PatientRightsAdvocate.org
1188 Centre Street
Newton, MA 02459

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-1850

June 3, 2019 RE: Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers (CMS-9115-P)

Dear Administrator Verma:

PatientRightsAdvocate.org appreciates the opportunity to submit comments in response to the CMS Interoperability and Patient Access Proposed Rule (CMS-9115-P). We thank CMS and support the proposed rules to increase interoperability and patient access to health information. Timely implementation will empower consumers with their health information, allow patients, employers, and the government to shop for their healthcare and health plans in a trusted, competitive market, and enable innovators to develop mobile tools for patients, their caregivers, and employers.

We support patient access to their complete electronic health information inclusive of digital access to real prices, system-wide, and comprehensive billing and payment information.

PatientRightsAdvocate.org further supports:

- That the definition of electronic health information is consistent with the broad HIPAA definition of health information which states that patients are to have access to information about their past, present, or future physical or mental health, the provision of care, and past present and future payment information.

- Patient and provider shared access to the electronic health information be readily available, automatic, free, and including but not limited to patient health record, lab tests, radiology results, actual MRIs, images, medications including prescription drugs and other supplements, devices, and physician notes through open, standardized APIs without special effort.

- Inclusion of requirements that all data needed for real price transparency are readily accessible to patients online and comparative to cash and other contract negotiated rates before they receive care as part of the definition of electronic health information and that patients have automatic, free, digital access to their complete payment and billing information.

- That EHR vendors and provider IT systems share patient electronic health information readily, timely, easily accessible and free with the patient and other providers through standardized APIs and free to patients and mobile app innovators acting on behalf of patients.

- The requirement that a patient's ADT (Admission, Discharge, or Transfer) information and care plan is automatically shared with the patient's primary care physicians, designated providers, and designated proxy or caregiver.

- Implementation of the interoperability and patient access regulations within one year. We oppose the HITAC Committee requesting delay of between two and five years, as the technology exists to provide health and clinical information as well as pricing and payment information, timely, and in a standardized, digital format.

- EHR vendors and providers that have benefited from the nearly $40 billion of federal funding and certification should enable standardized API access to patients free of charge and not be able to hold such information as proprietary, require source code, or hold hostage patient information from entities seeking access for patients through anti-competitive practices and financial demands. Withholding access to patient data and creating unwarranted barriers to open, standard API's should be considered Information Blocking.

We encourage CMS to continue within its administrative authority to free up proprietary oligopolistic and monopolistic practices and constraints on patients and their physicians, and to allow for a breadth of competition in the marketplace beyond the states to further restore the patient/physician relationship and increase competition and access. We urge HHS to allow for the freedom of innovation outside of this existing framework and certification such that novel approaches and innovators can catapult health information delivery systems and cost efficient care and access beyond yesterday's, and today's frameworks and vision.

The American public, employers, and our government will benefit with access to critical health information and transparency. Such discovery will empower all to best shop for our healthcare based on competition in price, quality, outcomes, service, and innovation.

The healthcare system will then be able to deliver the best quality of care at the lowest possible price through a trusted, competitive marketplace. "Sunlight is the best disinfectant" (Louis Brandeis, 1914). Access to information and transparency will reduce the many layers of opacity and unwarranted revenue optimization capitalizing on the patient's misfortune. Visibility into comparative prices and services across our country and broadened competitive choices in care and plans will also expose the price-gouging, overcharging waste, fraud, and abuse. As in other free, competitive markets (financial, grocery, retail, airlines, and ride sharing), transparency, choice, and freedom from monopolistic practices will drastically reduce today's runaway costs of care.

Administrator Verma, we thank you for your and your team's dedication to deliver interoperability and patient access throughout our healthcare system. We thank you for this opportunity to comment.

PatientRightsAdvocate.org's Detailed Comments follow in the subsequent pages of this letter, pages 4 through 8.

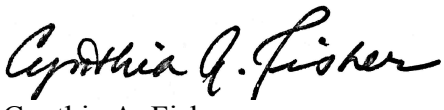
We have also attached the following appendices:

Appendix A explains the Ability for HHS to Achieve Timely Implementation of Negotiated Rate Disclosure Using Existing Examples.

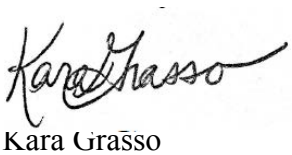
Appendix B provides the legal argument that Federal Healthcare Price Transparency Rules Are Constitutional And Pro-Competitive.

Appendix C provides the Minority Opinion Letter to the ONC Health IT Advisory Committee (HITAC).

Sincerely,



Cynthia A. Fisher
Founder, Board Chair, PatientRightsAdvocate.org
Managing Director, WaterRev, LLC
Founder, Former CEO, ViaCord, Inc.



