

PatientRightsAdvocate.org
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Newton, MA 02459

The Honorable Russell T. Vought
Acting Director
United States Office of Management and Budget
725 17th Street NW
Washington, DC 20503

The Honorable Alex M. Azar II
Secretary
United States Dept of Health & Human Services
200 Independence Ave, SW
Washington, DC 20201

January 31, 2020

RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Acting Director Vought and Secretary Azar,

PatientRightsAdvocate.org represents the concerns of the consumers of healthcare – patients, employees, employers, and taxpayers – to have real access, real prices, real choices, and a trusted, competitive market in healthcare. We thank the Administration for your critical interoperability and transparency rules. These rules will empower patients to get complete access to their electronic health information (EHI) and put them back in control of their health and wealth decisions. We firmly believe the Trump Administration’s timely delivery of these rules will restore trust and accountability to the healthcare system and greatly reduce the cost of both care and coverage.

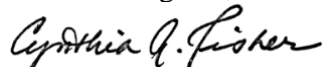
American taxpayers paid nearly \$40 billion to have portable access to their own EHI wherever they get care. Those that benefited from these funds are now oligopolies in their markets – the electronic health record vendors, the hospitals, and the networks holding and blocking this information. They are selectively brokering it and using it to maximize their profits while withholding that very data from the patients who need it most.

Yet again, entities such as Epic and others are information blocking – this time trying to trick public opinion with privacy concerns. In reality, it is a smoke screen to protect their market share, control, and financial interests. Attached are 15 personal stories shared with our organization explaining how this information blocking occurs on a daily basis, jeopardizing patients’ health and financial wealth under the veil of privacy.

We commend the Trump Administration for your bold measures to put the patient back in the driver’s seat and encourage you to stay strong. Only you can invert the system by holding these entities accountable and putting patients over profits.

We urge you to release these rules timely as a part of your transparency agenda. Technology innovators and new competitors are eager to disrupt and help cure the broken system through access to information and prices. They have told us that they can aggregate these data within three to five months in consumer-friendly apps, giving all consumers knowledge, control, and choice. This information will improve patients’ healthcare diagnoses, treatments, and outcomes while greatly reducing the individual and societal cost.

Warmest Regards,



Cynthia A. Fisher
Founder, Chairman, PatientRightsAdvocate.org

Patient, Provider, and Technology Company Stories Regarding Interoperability

- **Elderly Woman:** I am an elderly woman recovering from chemotherapy treatments and have been suffering from dehydration. I passed out and my son had to call an ambulance. The EMT's first question was "What medications is she taking?" My son did not know, because there is no simple way for him or any proxy to access my medical record.

Luckily, I was okay this time, but this lack of access could have had serious consequences. This situation demonstrates the need for complete, real-time, digital access to our electronic health record. I am able to authorize my son to access my financial records with the flip of a switch, and he can access them on his phone in real-time. Why can't the same be true for my healthcare? The same should be true for pricing in healthcare. We as patients deserve to have free, immediate transparency into the real price of all medical services, procedures, tests, and drugs. I am on a fixed income and am very conscientious about prices. I shop for everything else in my life and should be able to do the same thing for my healthcare. Please improve patients' access to their medical records, and please include pricing and billing in this rule. Thank you.

- **Health Care Provider:** Having run emergency medicine departments for decades of my medical career, it wasn't until recently that I got to appreciate as a patient how difficult it is to get access to my own medical records when treated in another emergency room, out of network, and out of state. I was recently treated in another hospital system's emergency department. I then came to understand firsthand the overcharging and up charging that was conducted in my care. This was my first experience realizing the out-of-network surprise billings and up charging coding that I know was not accurate. It took me many weeks to get access to the actual medical record and the actual charge coding. I made several attempts to negotiate on behalf of what was conducted to no avail. I am still in pursuit of being correctly charged. These charges need to be paid by me personally under my high deductible plan.

As a result of this recent experience, I have come to understand and appreciate why Congress enacted the 21st Century Cures Act and the proposed rules for patient and provider electronic health information access and the need for real price transparency and comprehensive electronic billing and payment information provided to the patient. Patient information should be readily available, free, and automatic, inclusive of MRI's, films, and labs through the existing bandwidth we have with today's technologies. Through the proposed transparency, we will greatly empower patients, their physicians, and employers with choices to significantly reduce the cost of care.

- **Patient:** Insurance includes an annual exam at no cost, but if you ask the doctor any questions (achy knee, ear wax, scan for growths) they code diagnostics that bring unexpected charges. The point of free annual visits is to detect issues before they become costly, but this billing practice discourages patients from bringing up any potential items. If the free visit is only to cover blood pressure, pulse, and shots, they could and should be done by PAs. MERSA is a high-end eye clinic that sends 13-sheet forms that patients have to sign explaining any costs not covered by insurance are to be paid by the patient.

