

Comments on the Office of the National Coordinator's Proposed Rule of March 4, 2019

To implement certain provisions of the 21st Century Cures Act with respect to "Interoperability, Information Blocking and the ONC Health IT Certification Program"

By Sean May and Monica Noether*

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*The authors are economists at Charles River Associates. The conclusions set forth herein are based on independent research and publicly available material. The views expressed herein are the views and opinions of the authors and do not reflect or represent the views of Charles River Associates or any organizations with which the authors are affiliated. Financial support was provided by Ciox.

Executive Summary

The Office of the National Coordinator for Health Information Technology (ONC) released a Proposed Rule to implement certain provisions of the 21st Century Cures Act with respect to “Interoperability, Information Blocking and the ONC Health IT Certification Program” [hereinafter, “Proposed Rule”] on March 4, 2019.¹ ONC describes the rule as critical “to support this Administration’s goals of interoperability, as well as the vision of the 21st Century Cures Act....”² We understand that the Office of Management and Budget (OMB) is currently evaluating the Proposed Rule to ensure that it meets the standards described in Executive Order 12866, which require that the proposed approach “maximize[s] net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)....”³ We also understand that ONC has submitted to OMB a proposed final rule, which may include changes from the Proposed Rule.

Accordingly, this report comments on the current complexities in providing patients with comprehensive access to their health records, the likely costs that the enactment of the Proposed Rule would involve, some principles relating to how patients’ access to their health information should be priced, and the potential benefits that would likely inure to patients and providers from providing that access. Specifically, we explain the following points:

- The Proposed Rule does not reflect the substantial effort that provision of comprehensive electronic health record information (EHR) to patients and their designees requires. The Rule seemingly discounts that health care providers currently maintain their EHR in multiple disparate systems which are not linked together or structured using a standardized approach. Rather, the Rule assumes that the primary hurdle to interoperability is automation of EHR transmission to patients and their designees.

¹ Department of Health and Human Services Office of the Secretary. 45 CFR Parts 170 and 171, 21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program. Proposed Rule, March 4, 2019. [hereinafter, “Proposed Rule.”]

² <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0938-AT79> ONC’s Statement of Need notes that “This final rule is intended to move the health care ecosystem in the direction of interoperability. This rule is part of the Agency’s broader efforts under the MyHealthEDData Initiative to empower patients by ensuring that they have full access to their own health care information. These policies aim to break down the barriers that prevent patients from gaining electronic access to their health information from the device or application of their choice, while keeping that information safe and secure. Additionally, these policies create and implement new mechanisms to enable patients to access their own health care information through third-party software applications providing them with the ability to decide how, when, and with whom to share their information. In this way, this rule offers a patient-centered approach to health information access and moves to a system in which patients have immediate access to their computable health information and can be assured that their health information will follow them as they move throughout the health care system from provider to provider, payer to payer.... to improve care and reduce burden and cost.”

³ https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf

- The automated system that the Proposed Rule envisions is insufficient to deal with the underlying complexities of EHR retrieval and compilation. Among other things, these complexities include considerations that some patient health information is designated as especially protected under HIPAA and must be separately reviewed and segregated, and that information must be retrieved from multiple sources, which may be formatted differently, archived, or use different patient identifiers.
- ONC's estimate of approximately \$540 million in up-front expenditures and approximately \$100 million in ongoing expenditures to achieve interoperability is implausibly low given historical experience. CMS has made nearly \$40 billion in Promoting Interoperability / Meaningful Use payments to health care providers between 2011 and 2018, and many health care providers have spent hundreds of millions or even billions of dollars to implement comprehensive EHRs within their own health systems. Based on the costs of industry participants, we estimate that more than \$1.3 billion (in 2016 dollars) was spent in the last year responding to requests for health records.
- ONC's proposal to require that electronic access to EHR be free will have unintended consequences. The proposal appears to be based on the incorrect assumptions that the incremental costs of providing electronic access to EHR is zero, and that firms should price their services at their incremental costs in competitive markets. However, the incremental costs of providing EHR are not zero, and even if they were, firms must be able to recover their fixed costs in order to participate in the market and have incentives to innovate.
- The benefits that ONC enumerates are incorrectly specified. First, the assumption that the burden EHR systems currently impose on providers ignores the major role that excessive data entry requirements plays in physician burnout. Interoperability by itself will not alleviate this burden. Second, ONC's estimates of the cost reductions associated with reduced utilization of inappropriate or unnecessary health services are based on a limited number of studies and speculative assumptions. Third, ONC assumes that enactment of its Proposed Rule will increase patient's use of their health records, but evidence suggests that only a small minority of patients would avail themselves of the opportunity. Further, ONC does not account for at least two potentially sizeable offsetting effects of greater access to patient records, including the increased costly practice of "defensive medicine" and the enhanced ability of health care providers to bill more comprehensively for their services.
- ONC's concern that costs incurred for EHR transmission will be passed on to patients are legitimate, but these concerns will exist regardless of whether providers are permitted to bill patients and their designees for EHR transmission directly.