Kara Grasso
President, PatientRightsAdvocate.org

PatientRightsAdvocate.org
CMS Interoperability and Patient Access Proposed Rule Detailed Comments

I. API Data Elements: Patient Access and Price Transparency

A. *We urge CMS to enact the vision of Congress set out in the Cures Act and ensure that all data elements in the patient's electronic record be made available to the patient, inclusive of all Real Price Information[1] through open, standard APIs, accessible without special effort and free.*

We support CMS' push for expanded API access to health information for individuals. We agree that individuals should be able to have their healthcare data including adjudicated claims data, such as provider remittances and beneficiary or enrollee cost-sharing data; encounters from capitated providers; and clinical data, including MRIs, films, images, laboratory results, care plans, physician notes, etc., easily available to them in a usable electronic, machine- and human-readable form.

We applaud CMS' proposal to include financial information including claims and cost-sharing as an initial step as well as provider directories that identify in-network providers. However, patients need access to both comprehensive Electronic Health Information and Real Price Information, and CMS should require payers to provide such information. FHIR resources exist to support the availability of many financial resources. We urge CMS to include these FHIR resources[2] in their technical requirements for APIs.

B. *In addition to information types included in the Proposed Rule[3], we support patients having real-time, free of charge access to Real Price Information through the open, standardized API to meet CMS' goal of supporting informed patient choice in their healthcare delivery. CMS should clarify that the HIPAA right of access includes Real Price Information inclusive of visibility into provider acceptable cash prices and all net negotiated rates per provider/insurer/plan agreements, and the provider and plan net negotiated rate, including the patient's plan. Average negotiated rates are not useful to individuals trying to make decisions.*

HIPAA requires that patients are able to access health information in electronic format if maintained electronically and readily producible in such form and format. Real Price Information should be readily available electronically through APIs, since EHRs and health plan

[1] Real Price Information is the amount paid to providers for healthcare by the patient as well as any other payers, either by an agreed upon cash price by the patient or contract negotiated rates paid by patients as well as any other payers. It includes discounts and other itemized financial incentives and payments transacted by middlemen or other actors in the healthcare supply chain. Real Price Information shall be real-time, dynamically updated, and in machine-readable format, to reflect the true, real price. When it pertains to a specific patient, it shall include the total and the net negotiated amounts paid including itemized payments paid to providers, regardless of the combination of payers, and the patient's complete out-of-pocket cost information, based on the benefit plan (including deductibles and co-payments).

[2] https://www.hl7.org/fhir/financial-module.html

[3] https://www.federalregister.gov/d/2019-02200/p-213, Adjudicated claims (including cost); encounters with capitated providers; provider remittances; enrollee cost-sharing; and clinical data and laboratory results.

payment systems are designed to facilitate billing and reimbursement. The HIPAA Transactions and Code Set rules specify standards and code sets for financial and administrative transactions between healthcare providers and health plans. See Appendix A.

As such, these standards exist, are incorporated into EHRs and health plan systems, and are already in widespread use. Each provider can readily disclose and post online not the acceptable cash price for services rendered by procedure all in and reinsured, or by CPT code, ICD-9 code, bundled and unbundled, and disclose all of the contract negotiated prices per agreed plans.

PatientRightsAdvocate.org has interviewed seven technology companies. Each has told us that once these prices are posted, innovators can aggregate and harmonize real pricing data within weeks to three months, and provide mobile applications for patients and employers to comparatively shop for care. Once price discovery is implemented, patient engagement reporting quality and value, outcomes, service can readily be incorporated and measured like the mobile apps of Yelp, Uber, Amazon, and Priceline. This price discovery can be realized by the American public before year-end 2020.

Plans are already obligated to provide patients with much of this information under the HIPAA individual right of access. HIPAA requires patients to have access to their designated record set, which includes "medical records and billing records about individuals maintained by or for a covered healthcare provider," records maintained for "the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for the health plan" and information "used in whole or in part to make decisions about individuals." The designated record set is much broader than Explanation of Benefits (EOB) information. Also, we note that the Net Price Information should be provided, as it is necessary for payment and claims adjudication and is used to make decisions about individuals with respect to the cost and payment for care.

In our comments to ONC regarding the definition of "electronic health information," (EHI) we suggest that ONC adopt a definition that is consistent with the HIPAA definition of "health information" which notes information relating to future payment:

> "Health information means any information, including genetic information, whether oral or recorded in any form or medium, that:
>
> (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
>
> (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."[4]

We suggest that the EHI definition should not be limited to identifiable information and should include Real Price Information. CMS should work with ONC to adopt a final rule that supports the inclusion of Real Price Information which can be provided by the provider in cash price and

[4] Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 CFR 160.103

contract negotiated rate postings. Additionally, comprehensive billing and payment information can be digitally delivered as part of the patient's access to their complete electronic health information. Achieving true interoperability in the healthcare industry is predicated on the correct alignment of financial incentives between stakeholders, including individual consumers of healthcare services. We cannot achieve interoperability or move toward a more functional, efficient healthcare market if we do not empower individuals to make decisions regarding the future payment for services. Stakeholders simply cannot make an informed decision without price and payment information.

