



September 21, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CCHF Public Comments on the Notice of Proposed Rulemaking titled, “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans” ID# CMS-9989-P

Citizens’ Council for Health Freedom (CCHF) is a national health freedom organization based in St. Paul, Minnesota. Our “Health Freedom Minute” radio program is heard in 37 states and on 158 stations nationwide. Our mission is to support patient and doctor freedom, medical innovation and the right of citizens to a confidential patient doctor relationship. Our website can be found at: www.cchffreedom.org

Overview of CCHF Comments

We oppose the overreach of federal authority, the false advertising, the false “flexibility” claims with no meaningful flexibility for States, the continued discussion of an HHS-run “federal” Exchange while the Administration has no plans or money to create or run one—every State-based Exchange will actually be a Federal Exchange—the controls implemented over patient care and the many uses of the word “require” and “must” while still claiming the Exchange offers choice, competition, clout, and “flexibility.”

In general, we are opposed to the proposed exchange regulation, which requires States to set up a federal structure by which the federal government can control virtually all facets of health care nationwide. **We conclude by asking HHS to withdraw the entire rule.**

We are responding to the Department’s request for public comments on the notice of proposed rulemaking (NPRM) for health insurance exchanges under the federal health reform law. Page numbers are often cited. The specific concerns we have chosen to address regarding the exchange proposals, although there are many more, are titled:

- Endless Stream of Exchange Regulations
- Overreach of Federal Authority – *proposed codification must be withdrawn*
- False Advertising
- Exchange is Government Entity
- Privacy Protection Ruse
- Myth of a “Federal” Exchange
- Ruse of “Flexibility” for States – *a long list of examples*
- Discrimination against Average Citizens
- Elimination of an Entire Industry by a Government Entity

Endless Stream of Exchange Regulations

Regulations have the full force and effect of law without the accountability of a Congressional vote. Given what we have already discovered in this proposed federal rule, we are not heartened to learn that this is the first of what could be many more proposed federal regulations to come. As the NPRM states,

“The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are working in close coordination to release guidance related to Exchanges in several phases.... (p. 41866)

“Subjects included in the Affordable Care Act to be addressed in separate rulemaking include but are not limited to: (1) Standards for individual eligibility for participation in the Exchange, advance payments of the premium tax credit, cost-sharing reductions, and related health programs determinations; (2) standards outline the Exchange process for issuing certificates of exemption from the individual responsibility requirement and payment under section 1411(a)(4); (3) defining essential health benefits, actuarial value and other benefit design standards; and (3) standards for Exchanges and QHP issuers related to quality. ... (p. 41868)

“[W]e propose that the Exchange must evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting... We anticipate future rulemaking on these topics...” (p. 41875)

“[W]e propose that each Exchange establish a process for appeals of eligibility determinations....[which] will be addressed in future rulemaking.” (p. 41888)

Overreach of Federal Authority

HHS proposes to make States responsible for keeping the Exchange running. However, the law does not require what HHS is now proposing to require by rule. HHS acknowledges this fact in the proposed rule when they say that they plan to, “codify the *implied* statutory requirement established in section 1311(d)(5)(A) of the Affordable Care Act that a State Exchange must be self-sustaining starting on January 1, 2015” [*emphasis added*]. The actual statutory language in the Affordable Care Act says,

(5) FUNDING LIMITATIONS. —

(A) NO FEDERAL FUNDS FOR CONTINUED OPERATIONS. —In establishing an Exchange under this section, the State shall ensure that such Exchange is self-sustaining beginning on January 1, 2015, including allowing the Exchange to charge assessments or user fees to participating health insurance issuers, or to otherwise generate funding, to support its operations.”

