CITIZENS' COUNCIL FOR Health Freedom
SECURING HEALTH FREEDOM FOR ALL

July 7, 2017

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9928-NC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Responding to RFI for Reducing Regulatory Burdens of PPACA

Citizens' Council for Health Freedom, a national health freedom organization located in Minnesota, and the initiator of The Wedge of Health Freedom (jointhewedge.com) is responding to your request for information on reducing the regulatory burdens imposed by the PPACA and moving American medical care to a more patient-centered system that "adheres to the key principles of affordability, accessibility, quality, innovation, and empowerment." Our recommendations are based on five key elements of health freedom and five essential rights:

Five Elements of Health Freedom (CCHF "5C" Solution)

- Cash for Care – payment by cash, check or charge for routine and minor care
- Catastrophic Coverage – indemnity insurance for insurable events
- Charity – foundational ethic for the practice of medicine
- Confidentiality – patient consent for data-sharing required
- Compassionate Care – work for patients, not payers

Five Essential Rights of Health Freedom

- Right to Privacy (property right)
- Right to Real Insurance
- Right to Refuse Insurance and Medicare
- Right to Private Contracts
- Right to Be Charitable

Because many of the following 21 recommendations deal with patient privacy rights, please remember that freedom and privacy are inextricably linked together. There is no freedom in a system of surveillance. And as we often say, "He who holds the data makes the rules." Thus, we emphasize the importance of patient control, patient choice and patient privacy as we make the following recommendations:

1) **Expand Hardship Waivers to Every American.** Under Obamacare, HHS has authority to establish hardship waivers. The Obama administration granted the 14th hardship waiver but didn't announce it and made it contingent upon federal approval. The Trump administration should authorize every American to simply claim a hardship

waiver on their IRS tax form, and herald this option at every possible opportunity. Do not require any submission of any documentation and make the waiver automatic without any additional acceptance or approval. Give Americans an easy opt-out, and let them know it's available without penalty or condition.

2) **Let States and Individuals Determine Essential Health Benefits.** Under the ACA, HHS has the authority to determine "essential health benefits." Publish a federal rule authorizing states to determine the list of "essential health benefits" at the state level (and authorizing individuals to buy customized policy by choosing their own benefits). States may notify the federal government of their EHB list for federal publication. Make no conditions, and make it permanent for up to 10 years -- unless changed *by the state.*

3) **Alert Healthcare.gov Applicants to Federal Health Exchange Database.** Prior to being able to use Healthcare.gov (or any connected state exchange), a click-through window should notify potential enrollees that: 1) they are applying to the federal government for coverage, and 2) their information will be retained by the federal government in the Health Insurance Exchange Program database. Potential enrollees must be required to click "I agree" or "I understand" before proceeding to search for or apply for coverage. Today's exchange enrollees do not know these two facts.

4) **Encourage Direct Payment, not Managed Care.** Instead of managed-care Medicaid, provide *care* options for the poor when they need *care*. Focusing on coverage leads to 'universal coverage' and socialized medicine which is expensive, leads to dependency and limits access to care. Health plans are not true insurance; they are socialized medicine systems under corporate cover (centralized dollars, data and decisions). Sen. Ted Kennedy, advocate for a single-payer system, authored the HMO Act of 1973, which financed and mandated HMO establishment nationwide. Using block grants, states can be encouraged to end managed care and enter direct contracts with select clinics and hospitals. The fee-for-service Surgery Center of Oklahoma and the fee-for-service PATMOS clinic in Tennessee show how affordable care can be when the third-party payer and its blizzard of costly bureaucratic requirements are not part of the equation.

5) **Expand Charity Options.** Charity is the least expensive way to provide medical *care* to those who cannot afford it. Focusing on coverage instead of care only enriches the health plans (which are legally allowed to deny care), fleeces the taxpayers, and consolidates coverage into a relatively few controlling managed care corporations that increasingly make all the rules for Congress and states to follow. Charity is easier, develops gratitude, and is cheaper without all the bureaucratic headaches and low payments associated with Medicaid. Expand and encourage charity when *care* is needed. This could include tax deductions for medical charity, no restrictions on providing care at lower costs than insurers or government programs, and re-emergence of charity hospitals for the needy.

