December 31, 2019

TO: Office of Inspector General, HHS

RE: “OIG-0936-AA10-P - Revisions to Safe Harbors Under the Anti-Kickback Statute, etc.

Dear Inspector General,

Citizens’ Council for Health Freedom (CCHF), a non-profit health freedom policy organization that began in 1998, specializes in patient-centered care, free from outside third-party interference, privacy intrusions and government controls. We thank you for this opportunity to express our concerns about the proposed rule on kickbacks and safe harbors.

It is noteworthy that the proposed rule, in three-column, small-font text is 72 pages long. How many physicians, clinicians, and patients will read this proposal which will so significantly impact their access to care?

In the Summary of the Major Provisions, we count six new safe harbors, four modifications of current safe harbors, and “codification of the statutory exception to the definition of ‘remuneration.’” All of these changes appear to give the large corporations (who appear to be the ones who will benefit most from this rule) the freedom to more freely spend their money in ways that build their own power, profit structure, and control over the patient-doctor relationship and medical decision-making.

This includes the freedom to donate electronic health records (EHRs) that will be used by outsiders to “coordinate care,” which is another way of saying they will track and profile patients and doctors, collect and analyze confidential data without patient consent (as permitted by HIPAA), and intrude in private medical decisions using “value” equations, their own “medical necessity” definitions, embedded treatment protocols, and financial penalties.

We are opposed to this proposed rule on principle. The proposed rule fully supports a move away from the American way of paying for services (fee-for-service) to a centralized decision-making process called “value-based care” and “value-based payment.” As the proposal notes: “The Secretary of [HHS] has identified transforming our healthcare system to one that pays for value as one of the top priorities of the Department of [HHS].”

The American people have not asked for this transition; Indeed, most have no idea what’s happening behind the scenes of their care. They often don’t know their choices are limited or why they are being pushed to answer surveys, get immunized, or take a certain medication.
Furthermore, our organization does not support value-based payment because its is anti-ethical to free-markets, competition, medical ethics, and the critically-important confidential patient-doctor relationships.

Rather than using this proposed rule to embed anti-free market proposals into American medicine, OIG should drive policy and regulations in the other direction—back to freedom, back to free-markets, and back to affordable first-party payment and direct-pay relationships.

**Value-based payment is not the American way.**

Fee-for-service is the way Americans pay for all goods and services because it's the best way, the free-market way, the competitive way.

Imagine paying lawyers on “value.” Or how about AirBnB, grocery clerks, plumbers or contractors? Imagine paying policemen, not for the hours they work, but for the number of times they make an arrest. How would that work out? Imagine paying a restaurant for how good you, the customer, thought the meal was. How would this value-based payment go over with labor unions or hair stylists, or secretaries, or accountants or even members of Congress?

Value-based payment to doctors and hospitals is also wrong because no patient is asked if their private information can be accessed, shared and used for this specific purpose. Patients have no idea that their confidentiality is being violated to virtually “enter” the exam room, influence their physician’s medical decisions, and remove medical treatment choices that may be perfect for them.

Patients also have no idea that the cost of medical care is rising because of the bureaucratic costs of data collection, reporting and analytics for so-called “quality” measurement, pay-for-performance, and value-based payment. The annual physician cost for quality measurement is $15.4 billion. This is all happening behind the scenes. It’s a booming business for health care corporations and the data industry. Patients don’t even understand that the doctor’s and nurse’s incessant clicking on the EHR is not for their clinical benefit, but simply to satisfy the outsiders making “value-based” payment decisions.

Nothing about value-based payment arrangements is patient-friendly, free-market or will encourage medical excellence. It is solely about imposing outsider control over the exam room.

In other purchases, Americans pay for a service according to the listed price, not a perceived value of that service according to their own estimation. If they don’t like the price (perceived value according to the seller), they can look for another seller. This is free-market and direct payment.

**It is unethical and unconstitutional for OIG to impose rules that insert a conflict of interest between the patient and the doctor.** It is wrong to authorize self-interested outsiders (including CMS, ACOs, and HMOs) to decide the definition of “value” in the exam room and at the hospital, and to authorize these self-interested outsiders to direct the treatment of vulnerable patients by imposing their definitions of “value” on the patient’s doctors through financial penalties or bonuses.
Patients are vulnerable. They cannot protect themselves. They do not understand the words “value-based arrangement” or “value-based payment.” They do not understand that their doctors would be paid on the basis of the government’s definition of value, the HMO’s definition of value, or a black-box algorithm’s definition of value according to those who determined the values used to create the VBP algorithm embedded in an EHR.

Value-based payment will not save Medicare. It will not control costs. It will lead to fewer physicians, harmed patients, unethical decision-making, and decreased access to timely, excellent medical care. It’s already led to physician exodus, with 48% of more than 17,200 physicians surveyed in 2016 considering full or partial departure from hands-on patient care. Furthermore, the “value-based” definitions in the rule are nebulous, with all sorts of wiggle-room because “value” cannot be quantified as an objective, measurable standard—the same way “beauty is in the eye of the beholder.” As a recent study found:

2018 “State of Value” Study (Univ. of Utah):

“Then they need to consider how they will bridge the divergent interpretations of value. It turns out one reason there’s been such little progress in creating a value-based system is that the stakeholders in the U.S. health care system — patients, providers, hospitals, insurers, employee benefit providers, and policy makers — have no common definition of value and don’t agree on the mix of elements composing it (quality? service? cost? outcomes? access?).

“That’s the big takeaway of University of Utah Health’s The State of Value in U.S. Health Care survey. We asked more than 5,000 patients, more than 600 physicians, and more than 500 employers who provide medical benefits across the nation how they think about the quality, service, and cost of health care. We focused on these groups because we feel their voices have not been heard clearly enough in the value discussion.