The law’s language simply assures that no federal Exchange operating funds shall be available to States in 2015. Thus, “shall ensure” does not require. There is no federal REQUIREMENT that the Exchange be self-sustaining. HHS exceeds statutory authority and its regulatory authority with this proposed requirement. **Therefore, this proposed codification is unconstitutional and must be withdrawn.**

False Advertising

In the “Executive Summary” (p. 41866 of the Notice of Proposed Rulemaking (NPRM)), HHS makes statements that are negated by the language of both the Affordable Care Act and the NPRM. We create titles for the following HHS statements solely to summarize:

FALSE STATEMENT – “Starting in 2014, individual and small businesses will be able to purchase private health insurance through State-based competitive marketplaces called Affordable Insurance Exchanges, or “Exchange.” Exchanges will offer Americans competition, choice, and clout. Insurance companies will compete for business on a level playing field, driving down costs. Consumers will have a choice of health plans to fit their needs. And Exchanges will give individuals and small businesses the same purchasing clout as big businesses.” (p. 41866)

ONLY MANAGED CARE PLANS; NO TRUE INSURANCE POLICIES – “Exchanges should aim to maximize enrollment of eligible individuals into QHPs [qualified health plans] to increase QHP participation and competition which in turn increases consumer choice and purchasing clout.” (p. 41877) The Affordable Care Act makes it clearer: “An Exchange may not make available any health plan that is not a qualified health plan.” (§1311(o))

NO MOVEMENT ALLOWED - “[T]he Exchange may only allow an existing enrollee of a QHP to change plans within levels of coverage...As an example, if an enrollee is in a silver level plan and gives birth to a child outside of the annual open enrollment period, the enrollee may add the child to her existing plan or change from one silver level plan to another; however, she may not move to a gold level plan. We propose this limitation to maintain a single level of coverage throughout the year to avoid adverse selections...We recognize that limiting enrollees such that they must stay within a specific coverage level during a special enrollment period could pose a challenge for an enrollee in a catastrophic plan that becomes pregnant. We request comment as to whether we should provide an exception to such circumstances.” (p. 41885)

ONE EXCHANGE OPTION - “Only one Exchange may operate in each geographically distinct area. To the extent that more than one Exchange is established in a State, we encourage each Exchange to ensure that consumers understand which Exchange they would utilize to access health insurance coverage.” (p. 41871)

In fact, as opposed to the assertions on the first page of this proposed rule, we believe that competition and choice are limited by the Exchanges, not enhanced.

For instance, rather than being an option for purchase, individuals without employer-based insurance will be required to use the Exchange to buy health insurance. According to surveys and news reports, small and large businesses are now considering whether to drop health insurance for their employees and simply pay the federal fine, which is less expensive than the cost of coverage. This means more Americans could be forced into the Exchange to purchase health insurance. In addition, only health plans (prepaid managed

care coverage) will be allowed to offer coverage in an Exchange and the number and type of health plans can be limited by law. The federal health reform law created four levels and only allows “bronze,” “silver,” “gold” and “platinum” level of insurance coverage to be sold in the Exchange. (as noted on p. 41876)

In addition, there is no “clout” in dependency on government subsidies and entitlements.

The Exchanges expand government dependency into the middle class. An entire new class of citizens will be on subsidized policies to cover the higher cost of health insurance under the federal law. Our organization suggests that these subsidies are actually **“welfare health care” for the middle class.**

This dependency does not translate into “clout” as the proposed rule states. Instead, individuals will find their options limited, become dependent on federal subsidies, become vulnerable to federal budgets and political winds, and find themselves limited in employment opportunities. They’ll find the point at which subsidies can go from thousands of dollars to zero and make sure they earn not a penny more.

Exchange is Government Entity

Despite assurances in the media of a seemingly private market-based enterprise, the Exchange is all government, all the time.