An approach that imposes requirements on both providers and health plans will enable patients to shop for care before deciding on the provider of that healthcare service. Patient access to information regarding rebates or other relevant financial incentives related to a patient's healthcare will also allow patients and other providers to evaluate the entities' incentives when making care decisions. The inclusion of price information will help patients understand the data directly related to treatment that influences a provider decision, such as clinical decision support recommendations. This information may not include identifiable information but is directly related to the health of a particular individual.

We believe that our suggested changes to the broader definition of EHI is best aligned with Congressional intent and also meets the goal of providing patients with critical information that they need to make decisions.

C. *We suggest that CMS introduce the term Real Price Information as defined above. To comply with the rule, providers and plans must make available all of the information that they, their contractors and administrators have and use to arrive at Real Price Information to individuals, their authorized representatives (including third-party application developers accessing data with the individual's authorization) and the public, free of charge and easy to access electronically on their websites, in machine-readable format via the open, standard APIs*:

- For individuals and the public: Provider accepted cash prices, bundled and unbundled, and procedure based, and/or as displayed in price transparent surgical centers and physician practices, guaranteed or reinsured.

- For individuals and the public: Contract terms, cost-sharing arrangements, and prescription drug prices, including any payments, rebates, reimbursements, or other form of remuneration that plans make to providers for healthcare services, prescription drugs, medical devices, and medication, publicly available.

- For individuals: Individuals' coverage and benefits information, including cost-sharing arrangements such as co-pays, co-insurance, and progress toward meeting their deductible;

- Contract terms include: Percentage of provider's fee schedule or chargemaster; percentage of the applicable CMS fee schedule; plan fee schedule; negotiated rates for specific healthcare services; any applicable carve-outs including negotiated prices for specific line items, individual services, procedures, or treatments; prices, including those derived from base rates or multipliers or for bundled healthcare services.

- Cost-sharing arrangements include: Costs for healthcare services that are not reimbursed by a health plan, including any deductibles, co-payments, or coinsurance amounts.

D. *We suggest that CMS require MA organizations, Medicaid state agencies, state CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in Federally Funded Exchanges to provide all patient data, including Real Price Information, and billing, and payment information through open, standard APIs.*

II. API Requirements

A. *Patients must have real-time, free, machine-readable electronic access to their Complete Health Information through open, standard APIs, without any delays or burdensome requirements – without "special effort" as intended by Congress in the Cures Act. Patients should not be required to pay for any access, exchange, or use of their electronic health information (EHI).*

Patients are not currently able to access the information they need to make care decisions, seek second opinions, or effectively care for family members or other loved ones. Breakdowns in patient access to health information lead to inefficiencies across the healthcare system, including duplicative testing, increased volume of services, and inflated costs. Healthcare providers, health plans and other entities artificially limit access to EHI in a variety of ways, including requiring paper consent forms, charging egregious fees for electronic access, or outright refusing to facilitate patient access to health information – despite patients' legal right to receive this information under HIPAA. These practices are widespread across the healthcare industry.

B. *Claims and encounter data should be updated in real-time and should be accessible by open, standard APIs. CMS should take this opportunity to enact timeliness requirements that allow patients to access their information at any point during the provision of healthcare and optimize the industry.*

Real-time access to electronic health information is critical for meeting the needs of patients that require that information to manage their care. Delays of any duration can negatively impact patient safety, prevent effective care coordination, or clinical decision-making by a patient, provider, or authorized third-party. Any data collected as a result of a patient encounter or which may directly support the provision of care (such as provider notes, lab test results, images, etc.) must be included when exporting data for a patient access request, as it may have significant clinical implications for the patient.

C. *We support CMS' proposal that requires the provider directory information to be publicly available through API technology. Importantly, updates to provider directory information should be available in real-time when provider changes are made.*

MA organizations, state Medicaid and CHIP Fee for service programs, Medicaid managed care plans, and CHIP managed care entities are currently required to provide provider directory information online and to enrollees at no-cost. We agree with CMS that the availability of this information in open, standard APIs would allow patients to better understand their individual

healthcare options and note that this proposal would allow third parties to process and display this data in ways that will improve care coordination and reduce healthcare costs.

The proposed requirement that provider directory information be updated within 30 days of a change will impede the goals of this rule – entities should be required to update provider directories in real-time.

D. *We support CMS' proposed revisions to the Conditions of Participation that would require hospitals to generate electronic patient event notifications (ADT messages) regarding a patient's admission, discharge and/or transfer from the hospital.*

Real-time notifications of clinical events are an effective tool to manage patients' care coordination. Patients should be able to indicate their primary care providers and which other providers and proxy or caregiver should receive alerts regarding changes to their status as they are tracked in the hospital's electronic health record. Hospitals should transmit a patient's real-time clinical data to their providers upon admission, discharge, and/or transfer in order to ensure that providers can determine the appropriate follow up care in a timely manner. The proposed ADT message requirements will help ensure that patients receive adequate post-discharge care and will improve efficiency by reducing readmissions.