Given a high deductible I called in advance to ask what a basic visit would cost. \$250 they said and insisted on up-front payment. The physician recommended an extra procedure so I asked what the cost would be. They came back and said \$70. I agreed. A month later I get a bill showing three procedures all over \$100 and saying I owed the difference. When I called, they

said they quote a min fee and they can't tell what insurance plan will charge them for each. I find it hard to believe that they don't have enough Tuft members to know what the actual cost will be. I can afford these charges, but what they do to lower income people gets me boiling mad.

- **Mother:** Access to our electronic health information, in real-time, is critical for patient safety. I had a syncope episode after being in the heat too long and my adult daughter and her children could not provide any information to the EMTs re: my current medications or health history when they arrived at the outdoor event. This situation could have been seamless if I had my medical information to share on an app of my choice. I also believe that I should see the real prices for medical procedures prior to an encounter just as I am able to see prices on a menu. Price transparency will create competition and drive down all the prices, allowing me to shop for price and quality. Thank you for allowing me the opportunity to comment on the importance of these issues to the US consumer.
- **Athlete:** As an athlete, I've had to have several MRI's for athletic injuries. I find it absolutely baffling that unbeknownst to me, I have witnessed price differences only after the fact where Partners Healthcare is thousands of dollars more than Shields MRI and Longwood MRI is the cheapest to me, both out-of-pocket, and to my employer's self-insured plan. My healthcare premiums and out-of-pocket costs are higher than what I pay in taxes, suppressing my overall earnings potential. Each year, my employer and I face a higher health plan cost. I totally support and thank the Administration for making providers and insurance plans reveal their secret, hidden prices. We need to get all of our information available to our choice of mobile apps and allow for technology to let us manage our health and financial decisions, just like we do in other areas of our lives.

Thank you for taking the measures to hold providers accountable through Information Blocking penalties if they don't comply. We will all be better off when we have full access to our health information on our mobile device to share with other physicians, hospitals, family, and friends as we choose. Thank you for giving patients the freedom to see prices in their healthcare and their health plans. We should be able to get healthcare anywhere at the lowest possible price. Providers should determine what price they will charge, and everyone going to that provider should be charged the same price in fairness, and the bill should be available on my phone after I receive my results and should match the price. I should be able to dispute egregious pricing and choose to get care where I can save both out-of-pocket and, on my employer, and my premiums. I am really frustrated that, needing regular planned visits and procedures, I cannot find the prices anywhere. Oh, by the way, the cost estimators don't work. Those prices aren't real and aren't what I end up getting charged. Thank you for making sure the real prices are known to us.

- **Parent:** As a parent of a child with special needs, being able to access your child's medical information would be a game changer. Having been to hundreds of doctor and specialist visits over the years, being able to access information from other doctor visits would have saved us a lot time and money. In a visit to an endocrinologist, we had to repeat blood work because she was unable to access my daughter's information from her recent visit with the cardiologist at the same hospital system. With access to her medical history, we could have prevented additional lab work. I am also highly in favor of being able to shop the price for many procedures. Too many times we have faced an enormous medical bill that we were not anticipating. The most shocking was the \$3,500 lab bill we received for genetic testing that was not covered by our insurance.

- **Mother:** My second child was born via c-section. My health insurance plan was to cover everything and after my son was born the hospital billed me for \$1000 and my OB provider billed me for over \$900. I was completely blindsided by these charges and both my provider and insurance gave me the 'whoops, yes, someone should have told you how much it would have cost,' or 'we don't' know how much it costs until after we bill your insurance.' My routine visits while pregnant were all covered by my insurance, or so I thought, until after I delivered and received a bill from my provider for the last 5 weeks of my pregnancy. I was charged for the weekly non-stress test that I was told I needed to have done leading up to the c-section. NO ONE told me I would owe extra or that it would not be covered by insurance and it was not something I would have asked during the routine weekly OB visits.

This information about pricing should have been given to me BEFORE any testing was done so that I could decide if it was necessary and budget myself accordingly instead of going into each visit with a blank check book. My next challenge will be to get my health records for my c-section and my son's birth records. I will have to go to the hospital and sign a request and pay money for MY health records. The hospital then gets up to 6 weeks before sending me the results. MY health records should be immediate and free. They should be sent to my phone automatically via an app. It should not be this difficult to have price transparency or medical record information transferred to myself. Let's fix this system!!!