The NPRM, in discussing whether the Exchange should be a government entity or a non-profit, states,

“Non-profit entities may be able to operate without some of the restrictions that can limit the flexibility of governmental agencies; however, non-profit entities may face limitations performing functions that are *typically governmental in nature*” [emphasis added]. (p. 41870)

We note too how HHS mentions in this proposed rule that commenters are already suggesting that States establish governmental entities or “non-profit entities with governing bodies that are appointed and overseen by States.” (p. 41870)

Finally, some earlier commenters suggested according to the NPRM, “HHS establish more restrictive standards, citing concerns over conflicts of interest and non-governmental entities carrying out activities that are *inherently governmental.*” [emphasis added] (p. 41872)

Privacy Protection Ruse

HHS recently reported that 5.4 million people had been impacted by a breach of privacy in 2010. Another privately funded survey found that 70 percent of health care organizations had experienced a privacy breach. They also found that more than 60 percent of privacy breaches are committed by insiders (employees).

The public is not likely to understand the extraordinary privacy and security problems inherent with the Exchange until they go online and are asked to answer a host of personal questions to elicit an insurance policy created specifically for them.

The proposed rule does not require consent for the broad sharing of data that is expected to occur. It simply states, “applicants should be given notice of an entity’s information practices before any personal information is collected from them so that they are able to make an informed decision about whether and to what extent to disclose their personal information.” (p.41882)

HOWEVER, we believe that citizens who choose not to disclose their personal data will not be allowed to obtain health insurance. And furthermore, the required disclosures are required by the federal government, not the entity (Exchange), so the statement in this rule provides false assurance. Thus the Exchange will essentially coerce individuals to hand over very private personal data if they want to be insured.

Although the proposed rule makes reference to the so-called HIPAA “privacy” Rule and the so-called HIPAA “security” standards, there is nothing private about the more than **2.2 million entities that have access to medical records without patient consent under the HIPAA privacy rule.** (NOTE: this statistic comes from HHS rule, 8/2010).

Given this broad access, the proposed Exchange rule makes at least five statements related to data that should give citizens more reasons to doubt the authenticity of the so-called HIPAA privacy rule and any privacy/data control rights under the proposed rule. Again, we create CCHF titles for the following HHS statements solely to summarize:

BROAD COLLECTION – “Each Exchange will need to obtain applicants’ personally identifiable information, such as names, social security numbers, addresses, dates of birth, and tax returns or other financial information during the application process...”

ONGOING SHARING – “In addition...part 156 requires QHP issuers to provide personally identifiable information to the Exchange on a regular basis...”

BROAD DISCLOSURES – “Privacy policies for the Exchanges will need to allow for the appropriate collection, receipt, use, disclosure and disposal of the various kinds of information including health, financial and other types of personally identifiable information.”

ELECTRONIC TRANSACTIONS – “We propose to apply certain standards and protocols to the operation of Exchanges. We consider these requirements to be important considerations in the development and operation of Exchange information technology systems and as such, propose them here as requirements for Exchanges.”

ACCESS TO MEDICAL RECORDS/PROFILING PATIENTS AND DOCTORS - “[W]e propose that the Exchange must evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting... We anticipate future rulemaking on these topics, but propose here the basic requirement that the Exchange will have a role in the implementation,

oversight, and improvement of the quality and enrollee satisfaction initiatives required by the [ACA]. This will include requirements for quality data collection, standards for assessing a QHP issuer's quality improvement strategies, and details on how Exchanges can assess and calculate ratings of health care quality and outcomes using methodologies made available by HHS or alternatives, if applicable. (p. 41875)

As Kristie Loescher, McCombs School of Business Senior Lecturer who specializes in the health care industry, told the *Texas Enterprise*,

“As you create insurance exchanges, you create more people who have this information that have to keep it secure. As you create the integrated delivery systems, you create more sharing that could cause potential for leaks...” (Patient Privacy in the Digital Age,” Rob Heidrick, *Texas Enterprise*, September 6, 2011)

Myth of a “Federal” Exchange

On page 41871, the proposed rule gives States an option to NOT have an Exchange in place by the law's January 1, 2014 deadline. This allowance is a clear sign that HHS does not plan to run a “federal” exchange in any State as threatened, but is willing to let the process of state implementation take as long as necessary beyond the deadline to make sure that each State builds and runs a federally-controlled Exchange.