III. Conclusion

We applaud HHS' effort to make patient information easily and automatically available for patients in free, human and machine readable formats to support patient care. CMS must ensure that this information includes all information that patients need to make decisions about care, including comprehensive Electronic Health Information, Real Price Information, and billing and payment information.

Concerns raised by those who hold this information about the complexity and cost should not overshadow the important needs of patients. Patients pay for their care and deserve to have their own information related to that care and to know the real price in advance of care. Real-time, free, electronic access to comprehensive Electronic Health Information including real prices, billing, and payment is critical for patient empowerment, the ability to reduce costs, improvements in quality of decisions, care, and outcomes while creating a trusted, competitive marketplace in healthcare.

Thank you again for the opportunity to submit comments on this important topic.

Appendix A

Ability for HHS to Achieve Timely Implementation of Negotiated Rate Disclosure Using Existing Examples

Background

Recently, the Centers for Medicare and Medicaid Services ("CMS") has moved to require health insurance companies and health care providers to make public their contracted rates, affording the public a more transparent picture of the 'true cost' of the health care services they receive. Both health insurers and providers are opposing the proposed rulemaking requiring the publication of contracted rates, arguing that the information is proprietary and a release would violate contractual confidentiality provisions.

Another argument made by stakeholders in opposition is that disclosing the information will be overly burdensome, difficult to standardize, and result in additional consumer confusion. It will be important for policymakers to address this point, both as they look to enhance transparency, but also as they design a framework that proves effective in providing consumers accurate information to assist in making health care purchasing decisions.

Hospital and Physician Groups Mergers and Acquisitions (M&A): Examples of Negotiated Rate Disclosures

Each year hospitals and health systems, physician groups, and other health care providers engage in M&A activity. Over the last decade, activity in the hospital and physician practice sector has been at all-time highs, with more than 100 hospital deals each year, on average, and significant interest in physician practices by health systems, private equity firms, and large strategic acquirers (e.g., Optum). Other than in cases where a potential antitrust issue may be raised, almost all of these transactions result in the exchange and analysis of proprietary rate information prior to consummation.

The exchange of this information, which occurs in the later stages of a M&A process, could provide a framework for disclosure that seeks to provide greater consumer transparency, also dispelling the notion that obtaining such information is 'difficult if not impossible.' Rate information disclosure in an acquisition process generally follows a pattern, as follows:

- A party that is being acquired will post its rate card information and contracts to a data room, where the acquiring party can access the information
- The acquiring party will run an assessment of how the rates compare to market level health insurance reimbursement, or to the actual rates that the acquiring entity is being paid by health insurers—if applicable market overlap exists. This assessment will often be done by a third party firm (e.g., Big Four accounting firm or leading consulting firm)
- This assessment will inform the final purchase price, or at a minimum, inform go-forward decisions around capitalization and revenue growth opportunities

In the context of a M&A transaction, rate information is generally disclosed in a time efficient manner. While it may take additional effort from finance executives, it is neither impossible nor prohibitive to produce. Further, the ability of third party firms to quickly assess the disclosed negotiated rate information and create go-forward financial models is well established.

Appendix B

Federal Health Care Price Transparency Rules Are Constitutional And Pro-Competitive

Jeffrey M. Harris
Consovoy McCarthy PLLC
June 3, 2019

This memorandum responds to two of the principal legal objections to federal regulations that would promote increased price transparency in health care markets: first, that such regulations would violate the First Amendment; and, second, that such regulations would interfere with contractual confidentiality clauses that prohibit disclosing prices. Those arguments are without merit, and the Supreme Court has rejected nearly identical contentions in a number of cases. We address each in turn.

I. Price Transparency Rules Are Consistent With The First Amendment.

The Supreme Court has emphasized that "[s]o long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions." *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976). It is thus "a matter of public interest that those decisions, in the aggregate, be intelligent and well informed." *Id.* "To this end, *the free flow of commercial information is indispensable.*" *Id.* (emphasis added); *see also Snyder v. Phelps*, 131 S. Ct. 1207, 1215 (2011) (First Amendment reflects "a profound national commitment to the principle that debate on public issues should be uninhibited, robust, and wide open").