“What we discovered is that there are fundamental differences in how they define value in health care and to whom they assign responsibility for achieving it.

“Value, it seems, has become a buzzword; its meaning is often unclear and shifting, depending on who’s setting the agenda. As a result, health care stakeholders, who for years thought they were driving toward a shared destination, have actually been part of a fragmented rush toward different points of the compass.” - Harvard Business Review, February 27, 2018 [emphasis added], https://hbr.org/2018/02/we-wont-get-value-based-health-care-until-we-agree-on-what-value-means

The proposed rule does not even define “value.”

Thus, OIG proposes to let federal agencies and health plans define “value” in whatever way they decide to define it, in every medical encounter even if it hurts the patient, violates the practitioner’s conscience, or causes physicians to leave the profession.

Government agencies and health plans (the payers) do not (and indeed cannot) have the best in mind for the patient. Only America’s physicians and clinicians and their staff can do that. They alone
know the patient, and have a professional obligation to the patient. Corporations and government agencies have obligations to stockholders, taxpayers, and Congress.

The troubling goal of value-based payment is found in the definition of "value-based purpose." As defined on page 55762:

Value-based purpose means—
(1) Coordinating and managing the care of a target patient population;
(2) Improving the quality of care for a target patient population;
(3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Notably, there’s no definition of “quality” in the proposed rule so it seems federal agencies and health plans will be able to define that to their own benefit, not to the patient’s benefit or the practitioner’s ethical standards. As an Institute of Medicine paper once noted, quality is difficult to judge and requires “value judgments” (making VBP and quality definitions a circular process):


"Defining health is difficult because of differences in what may be valued and attainable and because of the sometimes tenuous relationship between health services and health outcomes.

"These are not theoretical issues for those responsible for operating a program to assure quality health care. The process involves eliciting and balancing value judgments, often when legitimate interests are in conflict. Responsibilities are often shared and are therefore ambiguous.

"Even when the decisions are sound and the appropriate services are delivered with technical proficiency, poor outcomes can occur. Conversely, bad decisions or inept care will not always be followed by poor outcomes. The quality of care cannot necessarily be judged by the outcome for an individual, so accountability is further diffused.

"These issues must be understood in defining quality health care and designing programs and systems to assure it. (https://www.ncbi.nlm.nih.gov/books/NBK235460/)
Most interesting in the value-based purpose definition is (4): “transitioning from health care delivery and payment mechanisms based on volume of items and services provided to mechanisms based on the quality of care and control of costs….”

The clear purpose is to leave the American free-market system of paying a stated fee for a stated service behind and to move to a more centralized (socialized) manner of paying America’s doctors. This does not bode well for patients, doctors, American freedom, customized care, or medical excellence.

Medicare and third-party payment are the cause of this continual move to centralized decision-making, centralized payment, and centralized control over doctors -- the foundation of a socialized health care system, like Medicare for All, which President Trump said on October 3, 2019 that he does not support. The president doesn’t want to: "put everyone into a single socialist government-run program that would end private insurance."

Therefore, CCHF suggests a different direction. OIG should focus on how to let citizens escape the failing Medicare system before it becomes a rationing-trap to the 10,000 people entering it every day. OIG should not help Medicare and medical care in general become a system of “value-based rationing” through value-based payment.

Specific Suggestions:

1) Withdraw this proposed rule.

2) Require patients to be warned, verbally, and in a specific separate written document (that they sign upon registration and admission), which acknowledges that they (the patient) have been informed that treatment decisions will be influenced by how the government and health plans define value, and that physicians, other clinicians and medical facilities may be financially penalized if they do not follow the treatment algorithms and standards valued by payers, and that these values may or may not align with the patient’s values and needs.

3) Broadly announce and encourage Americans to take advantage of the freedom provided by President Trump’s Executive Order 13890 (Section 11). The EO allows Americans to opt out of Medicare without losing Social Security benefits.

4) Rapidly move to “remove unnecessary barriers to private contracts that allow Medicare beneficiaries to obtain the care of their choice and facilitate the development of market-driven prices.” (also EO 13890, Section 11)

The administration should address the core issue of Medicare insolvency and costs: third-party payment of medical bills, which is a moral hazard, and Medicare itself -- a government program that cannot deliver, has high bureaucratic expenses, provides improper payments and is rife with fraud.
It is wrong not to address the real financial culprits and to instead propose an unconstitutional system that puts doctors in conflict with patients, puts outsiders in control of medical decisions, and uses outsider “values” to ration care to unsuspecting, vulnerable patients.

If Medicare trustees are correct in the most recent predictions, Medicare insolvency begins in 2026. Value-based payment isn’t the answer to the cost woes of a system set up in 1965 as a Ponzi scheme; a system where today’s recipients are receiving care that costs up to three times as much as they paid in payroll taxes.

Americans need to be warned about the realities of Medicare, and given a whole set of reasons to leave and opportunities to do so.

The Trump administration should do everything possible to put patients and doctors and their hospitals back together in direct-pay, private-payment relationships that align the interests of patients and doctors, and let patients and their doctors make their own value-based decisions for medical care.

The following is a diagram from our Wedge of Health Freedom website (jointhewedge.com) that looks into the future and sees a better way—direct payment, affordable care, patient-centered medical decisions, no interference, confidentiality, and the end of third-party payment:

![Diagram showing today and future medical care models.]

This proposed kickback and safe harbor rule to establish and embed a value-based payment system for American medicine is not the answer to what ails health care today.

It will only make things worse. It will hurt patients and encourage the exodus of the physicians that patients need. Therefore, CCHF requests that it be withdrawn.

Sincerely,

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