Nevertheless, the proposed rule continues to further the idea of an HHS-run exchange—even though POLITICO has reported that HHS has no funding to create a so-called federal exchange and no plans to write any regulations to do so. This proposed rule states,

“[W]e propose that such a State must work with HHS to develop a plan to transition from a Federally-facilitated Exchange to a State Exchange.” (p. 41871)

“[W]e propose a process to allow a State-operated Exchange to cease its operations after January 1, 2014 and to elect to have the Federal government establish and operate an Exchange within the State.” (p. 41872)

“[W]e estimate that we will need 12 months to establish a Federally-facilitated Exchange in a State due to the time required to set up the necessary information technology and QHP certification process.” (p. 41872)

The Ruse of “Flexibility” for States

The regulation mentions flexibility 37 times on 19 pages, **while the word “require” is mentioned 628 times and on all 61 pages.** The word “must” is mentioned 439 times on 57 pages. In word mass alone, it is clear that so-called “State” Exchanges are actually state-run federal Exchanges.

The federal law is clear: “(k) CONFLICT.—An Exchange may not establish rules that conflict with or prevent the application of regulations promulgated by the Secretary under this subtitle.” The proposed rule clarifies. As evidence of how false the Department's claim of flexibility for States is, we provide the following statements from the proposed rule (plus CCHF summary titles) as only a small subset of myriad federal requirements:

COMPLIANCE REQUIRED - “Section 1311(k) of the Affordable Care Act requires that an Exchange may not establish rules that conflict with or prevent the application of Exchange regulations promulgated by HHS, which we propose to codify in paragraph (a). (p. 41873)

CURRENTLY OPERATING STATE EXCHANGES MUST COMPLY – “Some States have established operational health insurance exchanges that are currently providing access to health insurance coverage to certain individuals in their States. These State exchanges were established prior to passage of the Affordable Care Act and may not meet all the requirements set forth in the Affordable Care Act or this proposed rule. Section 1321 (e) requires the establishment of a process for determining any areas in which the State may not be with Federal standards...” (p. 41874)

NON-COMPLIANCE NOT ALLOWED - “[W]e propose that any State that is currently operating a health insurance exchange that meets the description of such a State under paragraph (a) must work with HHS to identify areas of non-compliance with the requirements of this part.” (p. 41874)

MONTHLY REPORT TO HHS – “[T]he Exchange must establish maintenance of records procedures for termination of coverage, track the number of individuals for whom coverage has been terminated and submit that information to HHS on a monthly basis, establish terms for reasonable accommodations, and retain records in order to facilitate audit function.” (p. 41885)

POLITICAL CORRECTNESS REQUIRED - “[W]e propose that a State must comply with any applicable non-discrimination statutes. Specifically,...we propose that an Exchange and a State, when fulfilling or carrying out the requirements of this part, must not operate an Exchange in such a way as to discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. Examples of actions to which this standard applies include marketing, outreach, and enrollment.” (p. 41873)

HHS ASSESSMENT - “We propose that each State applying for approval of its Exchange be subject to an assessment to be carried out by HHS ...” (p. 41871)

HHS ACCESS TO MEDICAL RECORDS - “[W]e propose that the Exchange must evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting... We anticipate future rulemaking on these topics, but propose here the basic requirement that the Exchange will have a role in the implementation, oversight, and improvement of the quality and enrollee satisfaction initiatives required by the Affordable Care Act. This will include requirements for quality data collection, standards for assessing a QHP issuer’s quality improvement strategies, and details on how Exchanges can assess and calculate ratings of health care quality and outcomes using methodologies made available by HHS or alternatives, if applicable. (p. 41875)

MUST CONSULT - “We propose that that Exchange consult on an ongoing basis with key stakeholders...” (p. 41873)

HHS CONTROL OVER GOVERNANCE - “...HHS may periodically review the accountability structure and governance principles of an Exchange.” (p. 41873)