- **Mother:** It's critical that my family members and I have real time, free of charge access to our electronic medical records. It's important in this day and age because I don't want duplicate testing performed or the possible risk of giving a family member of mine medication they cannot take. My husband recently had a major surgery requiring him to be on a blood thinner for the rest of his life. He travels in and out of the country for work. He should be able to carry his electronic records on his phone and give info to an ER doctor or a specialist. I have two kids in college and a third approaching college soon. They are athletes and that also poses a risk of injury. They travel in and out of state and it's so important that they have access to their medical records instantly. Also, so important to know prices before receiving care. We need price competition because healthcare costs are out of control. I'm often baffled at the outrageous cost of procedures. It would be so helpful to know cost ahead of time.
- **Lawyer:** My husband and I were buying a new home and applying for a mortgage when we discovered that my FICA score was significantly lowered by a four-year-old dermatology bill that I never received. The bill was sent to an old address. I am an attorney and fortunately was able to negotiate with the debt collector and the dermatologist. I had to draft letters for them to submit to eliminate this bad debt reporting. Those fees had been covered by my insurance at my current address. They were erroneously reported as bad debt to the debt collector and the credit bureau. After several weeks of written documents, my FICA score was corrected to where it should be. Then, I was able to get a mortgage at a competitive interest rate. It occurred to me that this FICA score reporting that I was unaware of until this mortgage event negatively impacted me financially - both at the higher interest rate, as well as my car insurance, as the FICA score is part of the algorithm for the risk rates assigned to me. I likely had been overcharged by other entities and services for the past four years, unbeknownst to me. Fortunately, I had the education, tenacity, and fortitude to fight this issue once I became aware of the problem.

As an American citizen, it deeply concerns me about the breadth of this problem across our country. This medical debt, even when erroneous, has a ripple effect across the financial lives of

all patients and consumers. How many people's FICA scores are affected every day by erroneous, price-gouged, or even fraudulent medical billing? It appears that the healthcare system and its opacity has a more severe effect than even what we can see on the surface. How could this have been prevented? Well, if I as a patient had digitally received both pricing, billing, and closure of the billing account electronically, as well as any credit reporting as part of my patient health record, that comprehensive information would provide proof that bills had been paid, independent of any physical address. I would no longer have to depend on "snail mail" to deliver my data, including pricing and billing. I know that all of this data is electronic now and can be provided to me in real-time, comprehensively to my mobile device. If there is fraud, errors, or price gouging, patients like me need to be able to easily dispute and prove our case. I support electronic health information definition to be broadened to the original definition from HIPAA which includes mental and physical health, clinical care plan, and past, present, and future payment information. This information is all digital today, and we as patients should have access to our health information inclusive of our care, pricing and payments - automatic, free, and in real-time.

- **Wife:** When my husband was the only one employed at his church, I spent dozens of hours every year trying to figure out which health plan would be the best for our family of four. My part time job in the health care industry did not offer benefits, so we were resigned to pay whatever the church could not afford that year. Premiums, deductibles, and co-pays were all carefully weighed together to make sure that our family could have health care and food on the table. The amount of phone calls to the insurance companies to select our insurer for the next year turned out to be a part time job.

Over the years, each member of my family has all had significant surgeries and we never knew with clarity the final price until months after the surgery when all the bills had come in. The anxiety of surgery / recovery is high enough without also having to worry about if the hospital is charging you the right amount and what the negotiated rate will be for who-knows-who that attended your operation that day. The game would change if there were a competitive market where prices were published ahead of time so I could more easily shop not only for my insurance, but where to get my care. Isn't it ridiculous that a blood draw at the local hospital is \$200 but down the street at Quest it is free? The choice you make sounds financial until you realize that it will take signatures and faxes and manual labor to get the information from Quest's diagnostic portal to the portal through which your doctor can see the information. With some medical conditions, time is pressing and so you pay the \$200. When your health is on the line, your time should be spent in recovery, not in waiting for high bills and doctors' portals to upload your information.

Today, I struggle with a rare muscular disease. Daily PT would strengthen my core and allow for more freedom of movement and strength. However, a \$20 daily copay is not something my family can commit to. So, instead we are selling our home to move into a handicapped accessible house so that I can worry less about following down the stairs when my muscles are too weak. Additionally, I have a form of diabetes whose effect is lessened by an expensive nasal spray. I can stay home and manage my diabetes without the spray, or I could pay for the spray and have more freedom in my life. The industry feels like a game, but it is playing with real people. Please ensure that the bill passes where we can access and share our health information and prices in a secure app.