6) **Rescind SSA Rule that Prevents Access to Social Security Benefits if Citizens Refuse Medicare Part A.** In 1993, the Clinton administration, which supported a single-payer system, issued a Social Security Administration rule without public notice or public comment restricting access to Social Security retirement benefits if a citizen refuses to enroll in Medicare Part A. This prevented escape from Medicare. The Bush administration strengthened the restriction by requiring seniors to pay back all SSRB and Medicare benefits received if they disenroll from Medicare Part A. In 2008, former House Majority Leader Dick Armey and others sued to lift this unconstitutional and coercive restriction. In 2013, the U.S. Supreme Court refused to hear the case.

   Senior citizens have a right to their Social Security benefits independent of Medicare enrollment, and they have a right to refuse Medicare without penalty. Working with SSA to rescind these rules will acknowledge these rights, restore health freedom, improve Medicare's financial situation (many with TRICARE, FEHBP and private insurance will not enroll) and encourage the development of a new post-65 private market for health insurance and advance lifelong health insurance policies for Americans.

7) **Rescind PPACA "Nondiscrimination in Health Programs and Activities" Rule.** As we wrote in public comments on November 9, 2015,

   > "CCHF opposes the proposed nondiscrimination rule. Despite the subjectivity of the proposed 'internal sense of gender' definition – and no statutory authority to back up the imposition of an unnatural definition of 'sex' and sure-to-be-controversial nondiscrimination prohibitions – HHS proposes to potentially force physicians to perform or allow questionable, harmful, unethical, medically-unnecessary and permanently disfiguring treatments requested by a transgender individual – or possibly face lawsuits, penalties, or loss of licensure for refusal. Furthermore, the proposed rule runs counter to deep public opposition welling up around the country and can be expected to have negative impacts on patients, the practice of medicine, ethics, professional integrity, the physician shortage, religious freedom, personal mores, patient safety and health, the freedom of conscience of practitioners and institutions, and health care costs."

8) **Restore Practitioner 'Freedom of Conscience' Language.** As we wrote in our April 9, 2009 comments opposing the Obama Administration's rescission of much of the Bush administration's rule: "No patient, no government official, no policy maker should be able to require a practitioner to do what is viewed as unethical, morally objectionable or a violation of the religious beliefs of that practitioner." However, the Obama administration stripped away most of the protective Bush rule. HHS can now restore it.

9) **Prohibit Coercive One-Signature Consent Forms:** Prohibit all hospitals and clinics that receive federal funds of any kind from using a multi-consent, single-signature

consent form. These forms often combine consent for treatment with consent for data disclosures for billing, research, NPP acknowledgement, entry into a health information exchange, HIV testing, third-party access to entities unrelated to the patient's care and "health care operations" (a sweeping more than 400-word definition under HIPAA).

A patient, vulnerable and often in pain or under duress, feels compelled to sign lest treatment be denied or care be compromised. But those who sign these forms are signing away their privacy rights under coercion. One patient shared a consent form with CCHF that has **23 separate consent provisions** and only one signature. After refusing to sign, and being told she could not cross out various sections, she was denied treatment. The move to electronic signature pads has often hidden these coercive forms. We've heard from individuals who are asked to sign the electronic pad without a word of the consent form visible. Some have demanded a paper copy of the form, but still have no idea if that's what they're actually agreeing to when they sign on the electronic pad.

That said, one clinic in Minnesota is using a consent form that provides the patient with the opportunity to say "Yes" or "No" to the various possible uses of their data. This should be the standard for all multi-consent/single-signature forms.