NO CHANGES WITHOUT HHS - “We propose that a State must notify HHS before significant changes are made to the Exchange Plan and that an Exchange must receive written approval of significant changes from HHS before they may be effective.” (p. 41871)

COMPLIANCE REQUIRED - “By establishing an ongoing dialogue with each State, HHS will be able to provide technical assistance and support to ensure that each Exchange is operating in compliance with Federal requirements.” (p. 41871)

ALL FEDERAL REQUIREMENTS - “[W]e propose that the Exchange remains responsible for meeting all Federal Requirements related to contracted functions. Pursuant to these provisions, States have flexibility to determine appropriate contracting entities within legal limits.” (p. 41872)

GOVERNMENTAL CONTROL - “[A]n Exchange must be a governmental agency or non-profit entity established by the State. We also propose that the governance structure of the Exchange must be established and operated consistent with the requirements in §155.110.” (p. 41870)

HHS DECIDES - “This subpart sets forth approval standards for State Exchanges as well as the process by which HHS will determine whether a State Exchange meets those standards.” (p. 41870)

MEMBERSHIP REQUIREMENTS - “[A] State may choose to include additional membership as long as composition of the board still meets the minimum Federal requirements.” (P. 41872)

FEDERAL-STATE “PARTNERSHIP” - “Some States have expressed a preference for a flexible State partnership model combining State-designed and operated business functions with Federally-designed and operated business functions... We note that States have the option to operate an exclusively State-based Exchange. HHS is exploring different partnership models that would meet the needs of State and Exchanges.” (p. 41870)

SHARING DATA - “Underlying this NPRM and the cooperative agreement funding opportunities provided to States is a philosophy of Federal and State partnership. As States, and the Federal government in connection with the Federally-facilitated Exchange, develop expertise and implement the infrastructure for Exchange operations, we anticipate sharing of information and ideas....” (p. 41872)

HHS SETS THE STANDARDS - “[W]e set forth the minimum duties of a Navigator. The Exchange may require that a Navigator meet additional standards and carry out duties so long as such standards are consistent with requirements set forth herein. (p. 41877)

MUST PARTICIPATE - “The Exchange must participate in the data matching program required by section 1413(c)(2) of the Affordable Care Act... We expect Exchanges and the Medicaid and CHIP [Children’s Health Insurance Program] agencies to execute data use agreements...(p. 41880)

HHS OVERSIGHT - “We propose requiring that the policies and procedures be in writing and available to the Secretary of HHS...” (p. 41880)

SINGLE APPLICATION – “We propose use of a single streamlined application to limit the amount of information and number of times an individual must make submissions to receive an eligibility determination and complete the enrollment process...if the Exchange seeks to use an alternative application, it must be approved by HHS. (p. 41881)

GENERAL COMPLIANCE STANDARD - “[W]e propose a general standard that an Exchange must perform the required functions set forth in this subpart and in subparts E, H, and K of this part.” (p. 41875)

REQUIRED FUNCTIONS - “[W]e propose that an Exchange must perform required functions related to oversight and financial integrity requirements in order to comply with section 1313 of the Affordable Care Act.” (p. 41875)

Discrimination Against Average Citizens

The rules require Exchanges to consult with a variety of individuals, including “educated health care consumers who are enrollees in QHPs.” This discriminatory language results from passage of the Health Care and Education Reconciliation Act (HCERA) and its amendments to the so-called Patient Protection and Affordable Care Act (PPACA). The PPACA required consultation with “health care consumers.” HCERA added the word “educated” to the law.

Under PPACA, as amended by HCERA, an “EDUCATED HEALTH CARE CONSUMER” means “an individual who is knowledgeable about the health care system, and has background or experience in making informed decisions regarding health, medical, and scientific matters.” This eliminates much of the population.

Despite Exchanges becoming possibly the only option for purchasing health insurance for many people, average citizens who have expertise in their own medical conditions, needs, preferences and concerns are not on the list of those that must be consulted.