In *Virginia Board of Pharmacy*, the Supreme Court struck down as unconstitutional a state law that prohibited pharmacists from advertising the prices of prescription drugs. As the Court explained, the suppression of information about health care prices "hits the hardest … the poor, the sick, and particularly the aged," who spend a significant part of their income on health care but "are the least able to learn … where their scarce dollars are best spent." 425 U.S. at 763. The Court emphasized that, given the "striking" variations in the cost of different prescription drugs, "information as to who is charging what [is] more than a convenience," and "could mean the alleviation of physical pain or the enjoyment of basic necessities." *Id.* at 763-64. At a more general level, there is a powerful public interest in "the free flow of commercial information." *Id.* at 764. The Court thus concluded that any attempts to stifle the publication of information about prices would violate the First Amendment. *See also Bates v. State Bar of Arizona*, 433 U.S. 350 (1977) (holding that state's prohibition on attorneys advertising their fees violated First Amendment); *44 Liquormart v. State of Rhode Island*, 517 U.S. 484 (1996) (holding that ban on price advertising for alcoholic beverages violated First Amendment).

Just as the Supreme Court has struck down laws that seek to *prohibit* the disclosure of information about prices or costs, it has also upheld laws that seek to *promote* public access to pricing information. In the landmark case of *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), the Court rejected a First Amendment challenge to an Ohio regulation that required attorneys to disclose in their advertisements certain information about their fee

arrangements. As the Court explained, there are "material differences between disclosure requirements and outright prohibitions on speech." *Id.* at 650. A price-disclosure requirement does not "prevent" anyone from "conveying information to the public"; instead, it merely "require[s] them to provide somewhat more information than they might otherwise be inclined to present." *Id.* The Supreme Court thus applied a rule under which the relevant First Amendment rights "are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651. Applying that standard, the Court upheld an Ohio law that required attorneys to disclose in their advertisements if clients in contingent-fee cases could be forced to pay costs following an unsuccessful suit. *Id.* at 652.

Price transparency rules are common in other industries, and—consistent with the Supreme Court's decision in *Zauderer*—those laws have never been found to violate the First Amendment. For example, to enable comparison shopping, the Department of Transportation requires airlines to prominently advertise the all-in price of a ticket that shows *what the customer will actually pay—i.e.*, the fare charged by the airline plus all applicable taxes and fees. The U.S. Court of Appeals for the D.C. Circuit rejected a First Amendment challenge to that price-transparency regulation, holding that it was merely "a disclosure requirement rather than an affirmative limitation on speech." *Spirit Airlines v. Dep't of Transp.*, 687 F.3d 403, 412-13 (D.C. Cir. 2012). As the court explained, "the Airfare Advertising Rule does not prohibit airlines from saying anything; it just requires them to disclose the total, final price and to make it the most prominent figure in their advertisements." *Id.* at 414. In short, the rule did not violate the First Amendment because it "is aimed at *providing accurate information*, not restricting it." *Id.* (emphasis added).

Similarly, the Federal Trade Commission has promulgated a "Funeral Rule" that imposes extensive price-transparency rules on providers of funeral-related goods and services. *See* Final Rule, *Funeral Industry Practices*, 47 Fed. Reg. 42,260 (Sept. 24, 1982). A key provision of that rule requires funeral providers to give their customers an itemized price list that displays "standardized price information" for each available service, thereby "enabl[ing] consumers to weigh the costs and benefits both of the various alternatives to a traditional funeral and of the individual items which they might select for use with a traditional funeral." *Id.* at 42,272. The concerns that led to the adoption of the Funeral Rule apply with full force in the health care context: both situations involve expensive, often one-time transactions that are necessarily undertaken during a stressful and emotional time for the consumer. No court has ever so much as suggested that the Funeral Rule's disclosure requirements violate the First Amendment, and the same underlying interests would justify price-transparency regulations in the health care context as well.

In raising First Amendment objections to price transparency regulations, critics have pointed to cases such as *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), *Am. Meat Institute v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc), and *Am. Beverage Ass'n v. City & Cnty. of San Francisco*, 916 F.3d 749 (9th Cir. 2019) (en banc). But none of those cases casts doubt on the constitutionality of price disclosure requirements. For example, in *American Meat Institute*, the D.C. Circuit *rejected* a First Amendment challenge to the Department of Agriculture's country-of-origin labeling requirements for food products, holding that the rules were permissible under *Zauderer* because they merely sought to ensure that consumers had

accurate information about the products they were purchasing. And, although the same court in *R.J. Reynolds* had struck down as unconstitutional a requirement that cigarette companies put graphic images of smoking-related health conditions on their packages, the D.C. Circuit *overruled* key aspects of that decision in *American Meat Institute*. *See* 760 F.3d at 22-23. The court held that the government had a legitimate interest not only in preventing deception but also in ensuring that consumers had accurate information upon which they could base their purchasing decisions. *Id.* at 22-25.

The Ninth Circuit's decision in *American Beverage Association* is also readily distinguishable. That case did not involve disclosure rules regarding prices. Instead, it involved a San Francisco ordinance that forced soft-drink makers to include government-written warnings in their advertisements about the alleged health effects of their beverages. Because San Francisco required the warnings to occupy at least 20% of the space of the advertisements—thereby commandeering a significant portion of the companies' message—the court found that these regulations were "unduly burdensome when balanced against [the] likely burden on protected speech." 916 F.3d at 757. But that reasoning would have no application to regulations that merely required disclosure of *prices*.