- **Patient:** I am blessed to have Medicare coverage and a very good supplemental plan. However, I worked hard all of my life for this coverage and understand that many are not as lucky to have such wonderful coverage. Many people are just one bill away from financial distress over surprise bills, out-of-network charges, and overall overwhelming healthcare prices. It doesn't have to be like this.

If HHS could insist that all providers and all of the middlemen show the real prices of care, we could save so much money for ourselves, our employers (ultimately our wages), our government (ultimately our infrastructure), and our country. Specifically: Future payment as part of Health Information should be transparent, publicly posted, and available on demand to support patient decision making. Patients need real-time, free, machine-readable electronic access to their health information and real price information without special effort. These data need to be provided through Open API's, as is the data for every other part of our lives. Patients have already paid for the care. The information generated are just the results and should not be charged for. Health Information Networks should include health plans, as they have so much control over their provider networks. The definition of Electronic Health Information should be broad enough that is not limited to identifiable information and includes price information. Thank you for allowing our citizens to see the real prices of their care in advance of their care.

- **Patient:** I demand that government stay out of my healthcare, and that there is transparency in pricing and medical records. No thanks to HIPPA, staff routinely make the patient the least of their priorities - instead they bow to lawyers, govt, big pharma etc. I constantly have to fight to get any of MY OWN medical records which is UN-American and NOT good for my health. I found out that CIGNA has forms for ME to fill out to stop there selling of MY PRIVATE info and for me to get my OWN info, but they never even bothered to tell me this. There is very little info currently to help in choosing doctors or other providers. I have wanted pricing for decades now, in dental and medical health. I rarely have had to use medical care, and I do avoid it because of all the extra work on my part to have to get treated properly, amongst all the paperwork which takes precedence. I am fearful of something not being covered especially since CIGNA's system is lousy. They did not have my occupational therapist listed, but who actually is supposed to be covered. Their website is atrocious.
- **Parent:** We are moving in the right direction on price transparency, but it is not enough. In order to have a true competitive market, the real prices need to be revealed. Until then, patients will suffer the financial burdens placed on them from not being able to shop around for care at the lowest price possible. I have heard some claim that price transparency may increase prices because lower price providers will want to charge the same prices as their higher charging colleagues. Every other market has shown that this will not happen; **COMPETITION WILL DRIVE DOWN PRICES!** In addition, patients deserve to have readily available access to their electronic health information. It could mean the difference of a life or death situation. Fortunately, this was not the case for me, but I had to take several hours away from work to get 'paper' access to my children's' health records after moving out of state. It took at least two dozen phone calls and signing several informed consents for release of their records only to receive piles of paper in the mail that made no sense to me at all. In addition, there was missing information from the birth of one of my children which I found to be neglectful. We can do better than this. We need to do better than this. We deserve real-time electronic access to our health information and price transparency to drive down prices.

- **Technology Firm:** Standardized APIs allow third party companies to build tools that can access data in health IT products in a repeatable fashion, meaning we do not have to rebuild interfaces over and over again which is costly and time consuming. It is difficult as a third-party technology company to build connections to health IT products in a cost-effective manner. I urge ONC to finalize its proposal that as a condition of certification all health IT developers that produce or maintain electronic health information be required to provide access to the USCDI via FHIR APIs. Further, I encourage ONC to require FHIR v4 which has far more capabilities and more standardization than v2. 24 months is too long to adopt this new criterion. The industry simply cannot wait that long to adopt FHIR APIs that will unleash innovation into the industry. Please shorten the timeframe to 12 months from finalization of the regulation.

I support ONC's proposal that developers who produce or maintain electronic health information make such information available electronically in a data export along with a data map. Please require the data map to be provided as it would make it nearly impossible for another developer to make sense of the data without it. I encourage you to require health IT developers to allow patients or a third-party application to generate the data export without requiring a user to do anything. This allowance will make it easier for patients to access their data, and we are concerned that if it is limited to users only the capability will be much less effective for patients. If patients are the only ones who can receive the data export that they will not know what to do with it.

Please finalize this requirement to allow a third party working on behalf of the patient to directly access the data export and data map. Please finalize the requirement for health IT developers to publicly publish their service base URLs. Any privacy/security concerns raised by health IT developers are unfounded and likely driven by anticompetitive attitudes. It is common practice in other industries to publish these endpoints so they can be found. The security protocols built into the API itself ensure that only those with appropriate authorization have access. API Data Providers should have the sole authority to allow or prevent third parties from using APIs that allow access to their data. A health IT developer should have no authority to tell an API Data Provider with whom they can and cannot work. Too often, health IT developers prevent third parties from working with API Data Providers because they are offering a competitive service. They should not be allowed to use their control over the technology to insulate their products from competition. This issue is the root cause of much of the usability issues that providers complain about. Giving API Data Providers the ability to work with any third party they choose will allow for innovation that can create more usable software for providers.