Introduction

ONC's Proposed Rule envisions a world in which an information technology (IT) infrastructure is developed that would enable health care providers, such as hospitals, physician groups, or outpatient treatment centers, to provide patients and their designees with comprehensive EHR at no incremental cost. Unfortunately, while providing patients unfettered access to their EHR would undoubtedly benefit them, ONC's Proposed Rule substantially underestimates the complexity of assembling and providing such information.

In particular, the Proposed Rule contemplates a world in which complicated Application Programming Interfaces (APIs) are developed and maintained that can extract and transmit EHR at no incremental (or variable) cost. The Proposed Rule estimates that the total cost to implement interoperability across all EHR products, environments and developers would average \$539 million in the first year of implementation, with a range of between \$304 and \$773 million (in 2016 dollars).⁴ Ongoing annual costs for the Proposed Rule would average \$103 million, with a range between \$59 and \$147 million (in 2016 dollars).⁵

We believe that these figures underestimate the likely costs of developing and maintaining this infrastructure. Indeed, these estimates are dwarfed by the amounts that the Centers for Medicare and Medicaid Services (CMS) has already spent in incentive payments to health care providers for complying with various standards related to Meaningful Use (now referred to as Promoting Interoperability) that are intended to encourage providers to adopt, utilize, and transmit EHR. These federal payments, which comprise only a fraction of the total costs of developing, installing, and maintaining EHR systems, have amounted to nearly \$40 billion as of October 2018.⁶

Many additional billions have been spent by other government agencies and the private sector as well. Indeed, major hospital systems have reported EHR implementation costs that exceed \$1 billion. For example, the Mayo Clinic estimated that its technology modernization project, which included installation of Epic, cost approximately \$1.5 billion, and Partners Healthcare spent at least \$1.2 billion to implement Epic across its system.⁷ More recently, the budget to implement Cerner throughout the Veterans Administration on an interoperable basis increased from an initial target of \$10 billion to \$16 billion, and the project is anticipated to require several

⁴ See *infra* Table 1.

⁵ See *infra* Table 2.

⁶ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/October2018_SummaryReport.pdf

⁷ <https://www.beckershospitalreview.com/ehrs/mayo-s-rochester-campus-readies-for-may-5-go-live-on-epic.html>, <https://www.bostonglobe.com/business/2015/05/31/partners-launches-billion-electronic-health-records-system/oo4nJJW2rQyfWUWQlvydkK/story.html>.

years.⁸ One of the earlier innovators in electronic health records, Kaiser Permanente, spent \$4 billion and took ten years to install EHRs across its entire health system.⁹ As Kaiser's chief information officer explained, this implied approximately \$444 per member. Extrapolating that figure to the U.S. population of 327 million implies total implementation costs that would exceed \$145 billion.¹⁰

An analysis of the costs incurred by 26 primary care physician practices found the average per physician implementation cost to be approximately \$32,000 with an additional \$17,000 in maintenance costs in the first year of operation. With approximately 810 thousand physicians in the U.S. engaged in patient care,¹¹ this suggests approximately \$26 billion is required to implement EHRs in all physician offices in the U.S., and \$14 billion in annual maintenance costs.¹²

Another approach to assessing the reasonableness of ONC's estimated costs is a comparison with current total annual expenditures on EHR system implementation and maintenance. While there is no comprehensive analysis of the revenue associated with the EHR industry in the U.S., various estimates place it between \$8.5 and \$11 billion in 2018.¹³ Relative to annual expenditures of this magnitude (which do not include the salaries of IT personnel employed by health care providers, nor the revenue associated with firms like Ciox), ONC's much smaller estimates of the cost of implementing and maintaining interoperability seem implausible.

Despite these enormous outlays, no one (including presumably ONC) believes that the U.S. health care sector is anywhere close to being capable of the sort of seamless, inexpensive EHR

⁸ <https://ehrintelligence.com/news/va-cerner-implementation-contract-balloons-to-16-billion>. See, also, <https://www.bizjournals.com/kansascity/news/2019/09/27/veterans-affairs-cerner-ehr-scheduling-delays.html>

⁹ <https://www.infoworld.com/article/2614353/how-kaizer-bet--4-billion-on-electronic-health-records---and-won.html>

¹⁰ Other substantial installations, such as the Henry Ford Health System at \$350 million, are reported here. <https://www.beckershospitalreview.com/healthcare-information-technology/unpacking-hospitals-ehr-implementation-costs-what-s-behind-the-million-dollar-price-tags.html>

¹¹ American Medical Association, Physician Characteristics and Distribution in the US (2015), Table 1.1.