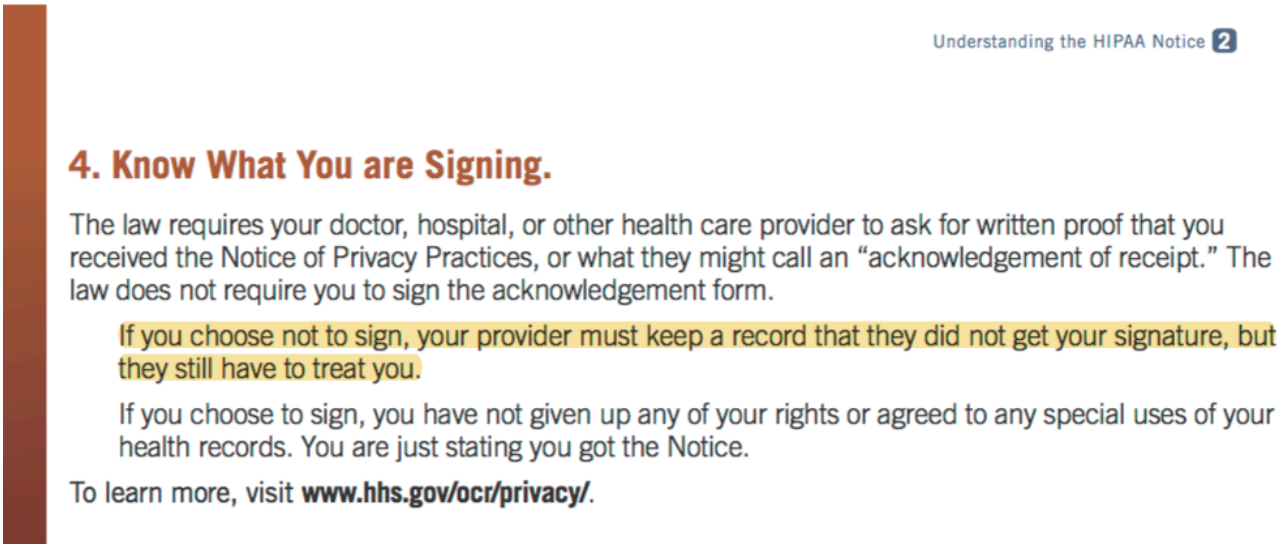
10) **Require Patients to be Notified of Right to REFUSE to Sign HIPAA NPP Acknowledgement Statement or Form.** Signing the form acknowledging receipt of the HIPAA Notice of Privacy Practices (NPP) propagates the myth that HIPAA protects patient privacy. The federal requirement that patients be asked to sign the form and the NPP title have long deceived Americans into believing they have privacy because of HIPAA. However, HIPAA eliminated most privacy and consent rights. Due to the title of the NPP, many people don't read the form, assuming it protects privacy, and therefore do not know that the form's title belies the actual text of the form. The NPP is a notice of *disclosure* practices, not a notice of privacy practices. It's time to tell the public the truth, including the fact that they don't have to sign the acknowledgement form or statement.

According to an August 2010 regulation issued by HHS, *more than 2.2 million entities,* including 1.5 million business associates, are under HIPAA, allowing them to access medical records without patient consent if those holding the patient's private medical information (700,000 covered entities) choose to share the data with other covered entities, business associates or government. The 2.2 million doesn't include government agencies authorized to receive data under the permissive HIPAA (no privacy) rule.

We've discovered that clinic staff and administrators often know little about the details of the law, or the rule, and tell patients that signing the form protects their privacy. They are also refusing care to citizens from around the country who are refusing to sign the form. CCHF has heard from many and helped some. But patients should not require our assistance because the HIPAA law/rule does not require their signature. Although

signing or not signing the form does *nothing* to limit data-sharing authorized under HIPAA, many patients still do not wish to participate in or propagate the nationwide deception that HIPAA, the NPP and the acknowledgement forms protect privacy.

