CITIZENS' COUNCIL FOR Health Freedom
SECURING HEALTH FREEDOM FOR ALL

September 27, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9975-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CCHF Public Comments on the Notice of Proposed Rulemaking titled, "Patient Protection and Affordable Care Act; Reinsurance, Risk Corridors and Risk Adjustment" ID# CMS-9975-P

Citizens' Council for Health Freedom (CCHF) is a national health freedom organization based in St. Paul, Minnesota. 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.cchfreedom.org

First and Foremost

This proposed HHS rule was not written with the public in mind. The words are college-level or higher. Myriad terms are foreign to average citizens, even very learned ones. Furthermore, the definitions of the terms are obtuse at best.

This proposed rule was meant for and written for insiders, the government workers, the policy wonks, the insurance executives, and the lawyers. This proposed rule is not a easily readable document, despite it is ostensibly written for the American public to comment on. This proposed rule poses an extraordinary threat to the constitutional, patient and privacy rights of each and every individual and how many will even know?

Many in the general public have never heard of the Federal Register, and if they read this NPRM, they would not understand that this proposed rule proposes to mandate that their private medical records be handed over to State and Federal government workers for creating INDIVIDUAL "RISK SCORES" on every citizen, every patient.

Most of the public will not understand that "claims data" means their personal and medical data going to their insurer to make a claim for payment for care received. And they will not understand that "encounter data" means PRIVATE MEDICAL RECORDS DATA FROM EACH AND EVERY ENCOUNTER THEY HAVE IN THE EXAM ROOM OR AT THE BEDSIDE WITH THEIR DOCTOR or other clinician.

Together, these two terms, along with the call in Section 153.340 for demographic data prescription data and enrollment data (which may include income) provide extraordinary detailed information on each and every patient – except those who pay cash for care.

KEY QUESTIONS THAT NEED ANSWERS:

1) **How will HHS prevent the fuzzy math fraud that this proposed regulation invites?**
2) **How does this proposed regulation NOT violation constitutional and patient rights?**
3) **What will HHS do to make sure the public understands the intrusions being proposed in this document -- and enable their response?**

We ask HHS to withdraw this proposed rule until HHS writes it legibly for the public to comment on and until a decision on PPACA comes down from the U.S. Supreme Court.

Overview of CCHF Comments

Citizens' Council for Health Freedom opposes this rule, particularly the sweeping data collection plan, the mandate to create "risk scores" on individuals, the redistribution of funds that will likely lead to rationing of care, the fuzzy math that is "risk adjustment", the "risk corridors" that will facilitate fuzzy math and fund transfers, and the power of the federal government to mandate reinsurance contributions by States.

Sections of Particular Concern

§153.220 Collection of reinsurance contribution funds

We oppose the proposed mandated collections and transfers of funds. We note that HHS "will set the contribution rate as a percent of premium through a forthcoming annual Federal notice of benefit and payment parameters." Also, "The State must adhere to a national contribution rate set by HHS…" We also note that reinsurance entities may collect more than those amounts if the State feels it needs more funds for reinsurance --- and to provide, "Funding for administrative expenses of the reinsurance entity."

QUESTIONS: What is the cost of all these reinsurance mechanisms at the State and Federal level? How many health care dollars will be spent doing reinsurance that could have gone to patient care? And how high could "administrative expenses" get? Please clarify and answer these questions for the public.

§153.230 Calculation of reinsurance payments

This section provides an opportunity to game the system and bleed the proposed reinsurance accounts dry. Such micromanagement, payment formulas, values for the "attachment point," reinsurance caps and coinsurance rates provide fodder for shifting dollars from patients to payers. As an example, we note that the proposed rule allows States to modify the reinsurance payment formula:

> States may use one or all of the following methods: (i) Increasing or decreasing the attachment point; (ii) Increasing, decreasing, or eliminating the reinsurance cap; and (iii) Increasing or decreasing the coinsurance rate.

This free-for-all methodology and determination power encourages fraud, allows gaming the system, and presents a formidable threat to the rule of law. We oppose it.

QUESTION: How does HHS propose to prevent fraud at the state and national level?

§153.250 Coordination with high-risk pools
The Federal government is dictating to states, by demanding that they eliminate state high-risk pools (state law) or modify current state law to comply with new federal law. This violates the 10th amendment and we oppose it.