Some critics of transparency rules have also argued that medical prices are so complex that public disclosure of certain pricing information would lead only to consumer confusion. But the Supreme Court has rejected this "highly paternalistic approach" to the First Amendment. *Virginia Bd. of Pharmacy*, 425 U.S. at 770. Rather than assuming that consumers will be confused by too much information, the First Amendment assumes "that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." *Id.* As between "the dangers of suppressing information" or "the dangers of its misuse if it is freely available," the First Amendment counsels in favor of openness and transparency. *Id.* In sum, the government has no legitimate interest in any policy that "rests in large measure on the advantages of [the public] being kept in ignorance." *Id.* at 769.

II. Gag Orders Or Confidentiality Clauses In Providers' Contracts Pose No Obstacle To Federal Price Transparency Rules.

Some critics have argued that federal price transparency rules would be unlawful to the extent they require the disclosure of price information that is deemed confidential under a contract between two parties in the health care distribution chain. For example, contracts between insurers and hospitals often contain gag orders providing that the negotiated prices for certain services must be kept confidential; those confidentiality clauses may also apply to employers who contract with the health insurers for coverage.

Any self-imposed gag orders or confidentiality clauses in private contracts pose no obstacle to federal price-transparency regulations. All private contracts "must necessarily be regarded as having been made subject to the possibility that, at some future time, Congress might so exert its whole constitutional power in regulating interstate commerce as to render that agreement unenforceable, or to impair its value." *Louisville N. & R. Co. v. Mottley*, 219 U.S. 467, 482 (1911). That is, "contracts must be understood as made in reference to the possible

exercise of the rightful authority of the government, and no obligation of a contract can extend to the defeat of legitimate government authority." *Id.* The Supreme Court has emphasized that it would be "inconceivable" that the federal government's authority "may be hampered or restricted to any extent by contracts previously made between individuals or corporations." *Id.* In short, "[p]arties cannot remove their transactions from the reach of dominant constitutional power by making contracts about them." *Norman v. Baltimore & O. R. Co.*, 294 U.S. 240, 308 (1935).

The Supreme Court has applied those general principles in countless contexts. In *Norman*, the Court held that "gold clauses" in private contracts were invalid to the extent they interfered with federal power to regulate the currency and establish a monetary system. *Id.* at 311. Similarly, a contract between a shipper and a common carrier for transportation at certain rates is invalid if federal regulators have prescribed different rates, *even if the rates were lawful when the contracts were made*. *Id.* at 308; *see also New York v. United States*, 257 U.S. 591, 600-01 (1922); *United States v. Village of Hubbard*, 266 U.S. 474, 477 (1925); *Armour Packing Co. v. United States*, 209 U.S. 56, 80-82 (1908). And, in the antitrust context, "no previous contracts or combinations can prevent the application of the Sherman Act to compel the discontinuation of illegal combinations." *United States v. Southern Pac. Co.*, 259 U.S. 214, 234-35 (1922).

These cases foreclose any suggestion that federal price-transparency regulations could be evaded through private confidentiality clauses or gag orders. Federal regulations carry the same "force of law" as federal statutes, and federal agencies have the power to promulgate "binding legal rules" pursuant to their statutory grants of authority. *See Mayo Foundation for Medical Educ. & Research v. United States*, 562 U.S. 44, 57 (2011). Price transparency regulations would thus supersede and take precedence over any contractual provisions to the contrary.

Finally, the Constitution's Contract Clause is also inapplicable here. In certain circumstances, that Clause prohibits any "Law impairing the Obligation of Contracts." U.S. Const., art. I, § 10, cl. 1. But the Contract Clause, by its express terms, applies only to the States; it does not impose any limits on the federal government's ability to abrogate contractual provisions.

CONCLUSION

In sum, far from being unconstitutional or unlawful, price-transparency regulations would promote the values at the core of the First Amendment by ensuring that consumers can make choices in their own best interest based on full and complete information about the costs of health care services. Price-transparency regulations are entirely consistent with the relevant constitutional and statutory constraints, and would represent an important step toward bringing the benefits of robust price competition to the health care sector.

Appendix C

Minority Opinion Letter to the ONC Health IT Advisory Committee (HITAC)

June 3, 2019

VIA EMAIL

Dr. Don Rucker
Office of the National Coordinator for Health IT
330 C Street SW
Washington, DC 20416

Re: Revisions to Information Blocking Task Force Recommendations

Dear Dr. Rucker:

I respectfully request that the HITAC transmittal letter to the National Coordinator regarding the Information Blocking Task Force recommendations be revised to include minority opinions that were expressed during the Health Information Technology Advisory Committee (HITAC) calls or documented as part of the Information Blocking Task Force (Task Force) meetings. I serve on this committee and task force to represent the millions of American patients, caregivers, and business owners that are affected by rising healthcare costs.