¹² Neil Fleming et al., "The Financial and Nonfinancial Costs of Implementing Electronic Health Records in Primary Care Practices." *Health Affairs* 30 (2011): 481-489. These dollar costs did not include the opportunity of the staff and physician time required to learn to use and maintain the system.

¹³ IBIS World estimates the size of the industry in the U.S. in 2018 at \$11 billion (<https://www.ibisworld.com/united-states/market-research-reports/electronic-medical-records-systems-industry/>). Grandview Research reports that the U.S. industry in 2016 totaled \$8.1 billion (or \$8.4 billion in 2018 dollars). (<https://www.grandviewresearch.com/industry-analysis/electronic-health-records-ehr-market>) MarketResearch Future indicates a market size of \$11.8 billion in 2017 (or \$12 billion in 2018 dollars) for the Americas. Finally, Healthcare IT Skills estimates that the top 10 EHR providers earned about \$18.2 billion in revenue in 2017 globally (\$18.5 billion in 2018). The U.S. is approximately 39 percent of the global total according to Grandview, implying that they earned approximately \$7.6 billion in 2018, which doesn't include a substantial fringe of smaller players. (<https://healthcareitskills.com/top-ehr-vendors-allscripts-athenahealth-cerner-epic-meditech/>)

transfer that ONC contemplates in its Proposed Rule.¹⁴ As a result, we believe that ONC's estimate of the cost of this transition described in the Proposed Rule is too low. Indeed, if true interoperability could be achieved for an investment of approximately \$540 million and ongoing costs of \$100 million, such investments would have been profitable for firms such as Ciox, which specialize in Release of Information (ROI) services, to have made already in order to expand and make more efficient their existing businesses. Instead, a sophisticated firm like Ciox employs more than 7,500 individuals, many of whom work on-site at Ciox's provider customers in order to accomplish all the manual and individualized efforts that are still required to comply with many information requests.¹⁵ This implies that there are substantial variable costs (in addition to the investments in IT infrastructure) associated with fulfilling each patient request for EHR.

Numerous Factors make the Provision of Electronic Health Information Unavoidably Costly

As noted above, CMS has already paid close to \$40 billion to health care providers to develop systems that store and facilitate the transfer of EHR to each other and to patients, and providers themselves have invested considerably greater sums. Despite these substantial expenditures by the government and by providers, it is evident that the U.S. health care system does not currently approach any interoperability standard. Indeed, ONC claims the purpose of its Proposed Rule is to "reduce burden and advance interoperability."¹⁶ As CMS Administrator Seema Varma noted in announcing the Notice of Proposed Rulemaking for a proposed CMS regulation closely related to the Proposed Rule, these efforts comprise part of an "*unprecedented* step toward a healthcare future where patients are able to obtain and share their health data, securely and privately, with just a few clicks, [which] is *just the beginning* of a digital data revolution that truly empowers American patients" (emphasis added).¹⁷ A variety of factors explain the

¹⁴ ONC analysis reports that in 2017, only 41 percent of non-federal acute care hospitals engaged in all four dimensions of interoperability (send, receive, find, and integrate.) Yuriy Pylypchuk et al., "Variation in Interoperability among U.S. Non-federal Acute Care Hospital in 2017. ONC Data Brief no. 42 (November 2018.) Furthermore, only 10 percent of office-based physicians conducted all four interoperability dimensions in 2017. Vaishali Patel et al. "Interoperability among Office-Based Physicians in 2015 and 2017." ONC Data Brief no. 47. (May 2019). See, also, Erika Fry and Fred Schulte, Death by a Thousand Clicks: Where Electronic Health Records Went Wrong," Fortune, March 18, 2019, which describes the results of a joint investigation by Fortune and Kaiser Health News, who spoke with more than 100 experts in the field. <https://fortune.com/longform/medical-records/> [hereinafter, Death by a Thousand Clicks.]

¹⁵ Ciox Health, LLC v. Eric D. Hargan and US Department of Health Human Services. US District Court District of Columbia, Case 1:18-cv-00040-APM, p. 4.