§153.320 Federally-certified risk adjustment methodology
We oppose the HHS proposal to require State compliance with risk adjustment methods, as well as the inclusion of intrusive elements in the HHS model for risk adjustment:

> "demographic factors, diagnostic factors, and utilization factors, if any; (ii) The qualifying criteria for establishing that an individual is eligible for a specific factor; (iii) Weights assigned to each factor; and (iv) The schedule for collection of risk adjustment data and determination of factors….

§153.330 State alternate risk adjustment methodology
We continue to oppose these data mandates as the intrusiveness of risk adjustment goes beyond demographic, diagnoses and utilization. Here HHS adds the following intrusive requirements for the methodology, which portend to directly impact physician's treatment decisions:

- Inclusion of performance metrics
- Explanation of the variation in the expenses of a given population
- Linking risk factors to daily clinical practice
- Clinically meaningful to providers
- Behavior modification "Encourages favorable behavior among providers and health plans and discourages unfavorable behavior"
- Provides stable risk scores over time and across plans

QUESTION: Please explain how does this requirement does NOT intrude on the patient-doctor relationship and does NOT threaten rationing? We believe it does.

§153.340 Data collection under risk adjustment
CCHF opposes the following intrusive requirements and methodologies:

> (a) "*Data collection requirements.* The State, or HHS on behalf of the State, must collect risk-related data to determine individual risk scores that form the basis for risk adjustment.
> (b) *Minimum standards.* The State, or HHS on behalf of the State may vary the amount and type of data collected provided that the State, or HHS on behalf of the State, uses the following standards for risk adjustment data collections…"
>
> 1) Claims and encounter data
> 2) Demographic and enrollment data

(c) "*Exception for States with all payer claims databases.* Any State with an all payer claims database that is operational on or before January 1, 2013, may request an exception from the data collection minimum standards…"
(d) "*Uses of risk adjustment data.* The State, or HHS on behalf of the State, must make relevant claims and encounter data collected under risk adjustment available to support claims-related activities…"

The threat to patient privacy and personal autonomy is even clearer on page 41940:

> …[A] robust risk adjustment process requires data to support the determination of an individual's risk score and the corresponding plan and State averages….[W]e propose that a State, or HHS on behalf of the State, is responsible for collecting the data for use in determining individual risk scores.
>
> HHS considered thee possibilities for data collection: (1) A **centralized** approach in which issuers submit raw claims data sets to HHS; (2) an intermediate **State-level approach** in which issuers submit raw claims data sets to the State government, or the entity responsible for administering the risk adjustment process at the State level; and (3) a **distributed approach** in which each issuer must reformat its own data to map correctly to the risk assessment database and then pass on self-determined individual risk scores and plan averages to the entity responsible for assessing risk adjustment charges and payments…" (emphasis added)

It would appear that HHS does not know what it is doing. Risk adjustment is not clearly defined or easily formulated (as their own statements indicate):

> A fully distributed approach would leverage existing infrastructures established to support Exchanges, A distributed approach also keeps individual-level data with the issuers, eliminating privacy risk related to transmission. ***However, there is reason to be concerned that some issuers would make errors in calculating individual risk scores and plan averages….*** (emphasis added)

If HHS thinks it can reach into patient data from Washington, D.C., "see" the patient through the data and properly calculate each patient's risk (cost) into the future and across the entire nation of more than 300 million individuals it is engaged in imaginary thinking.

"Risk adjustment" is not an exact science, if it is a science at all. Ostensibly, the idea is to level the playing field in terms of payments between providers. But patients are not concrete unchanging widgets of easily calculated risks and futures. Yet government is demanding reporting of private data which they will use to determine redistribution of large sums of money.

This is fuzzy math with lots of dollars going to those who do fuzzy math well, and few going to those who cannot, or are not willing to play the fuzzy math game.

In 2006, the World Health Organization published a definition of "risk adjustment":

> This statistical tool allows data to be modified to control for variations in patient populations. For example, risk adjustment could be used to ensure a fair comparison of the performance of two providers: one whose caseload consists mainly of elderly patients with multiple chronic conditions and another who treats a patient population with a less severe case mix. Risk adjustment makes it possible to take these differences into account when resource use and health outcomes are compared.