The HHS Office of Civil Rights (OCR) has published a document called *"Understanding the HIPAA Notice"* which states that patients are not required to sign the acknowledgement form or statement. But clinics and hospitals may choose to deny treatment because they are wrongly concerned about violating HIPAA and being forced to pay huge HIPAA fines to the federal government. Here is what the OCR form says (emphasis ours):



Understanding the HIPAA Notice 2

4. Know What You are Signing.

The law requires your doctor, hospital, or other health care provider to ask for written proof that you received the Notice of Privacy Practices, or what they might call an "acknowledgement of receipt." The law does not require you to sign the acknowledgement form.

If you choose not to sign, your provider must keep a record that they did not get your signature, but they still have to treat you.

If you choose to sign, you have not given up any of your rights or agreed to any special uses of your health records. You are just stating you got the Notice.

To learn more, visit **www.hhs.gov/ocr/privacy/**.

11) **Change Title of NPP to "Notice of DISCLOSURE Practices."** End the deception. The required HIPAA document has nothing to do with protecting privacy, but most clinic clerks and administrators believe the myth that HIPAA protects privacy and get upset when citizens claim otherwise and refuse to sign the form. Many deny patients their right to access medical services if they legally refuse to sign the form or statement acknowledging receipt of the NPP. Change the name of the document -- and enforce the patient's right to refuse to sign.

12) **Provide Protection by Ending Push for Interoperability.** As a result of the permissive HIPAA rule, patients have almost no control over their medical data, with rules that allow sharing to "run in the background" per ONC: *"HIPAA Permitted Uses and Disclosures 'run in the background.' That way, health information is readily available to be shared so that individuals get the right care at the right time. These background rules are made transparent to individual through Notices of Privacy Practices."* ("The Real HIPAA: Permitted Uses and Disclosures," *HealthItBuzz*, ONC, February 11, 2016). However, this is <u>not</u> transparent and vast sharing occurs. Due to the title of the NPP document, patients

believe their medical records are not shared without their consent because of HIPAA. Thus, interoperability under HIPAA would remove this limited barrier that currently protects patients *from* HIPAA's permissive and expansive sharing and use.

13) **Zero Out MU/MACRA/MIPS/APM Penalties Related to EHRs.** The EHR mandate has harmed Americans. The EHR was never made for patient care; it was made for outside surveillance and control. Government-imposed and government-prescribed EHRs have impeded patient care, diverted the doctor's attention from patients to paperwork, stymied the physician's critical thinking (focused is on computer checkboxes), coerced violation of professional obligation to protect patient privacy and per FDA testimony, led to deaths and injury. As Scot Silverstein M.D., a forensic expert in Health IT said in an October 20, 2014 interview with *Meaningful HIT News*, EHRs are:

> "enterprise-wide command and control systems through which all medical transactions have to pass, controlling physicians and clinical resources. They are beyond just a medical device. They're really command and control systems."

14) **Stop Building National Medicaid Database.** *Healthcare ITNews* reported on June 29, 2017 that CMS and state Medicare agencies "are struggling to submit data to an IT system created to improve health information quality and sharing," per an OIG report. That $100 million surveillance and patient-tracking system is called the Transformed Medicaid Statistical Information System (T-MSIS). This national database in the making is being built at a time when even GOP members of Congress are trying to expand Medicaid, or hesitant to restrict Medicaid from being expanding into the middle class.