¹⁶ ONC. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule: Overview. Slides for February 28, 2019 Webinar. <https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health>; <https://www.healthit.gov/sites/default/files/nprm/ONCCuresNPRMOverview.pdf>

¹⁷ DHHS. "HHS Proposes New Rules to Improve the Interoperability of Electronic Health Information." Press Release, February 11, 2019. <https://www.hhs.gov/about/news/2019/02/11/hhs-proposes-new-rules-improve-interoperability-electronic-health-information.html>. Ms. Varma also acknowledged that "we didn't think about how all these systems connect with one another." (Death by a Thousand Clicks.)

costliness of EHR assemblage and transmission to patients and their designees. We describe these factors briefly in the remainder of this section.

The typical hospital, even those that have fully complied with Stage 2 Promoting Interoperability standards, stores its EHR on multiple disparate systems that do not interface smoothly (if at all) with each other. Indeed, a recent survey suggests that the typical hospital operates 16 different medical record systems, the typical hospital system (which may be comprised of several hospitals, physician practices, and outpatient facilities) operates 18, and only two percent of all hospitals operate a single EHR.¹⁸ Despite this pattern, ONC's Proposed Rule only contemplates the development of APIs that transmit already-compiled information to a third party, not APIs that address the substantial complexity involved in first identifying and combining information that is likely to be spread across multiple disparate EHR systems at the patient's provider. This is true even if the types of electronic health information covered by the Proposed Rule were limited to the data elements included in the U.S. Core Data for Interoperability (USCDI) standard. The USCDI data elements may not be stored in a single EHR system, so even producing only the USCDI elements may require assembling data from disparate EHR systems. For example, the detailed clinical notes that are part of USCDI may be part of a separate medical record system than the patients' demographics or diagnostic imaging scans.

Moreover, even when diverse records for a single patient can be combined, unless the data housed in different systems are structured and identified using a standardized approach, their combination does not result in a useful integrated record without substantial additional effort. A recent article explained "that providing medical care requires many different languages" and that systems often don't have adequate "translators."¹⁹ Different EHR systems, or even different versions of the same system, may use different coding conventions, for example.

Many smaller hospitals and physician groups have not yet fully attained existing Promoting Interoperability standards. As of October 2018, only about 3,500 hospitals (out of a total of more than 5,000 in the U.S.) have complied with Stage 2. Physicians have made even less progress: only about 200,000 physicians out of the approximately 810,000 practicing in the U.S. have complied with the Stage 2 standard, and similar figures apply to other non-physician health care professionals.²⁰ It seems likely that these providers are even more poorly positioned to comply with ONC's proposed rule without substantial and unaffordable investments, given their lack of scale.

¹⁸ Tom Sullivan. "Why EHR data interoperability is such a mess in 3 charts." *Healthcare IT News*, May 16, 2018. <https://www.healthcareitnews.com/news/why-ehr-data-interoperability-such-mess-3-charts>

¹⁹ Matt Cardwell. "When data is lost in translation." *Health Data Management* (November 16, 2019). <https://www.healthdatamanagement.com/partnerinsights/intelligentmedicalobjects/article/when-data-is-lost-in-translation?mvt=i&mvn=7625a1ed9e7b4a789a9ee6b88bcc7a70&mvp=NA-HEALDATAMANA-11239209&mvI=%20%5BNative%20In-Brief%20%2F%20In-Article%20-%20NEW%20CMS%5D>

²⁰ https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/October2018_SummaryReport.pdf

The process to release health records to patients involves several activities, each of which may be complex. The Association of Health Information Outsourcing Services (AHIOS) outlines five types of activities that are required, which in all involve 44 steps. These include: 1) logging, tracking and verifying a request, 2) retrieving patient protected health information, 3) protecting sensitive information, 4) releasing authorized information, and 5) completing and invoicing the request.²¹ Even in the uncommon situation in which a health system operates a single, unified EHR system, many of these steps are not easily automated, for a variety of reasons.

Patient health information is by its very nature sensitive, and its confidentiality must be carefully preserved. Moreover, within the universe of this confidential patient health information, different degrees of sensitivity and confidentiality exist. For example, highly sensitive health information related to behavioral health diagnoses and treatments, substance use disorder, and HIV/AIDS is in its own category that requires particular safeguards to comply with important patient protections. However, automated processes may not exist that clearly distinguish and separate such highly sensitive health information from other protected health information. Therefore, each page of the patient's record that has been extracted must be reviewed to determine whether it contains highly sensitive PHI and, if so, such information must be segregated and separately tracked and logged. Under federal and state privacy laws, the patient's highly sensitive health information related to issues such as mental health, substance use and abuse, and HIV/AIDS must not be disclosed unless the patient expressly authorizes the disclosure of highly sensitive health information by category. When highly sensitive health information is identified in the patient file, a health care provider or ROI provider must provide a reason why certain records will not be disclosed without actually disclosing the existence of highly sensitive health information in the record. We understand that, in many instances, these rejection letters result in attorneys filing motions to compel and require an *in camera* hearing with a judge to preserve patient privacy. If the judge and or the parties agree to a limited release of the highly sensitive health information then the provider must comply with the subsequent order for disclosure. This process, while time-consuming and expensive, enables the patient's privacy to be maintained. Documentation of this process is key to demonstrating that the covered entity and business associate took the proper steps to comply with the request while still protecting patient privacy in their highly sensitive health information.