Yet according to a paper online at the World Health Organization, it's not so simple:

> Risk adjustment within health care aims to account for differences in the mix of important patient attributes across health plans, hospitals, individual practitioners or other groupings of interest before comparing how their patients fare. . . .This straightforward purpose belies the complexity of devising clinically credible and widely accepted risk adjustment methods, especially when resulting performance measures might be reported publicly or used to determine payments. ("Performance Measurement for Health System Improvement, Peter C. Smith et. al. *Health Economics, Policy and Management*, accessed September 27, 2011.)

§153.400 Reinsurance contribution funds

This section enables a broad stream of data and dollars -- although it may take someone with more than an English major to make heads or tails out of the convoluted language. In this language, HHS provides a ***broad bridge over which fuzzy math, fraud, and fictitious calculations can pass unrestricted:***

First the dollars:

- Each "contributing entity" must make payments as often and in a certain manner to the "reinsurance entity" for each State in which the contributing entity issues health insurance for the contributions specified…
- If the State establishes or contracts with more than one reinsurance entity, the contributing entity must make payments to each applicable reinsurance entity that covers each geographic area in which the contributing entity issues health insurance.

Now the data:

- Each contributing entity must submit to each applicable reinsurance entity data required to substantiate contribution amounts for the contributing entity.
- Each contributing entity in the individual and fully insured market must submit enrollment and premium data.
- Each contributing entity in the self-insured market must submit data on covered lives and total expenses.

§153.510 Risk corridor establishment and payment methodology

Payment is the purpose for risk adjustment, risk corridors and reinsurance, but the convoluted process, the fuzzy definitions, and the distributive system of payment to Qualified Health Plans (QHPs) through "risk corridors" shows the ***wide invitation for fraud and abuse --- and the potential for rationing to stay within HHS's parameters:***

(b) *HHS payments to health insurance issuers.* QHP issuers will receive payment from HHS in the following amounts under the following circumstances:

(1) When a QHP's allowable costs for any benefit year are more than 103 percent but not more than 108 percent of the target amount, HHS pays the QHP issuer an amount equal to 50 percent of the target amount in excess of 103 percent of the target amount; and
(2) When a QHP's allowable costs for any benefit year are more than 108 percent of the target amount, HHS pays to the QHP issuer an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

(c) *Health insurance issuers' remittance of charges.* QHP issuers must remit charges to HHS in the following amounts under the following circumstances:

(1) If a QHP's allowable costs for any benefit year are less than 97 percent but not less than 92 percent of the target amount, the QHP issuer must remit charges to HHS an amount equal to 50 percent of the difference between 97 percent of the target amount and the allowable costs; and
(2) When a QHP's allowable costs for any benefit year are less than 92 percent of the target amount, the QHP issuer must remit charges to HHS an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the allowable costs.

§153.610 Risk adjustment issuer requirements.
There is no end to the submission of private patient data. According to the proposed rule, all issuers that offer a risk adjustment covered plan,

"must submit ***all*** required risk adjustment data for those risk adjustment covered plans in the manner and timeframes established by the State, or by HHS on behalf of the State. This data may include but is not limited to:

1) Claims and encounter data for items and services rendered;
2) Enrollment and demographic information; and
3) Prescription drug utilization data " [emphasis added]

Penalties for failure to provide patient data. Health insurers must include data submission requirements in their contracts with "providers, suppliers, physicians, and other practitioners." These contractual provisions "may include financial penalties for failure to submit complete, timely, or accurate data." Notably there are no definitions for "complete" or "timely" or "accurate" leaving the definitions of these terms, and determinations of penalties at the discretion of the payers (insurers and government).

§153.620 Compliance with risk adjustment standards
To the very end of this proposed regulation, the clarion call – the directive -- is for government access to the private data of individual patients. But not only the data that must be reported by the proposed rule. HHS also wants access to **original source**

documents, such as the full medical record and other data sources that validate the reported data:

> "All issuers that offer risk adjustment covered plans must make available to HHS and the State ***any data*** requested to support validation of risk adjustment data reported under this subpart of this part." [emphasis added]

Conclusion

This proposed rule to analyze patients and issue a "risk score" on every individual is an egregious affront to the dignity of patients, the integrity of the medical profession, the confidential patient-doctor relationship critical to good medical care, the constitutional rights of individual citizens, and any remaining trust citizens may have in the American health care system.

We respectfully but firmly request that HHS withdraw the entire proposed rule.

Sincerely,

Twila Brase, RN, PHN
President