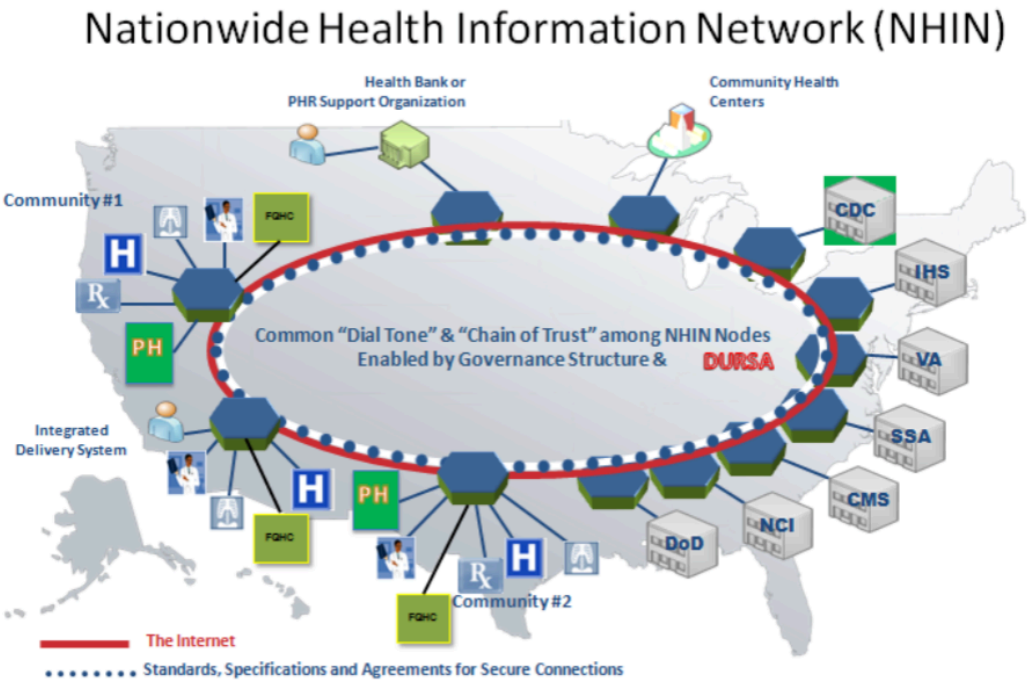
National data systems advance national healthcare systems. Medicaid was enacted in 1965 without a national database. To halt the bipartisan movement toward socialized medicine, we call on HHS to cease and desist building the national T-MSIS database.

15) **End CMS Plan for "Cloud-Based" Access to Patient Medical Records.** On June 14, 2017, *FierceHealthcare* reported the CMS plan to "improve public health data collection by moving to the cloud and accessing EHRs." Their plan: "tapping into EHRs" and "'moving toward greater use of shared digital data services and an interoperable integrated cloud-based platform' to further data sharing capabilities and track social determinants of health." This move to profile and analyze Americans by conducting federal surveillance through "on the grid" EHRs violates the privacy and Fourth Amendment rights of American citizens and patients. This initiative should be defunded and ended.

16) **Mandate Written Opt-In Consent for State Health Information Exchanges and the eHealth Exchange.** Millions in federal funds have been poured into creation of state health information exchanges and the eHealth Exchange, formerly called the

National Health Information Network (NHIN). No patient, by virtue of patient and privacy rights, should be required to have their information put "on the grid" and broadly shared and accessed through the Internet without their express consent.

Figure 1: The Network Approach



17) **Require Patient Consent for Locating and Linking Patient Records.** Patients have a right to keep their personal and medical lives private by prohibiting distribution of their private medical records. However, Congress passed a 2017 law at the behest of the health data industry and without sufficient public notice or debate authorizing HHS to provide technical support for the creation of a national "patient-matching strategy."

Congressman Ron Paul stopped the National Patient ID for 19 years, but HIMSS celebrated **President Trump's May 5 signing of the 2017 Appropriations bill** with a May 9, 2017 article titled, "After Nearly Two Decades, a Win in Congress for Patient Data Matching." *EHR Intelligence* titled their May 11, 2017 article: "National Patient Identifier Gains Congressional Support."

Although the language prohibits the HIPAA Unique Patient Identifier Rep. Paul stopped for 19 years, it advances a strategy to accomplish the goal of the UPI: locating and linking all patient medical records into a lifelong, longitudinal medical record. No escape. No fresh second opinions. No freedom. Within days, ONC began pouring its resources into the launch of the "Patient Matching Algorithm Challenge." HHS should impose consent.