This section of the health care reform law is discriminatory against the majority of America’s more than 300 million citizens. The rule should not further embed this discrimination into practice.

Elimination of an Entire Industry by a Government Entity

There are 10 groups that Exchanges must consult with according to the proposed rule. At the bottom of the list are health insurance brokers and agents (p. 41873):

1. “Educated health care consumers who are enrollees in QHPs.
2. Individuals and entities with experience in facilitating enrollment in health coverage.
3. Small businesses and self-employed individuals
4. State Medicaid and CHIP agencies
5. Federally-recognized tribes
6. Public health experts
7. Health care providers
8. Large employers
9. Health insurance issuers; and
10. Agents and brokers”

The law only requires the first five to be included. HHS added the rest due to public comments, yet nothing in the proposed rule assures that their input will lead to job protection. NOTE: If Agents and Brokers were meant to be included in #2, they would not likely be listed separately in #10.

Given that the key advertised function of the Exchange is enrollment – the long-time job of agents and brokers -- and the fact that each online state-run federal Exchange is expected to take the place of humans in the health insurance enrollment process, agents and brokers may only be listed to pacify them while the federal Exchanges are built in each state and their current jobs as agents and brokers are eliminated.

As the proposed rule states,

“We also believe that the Exchange call center should have the capability to provide assistance to consumers and businesses on a broad range of issues, including but not limited to:

1. The types of QHPs offered in the Exchange;
2. The premiums, benefits, cost-sharing, and quality ratings associated with the QHPs offered;
3. Categories of assistance available, including advance payments of the premium tax credit and cost-sharing reductions as well [sic] assistance available through Medicaid and CHIP;
4. The application process for enrollment in coverage through the Exchange and other programs (for example, Medicaid and CHIP).” (p. 41875)

HHS already anticipates problems with the public navigating through Exchanges and the Call Center, as noted in the proposed rule:

“Since consumers will likely require significant assistance to understand options and make informed choices when selecting health coverage, we believe it is important that Exchanges begin the process of establishing the Navigator program

by awarding grants and training grantees in time to ensure that Navigators can assist consumers in obtaining coverage throughout the initial open enrollment period.... (p. 41878)

“States have “the option to permit agents or brokers to assist individuals enrolling in QHPs through the Exchange.” However, “Any entity serving as a Navigator, including an agent or broker, may not receive any financial compensation from an issuer for helping an individual or small group select a specific QHP... (p. 41878)

“To ensure that individuals and small groups have access to information about agents and brokers should they wish to use one...we propose to permit an Exchange to display information about agents and brokers on its Web site or in other publicly available material....” (p. 41878)

Furthermore the proposed rule makes it clear that despite assertions otherwise, the Exchange is the hub where citizens will choose and purchase health insurance. HHS further acknowledges a need for an appeals process of this automated decision:

“We note that the aforementioned sections of the Affordable Care Act create a central role for the Exchange in the process of determining an individual’s eligibility for enrollment in a QHP, advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP and the BHP, if a BHP is operating in the Exchange service area. We interpret [sections of the ACA] to require the establishment of a system of streamlined and coordinated eligibility and enrollment through which an individual may apply for enrollment in a QHP...We also note that we interpret section 1413...to mean that the eligibility and enrollment function should be consumer-oriented, minimizing administrative hurdles and unnecessary paperwork for applicants. (p. 41875)

“[W]e propose that each Exchange establish a process for appeals of eligibility determinations...[which] will be addressed in future rulemaking. (p. 41888)

Conclusion

As we suspect is obvious to anyone reading the proposed rule, or the segments from the proposed rule as copied from it into our public comment, the federal government is poised, through the federal Health Insurance Exchange installed in each State, to take over the entire health insurance industry and the medical delivery system of the United States.

In the interest of patients and patient care, and to preserve and uphold the integrity of each citizen’s rights under the U.S. Constitution, we respectfully but firmly request that HHS withdraw the entire proposed rule.

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