I raised concerns about a number of the recommendations in writing and in the meetings, and I would like to make sure that my positions are included. In addition to my comments at the HITAC meetings, I contributed alternative language for the group's proposals, supporting documentation (e.g, existing statute or regulation), and suggestions for preamble or regulatory text, and I raised opposition to a number of the Task Force's proposed recommendations in my May 11, 2019 email in advance of the May 13, 2019 HITAC meeting vote. During the meeting, I abstained from verbal voting on recommendations with which I did not agree.

On May 22, 2019, I submitted objections to Robert Wah and Carolyn Petersen. The Task Force's June 3, 2019 recommendations addressed several of my concerns, however, there are a number of areas where the recommendations did not include my minority opinion. My outstanding objections are listed below.

Thank you for your consideration.

Recommendations 1 & 2

I oppose the Information Blocking Task Force's recommended definition of Health Information Network and Health Information Exchange.

The recommended definition is inconsistent with Congressional intent. The 21st Century Cures act clearly defines four actors that can engage in information blocking: health information

technology developers, Health Information Exchanges, Health Information Networks, and providers. Pub.L. 114 – 255 §3022(a)(1)(B), The 21st Century Cures Act (2016)

Defining HIE as a verb makes no sense since Congress defined HIEs as entities covered by the statute. Also, "exchange" is used elsewhere in the statute and regulation.

The definition of HIN should not be changed from what ONC proposed. This term as proposed is broad which is necessary to ensure all critical information is shared for patient needs. ONC should not delete "substantially influences" from the definition.

Recommendation 3

As mentioned in the minority opinion, I suggest we revise (3) of the recommended regulation as follows:

> (3) Electronic information which can reasonably be used to inform care decisions, by a provider or patient, including all pricing information whether or not it is identifiable to an individual patient and pricing information which can be attributable to an individual patient.

Price information should be provided whether or not it is identifiable to an individual patient.

Recommendation 6

I oppose the Information Blocking Task Force's recommended definition of "health IT developer."

The recommendation will likely inhibit innovation and create significant barriers for entry for products that may have important impacts to the patient experience in healthcare delivery. Furthermore, the enforcement authority section of Cures makes it clear that it was intended to apply only to certified health IT developers. Pub. L. 114 – 255, The 21st Century Cures Act (2016)

ONC should adopt a definition that retains the current limitations on the entities that can fall within the "health IT developer" definition. These Actors should only include health IT entities that have certified products.

Recommendation 8

I oppose the Information Blocking Task Force's recommendation regarding patient access. It is unclear as to what the Task Force is recommending.

ONC's focus should be on developing regulations that address information blocking practices, rather than the tools that consumers can use to understand their data. As data begins to flow, the market and innovators will begin to provide tools for interpreting patient data. Patient access must be in real-time and at no cost.

Recommendation 10

I oppose the inclusion of "Retailers who provide IoT type devices and services to collect patient information from connected consumer devices."

These organizations should not be defined as "Actors" and their inclusion in the rule will likely inhibit innovation and create significant barriers for entry for products that may have important impacts to the patient experience in health care delivery. "Retailers" that sell IoT-type devices and services to consumers typically offer APIs and greater patient control of data; this will empower patients to make informed decisions about their health care. Further, the Cures Act specifies that OIG will have enforcement authority over developers of certified health IT only. There is no history or context to suggest that Congress intended to include all developers of health technology under the scope of this rule. Doing so will discourage new entrants to the health care market at a time when patients and employers desperately need technologically innovative solutions.

Some of the entities that should be used as examples and clarified in the preamble that they are "networks" or "exchanges" include the following. ONC should emphasize that this is not an exhaustive list:

- Payers and health plans: Payers may enable, facilitate, and control the access of EHI between unaffiliated entities. Payers manage their contracted networks and determine the policies and agreements that define the business and operational requirements for participation in the network. Payers' networks consist of numerous unaffiliated entities such as physicians, pharmacies, pharmacy benefit managers, etc. Specifically, payers determine the reimbursement policies, including net negotiated rates for treatments, and may define the terms or requirements that enable or facilitate the access, exchange, or use of EHI between or among unaffiliated entities for those entities to submit claims for reimbursement.

- Pharmacy benefit managers (PBMs): Like payers, PBMs develop and administer pharmacy networks that consist of unaffiliated entities. PBMs may control, or at minimum, administer policies and procedures that define the operational and technical conditions for claims processing. PBMs may enable or facilitate the access, exchange, or use of EHI between unaffiliated entities such as pharmacies, providers, payers, third-party administrators, drug manufacturers, etc.