18) **Require Parent Consent for State Storage, Use, Dissemination and Research on Newborn Blood Spots ("Baby DNA") - as Prerequisite for Federal Funds.** State Newborn Genetic Screening programs are storing newborn dried blood spots for genetic research and other uses without parent consent. Parents have won three lawsuits against state health departments, yet most parents have no idea that the State has laid a claim to the DNA of their child. State officials are not allowed to take or store the DNA of *adults* without consent except in the context of committing a crime, but States are regularly storing, using, sharing and conducting research using the DNA of newborn infants, which was collected for the state's newborn genetic testing program.

19) **Restore Parent Consent Requirements for Federally-Funded Research Using Baby DNA.** As we wrote in a June 30, 2017 letter to HHSSecretary Tom Price and President Donald Trump:

> "On January 4, 2016, our organization submitted public comments on the proposed rule (with an addendum comment added later). Our concerns included:
>
> - No retention of parent consent requirements for research using newborn DNA
> - Need to retain 'human subject' designation for newborn DNA
>
> In December 2014, President Obama signed the Newborn Screening Saves Lives Reauthorization Act (NSSLRA). It included the language we worked on with the office of **Senator Rand Paul** and the **Senate Steering Committee.** The language required parental consent for the use of dried newborn bloodspots for federally-funded research. Hospitals prick the newborn's heel and send the bloodspots to state public health departments for newborn genetic screening programs. The bloodspots are often stored in perpetuity without parental consent. The 2014 federal law also designated the child's newborn bloodspot (DNA) as a 'human subject' and prohibited all waivers to the parental consent requirement.
>
> The law said this protective language would disappear from federal statute after the final Common Rule was published because – we were told – NIH leadership had committed to include the 2014 statutory language in the final Common Rule.
>
> However, when the rule was finalized, it **did not include** parental consent requirements or any other part of the protective language of Senator Paul's NSSLRA amendment. In fact, it specifies that the 2014 NSSLRA language *"will no longer apply after the effective date of this rule, January 19, 2018"* (page 7152). On page 7261, the definition of "research" specifically **excludes** *"public health surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority."*

20) **End the $25 Million Newborn Genomic Sequencing Project.** The federal government is funding four institutions for four 5-year projects (e.g. BabySeq Project) related to whole-genome sequencing of newborns for the purpose of determining the use of this technology in state newborn genetic screening programs. However, most parents today have no idea that newborn screening even takes place because most states mandate it (although there are religious and other opt-out options which most parents know nothing about) and doctors do not order it. Thus, there are no consent requirements for this nationwide genetic testing program and little to no discussion of the matter. Many parents have no idea that it's a state-mandated (and often federally funded) genetic testing of their child by the government, or that the blood is sent to and often kept indefinitely and used and shared by state health departments.

Full genomic sequencing would detail the entire genome – the genetic blueprint – of the newborn citizen, which would be entered into a government record (and the individual's permanent medical record) ending the child's genetic privacy *forever* -- before this newly born, someday voting, citizen can say no. There are children being sequenced today under these projects. Are the parents even asked to consider what their child will think when they discover that they've been sequenced without their consent?

21) **End all "Health Disparity" Data Collection/Reporting.** Individuals should not be categorized by government mandate, and clinics and hospitals should not be required to collect or report to the federal or state government the ethnicity, race, gender, sexual orientation, preferred language, disability or any other social determinants of patients. The health disparity initiative is divisive, intrusive and a violation of patient rights.

Thank you for your consideration of our recommendations. We believe each would reduce the Affordable Care Act's burdens on patients and doctors, enable physicians to practice medicine with ethical integrity, protect patient dignity, and enhance and protect the patient rights and individual freedoms of all Americans.

For questions about these recommendations or if you wish to discuss other possible ideas for your consideration, please do not hesitate to contact our office at 651-646-8935 or info@cchfreedom.org

Sincerely,

Twila Brase, RN, PHN
President and Co-founder