We often have seen API Technology Suppliers exhibit rent seeking behavior by charging exorbitant fees not only to API Data Providers but also to the API Users who are trying to provide valuable tools and services to a wide range of stakeholders. These practices limit innovation and particularly hurt start-ups and small tech companies who want to enter the market. API Technology Suppliers should only be able to charge fees to API Data Providers for use of the APIs, unless they are providing value-added services to API Users. Rent-seeking behavior by actors within healthcare have stymied innovation for an industry that is in desperate need of innovation. Health IT developers in particular often charge third parties who are offering competitive tools significantly more to access data they hold than others. These behaviors make it difficult if not impossible for start-ups with innovative tools to succeed. Please do not allow actors to charge fees in a discriminatory manner. Fees should not be based on who is accessing the data or how much money they can generate from their tools and services that make use of the data. The negotiated price should be included in version 1 of the USCDI to enable third parties to easily access pricing data via a standardized FHIR API. Many tech companies are

standing ready to use that data to provide services to patients and providers that will help them compare prices and make more informed decisions about where they seek care and even the health plan they choose. Price transparency has the potential to create a competitive market for healthcare, ultimately lowering the cost of care in the US. Finally, please include provenance data in the USCDI. When we are exchanging individual data elements about a patient, we must have provenance to ensure we are not duplicating data and that users have the most up to date data about a patient. The FHIR APIs cannot function at scale without provenance data. Thank you.

- **Technology Firm:** Patients should be provided a way to access their data using APIs in real-time and for free. Our employees deserve easy access to their health information so that they can manage their health and well-being. Every year we lose millions of dollars in productivity due to health-related issues with employees. We believe that making sure patients have access to their health information will help them manage their health better, ultimately increasing productivity. Further, patients can help prevent duplicative tests by having the ability to share their health information with all of their providers. We are concerned that the US Core Data for Interoperability (USCDI) does not include price information. We believe it is essential for not only patients to have access to this information but organizations that manage insurance plans and provider networks.

We strongly encourage ONC to include the negotiated price in the USCDI that is made available via APIs. We strongly encourage ONC to finalize this proposal that would require health IT vendors to provide an Electronic Health Information export for patients. We encourage ONC to consider requirements under the information blocking provision that would ensure that healthcare providers make this capability available to patients. We have seen many instances where healthcare providers have technology available to provide data to patients but choose not to for their own competitive reasons. We ask that ONC consider it information blocking if a healthcare provider does not make this capability available to his/her patients. We also encourage ONC to include the negotiated price information in the definition of Electronic Health Information. It is important for patients to have access to pricing data. When they make decisions about where they seek care that lower the overall cost of care, we reduce the cost of health plans. This in turn allows employers to put more money into employee wages, which have remained stagnant over the last few years often because the price of healthcare increases exponentially each year. We have an opportunity to create an economic stimulus to keep the money in the wallet of our patients and employees, and we encourage ONC to help us achieve this outcome by making pricing data more transparent for patients and employers.

We support ONC's proposal that sharing health information rather than withholding health information become the default. Too often we have been told by healthcare organizations that they will not share health information with us that we legally have the right to access, or these organizations make it incredibly difficult for us to access the data. While we agree with the importance of protecting patient information from those who should not have access or those who will not keep it secure, we strongly encourage ONC to ensure that HIPAA, state laws, and security concerns not be used as an excuse to withhold data from those who should reasonably have it. We urge ONC to be narrow and specific in their final rule to ensure there are no loopholes for not sharing data. We strongly support a requirement that net negotiated price information be made available on public websites and in a manner that API technology could access it. Price transparency is pivotal to creating a competitive market not only between health systems but also between health plans. Benefit administrators need insight into provider

networks and pricing information to choose the plans that work best for their members/employees. We urge ONC to create price transparency by ensuring pricing information is posted publicly and available via APIs. It is vitally important that plan administrators have access to pertinent information on the populations they manage. It is incredibly difficult to design a plan or make sure your plan is working for your members if you cannot access population level data, including price data. We urge ONC to include net negotiated price in the USCDI data set that would be made available via APIs. This information coupled with health information (as allowed under law to be accessed) will help plan administrators create benefits programs that meet the needs of their stakeholders. Further, we encourage ONC to finalize the requirement that health IT developers provide an API that allows for population level access (i.e. data on all members of a plan at one time). This will create efficiencies for plan administrators and ensure they have the data they need in a timely manner.