterans. It has been widely reported that veterans who may need help filling out complicated benefits paperwork are being administratively categorized (not "adjudicated" as required by statute) by unqualified persons wholly without due process of law. They are being placed on the NICS list, unconstitutionally depriving them of their Second Amendment rights.

2The Veterans Administration apparently considers a veteran who has been issued a fully automatic weapon to help defend the country against overseas threats, but who needs help to navigate its considerable bureaucracy, to be mentally incompetent and disqualified from owning a semi-automatic weapon upon his return to this country. Such classifications are insufficient as a matter of law because they do not constitute a finding, and are not based on findings, that meet the statutory standard of "adjudicated as a mental defective or who has been committed to a mental institution." Once so categorized, the veteran must navigate yet another bureaucracy to undo the damage that its claims processors do, only to discover that there is there is essentially little veterans can do to regain their Second Amendment rights.

Being exposed to battle not infrequently has some psychological effect on a soldier, and if Americans knew that service in the military in combat would disqualify soldiers from owning a firearm for life, few if any would volunteer to serve in the nation's military. Therefore ATF, and now HHS, through these regulations, are working together to undermine the volunteer basis of America's Armed Forces.

Lack of Constitutional Authority of the Privacy Rule

The HIPAA Privacy Rule is not based on a legitimate Congressional exercise of Constitutional power under the Commerce Clause. Rather, the HIPAA Privacy Rule is the product of an unconstitutional delegation of Congressional power to tax and spend for the general welfare, giving *carte blanche* power to the executive branch.

Without any reference to the impact on interstate commerce, the HIPAA Privacy Rule applies "to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form," subject to the HHS Secretary's discretion to determine whether any person or entity is a "covered entity."

According to the text of HIPAA, it amended the Internal Revenue Code which requires the Secretary of HHS to publicize standards for the electronic exchange, privacy, and security of health information. HIPAA specifically required the Secretary to issue privacy regulations governing individually identifiable health information, if Congress did not enact privacy legislation within three years of the passage of HIPAA. Because Congress did not enact privacy legislation, HHS developed a proposed rule and released it for public comment on November 3, 1999. After receipt of over 52,000 public comments, HHS promulgated the final rule which was published on December 28, 2000. In 2002, HHS modified the rule by the same process.

By delegating such powers to the Secretary, Congress unconstitutionally bypassed both the bicameral and presentment principles set forth in Article I, Section 7 of the United States

Constitution that requires before a bill can become law, it be passed by both houses of Congress and signed by the President. Instead, the HIPAA Privacy Rule became law by the public notice and comment process provided by the Administrative Procedure Act. The privacy standards embodied in the HIPAA Privacy Rule, then, are made out of whole cloth by an unelected, bureaucratic, fourth branch of government, in violation of the Separation of Powers of a tripartite federal government, as provided in Articles I, II, and III of the United States Constitution.

Violation of Authorities Allowing States to Offer Greater Privacy Protections

Lastly, the HIPAA Privacy Rule being modified, the purpose of which is to protect the privacy of health information, is an unconstitutional usurpation of the power of the States over the health, safety, and welfare, a power reserved to the States by the Tenth Amendment.

Consistent with the Tenth Amendment, 45 C.F.R. §160.203 allows States to enact certain privacy rules that deviate from the HIPAA Privacy Rule, by offering their citizens greater protection of privacy. Yet, if State privacy laws conflict with federal law, State laws governing privacy in the health care arena are allegedly be preempted by the HHS-enacted rule. *See* Summary of the HIPAA Privacy Rule, *supra*, p. 17.

Conclusion

For the foregoing reasons, the U.S. Justice Foundation requests the Department to withdraw its proposed regulations.

Sincerely yours,

/s/

William J. Olson Legal Counsel