- Joint ventures, mergers, and other combined entities: Entities such as pharmacies, laboratories, and rehabilitation centers would be defined as health care providers pursuant to section 3000(3) of the PHSA. Other entities such as medical device suppliers may also be health care providers if they are providing patient-specific services, such as customized medical devices. However, as health care delivery continues to evolve, collaborate, and merge, these entities may also be considered HINs if they engage in activities that enable, facilitate, or control the movement of EHI between or among other unaffiliated entities. To illustrate further, a pharmacy that establishes an effort that facilitates the movement between itself, unaffiliated providers, and the technology of health IT developers would be within the functional definition of an HIN if it administers

the program or sets policies and procedures for the technical exchange of EHI between these entities.

- Health insurance brokers: Brokers enable and facilitate the access, exchange, and use of EHI between individuals and unaffiliated payers in order to assist individuals with choosing the appropriate health plan coverage, and thus should be considered HINs.

- Group purchasing organizations (GPOs): These entities should be included as HIEs as they facilitate access, exchange, and use of EHI for a limited purpose, the purchase of health care products and services. As we noted in the Proposed Rule, HIEs may be established for specific health care or business purposes. In order to determine the appropriate purchasing orders, GPOs facilitate access, exchange, or use of EHI between hospitals, physicians, or other health care providers and unaffiliated medical supply vendors.

- Claims databases: These entities would be defined as HIEs as they are enabling access, exchange and use of EHI among particular classes of entities for a limited set of purposes.

Recommendation 12

I suggest editing the first sentence of this recommendation, as it is currently unclear.

I support a functional definition of the entities covered by the rules; however, I suggest the recommendation include the following:

"Actors must clearly describe their data practices to patients and must get meaningful consent from the actor to collect patient data, except in emergent circumstances. This description must identify current and future uses of the patient data, the methods by which the patient's data is shared, and the entities the data is shared with. Patients must be allowed to opt-in or opt-out from the actor's data practices upon request.

Recommendation 33

I oppose the Information Blocking Task Force's recommendation related to "basic access."

Patients should have free electronic real-time access to all their data in the designated record set. Allowing charges for patient access to any data will limit the patient's right of access and their ability to obtain needed information.

Furthermore, the recommendation unnecessarily narrows the types of pricing information that should be included in a "basic access" data set. All pricing information should be publicly accessible, including but not limited to contract negotiated rates (inclusive of co-pays, deductibles, etc.) and cash prices.

Recommendation 34

I oppose the Information Blocking Task Force's recommendation regarding "value-added services."

Patients must have real-time access free of charge to the electronic health information in their medical record. If a clinician incorporates or relies upon "value-added" services (e.g., risk scores), that information must also be included in the patient's medical record at no cost. The ONC notes in the Proposed Rule that actors are accountable to access requests from "patients who, as consumers of health care services, have paid for their care and the information generated from such care." Patients should not be required to pay for any access, exchange, or use of their EHI, regardless of its "value."

Recommendation 44

I suggest editing the recommendation to include the following:

"The TEFCA, as proposed, is complicated and will add layers of confusion and cost into the availability of data."

Recommendation 45

I suggest editing the recommendation to include the following:

"HHS should ensure that penalties for health care providers are consistent with other Actors under the information blocking rule."

Recommendation 49

I oppose the Information Blocking Task Force's recommendation regarding requirements for amending contracts that contravene the information blocking rule.

ONC proposed a reasonable timeline for health IT developers to amend contracts that contravene the information blocking rule. Health IT developers should not have five years to comply with these rules.

This recommendation would be a failure of the objectives of the interoperability and information blocking accountability. A delay of five years approaches ridiculousness. It effectively negates the goals of the Cures Act to provide patient and provider access to this critical patient health data and hold actors accountable. It is a technique of the entrenched special interests to continue their own self-interest and benefits of status quo – effectively a "kill by delay."

It does not take five years to modify agreements and practices. If renegotiation is too burdensome, ONC could just make it clear that any contractual provisions that are inconsistent with the rules would be unenforceable and void for public policy, consistent with the Task Force's recommendation 43. This would include provisions found in network agreements. The failure to disclose price information would constitute a violation of the information blocking rule regardless of contract limitations.

Recommendation 52

I oppose the Information Blocking Task Force's recommendation regarding the "fair use" of screenshots.

The recommended regulatory text should be revised to state:

> (2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section~~, and with the understanding that any actor disclosing the screenshots is responsible for communicating to the actor they disclose to that subsequent use is to be "fair use~~."

If a physician needed to take a quick screenshot and send it to a patient per his or her request, they should not have to report to an EHR vendor on "fair use," when they are trying to simply deliver efficient, timely care.

Thank you for including these opinions in the letter sent to ONC. I believe these views are critical for the HITAC to acknowledge, as they reflect positions that will directly benefit patients and caregivers.

Respectfully yours,

Cynthia A. Fisher