Furthermore, existing law requires that only the minimum necessary documents to comply with a particular request be provided.²² This consideration also necessitates the segregation of certain health records from others, and when these records are distributed across multiple systems in

²¹ AHIOS. The Release of Information (ROI) Process. http://ahios.org/images/ROI_Workflow.pdf

²² Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3 Modifications to Meaningful Use in 2015 through 2017, 80 FR 62761, <https://www.federalregister.gov/documents/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications>

varying formats, such segregation may also require manual intervention. Health care providers or ROI service providers must manually search multiple EHRs and review each and every page of a patient's medical record located to ensure only the minimum necessary documents authorized and required to be disclosed are actually disclosed. For instance, not all nurses' notes may be required to be disclosed for a particular request but those nurses' notes may be included in the EMR.

EHR systems also frequently use varying coding conventions (*e.g.*, patient identifiers) to identify specific patients. These differing identifiers must be matched correctly in order to ensure that only the records associated with the patient requesting them are sent, and that all relevant records are provided. A recent RAND review found that “the benefits of interoperability and health information technology have been hampered by the inability to reliably match patients and their records.” Despite identifying this limitation, the study “did not identify a ‘silver bullet’ or achieve consensus on a single solution.”²³ Even when patient identifiers match across multiple systems, information must be separately retrieved from each system, some of which may be stored offsite and/or on paper.²⁴ When paper records are part of the patient's file or records are maintained off-site, the health care provider or ROI service provider must be careful to locate all responsive patient health information. We understand that paper records are now commonly being stored off-site. Off-site records may require a request to a third-party vendor who holds the records in storage. Frequently it takes several days to request and receive records held off-site by a third-party. Once the paper records are received, the aforementioned page-by-page review must follow.

Requests for EMRs are diverse, potentially ranging from a simple request for specific lab tests or images performed at a specific time to all health records associated with a patient spanning multiple years, a request which could possibly include records that were transferred from other institutions, are housed in archived locations, or have been scanned from paper copies. Such requests clearly vary enormously in complexity and in the concomitant cost and time necessary to comply with them.

²³ Rudin, Robert S., Richard Hillestad, M. Susan Ridgely, Nabeel Shariq Qureshi, John S. Davis II, and Shira H. Fischer, *Defining and Evaluating Patient-Empowered Approaches to Improving Record Matching*. Santa Monica, CA: RAND Corporation, 2018. https://www.rand.org/pubs/research_reports/RR2275.html. This report further explained that “[a] 2014 report by the Office of the National Coordinator for Health Information Technology (ONC) suggested that when providers exchange records with other providers, rates of record matching—defined as the process of identifying and linking medical records for the same patient across different data sources—can be as low as 50 percent. Other studies suggest that even with dedicated effort, these rates may not reach above 95 percent. Because of inadequate record matching, too often, some or all of a patient's medical data are not made available at the point of care or, more worrisome, incorrect patient data are used to make medical decisions. It is widely recognized that correct record matching is critical to prevent medical errors, avoid delays in care, facilitate informed medical decision-making, and reduce administrative burdens.”

²⁴ Only 3.4 percent of all hospitals are completely paperless. AHIOS. *The Release of Information (ROI) Process*. http://ahios.org/images/ROI_Workflow.pdf (step 6).

The time in which a provider must complete a Release of Information request also affects the cost to comply with the request. Expedited response requests (referred to as STAT requests) can have the unintended consequence of delaying routine requests and possibly jeopardizing patient privacy.

ONC's Estimates Costs of Complying with the Proposed Rule Are Too Low

As mentioned above, the Proposed Rule appears to envision an environment in which initial investments enable health care providers to produce EHR to patients and their designees at no incremental costs. These initial investments would include, among others, the costs 1) of adopting the USCDI standard, 2) of developing export functionality, 3) related to developing APIs to interface with the installed EHR systems at health care providers, 4) related to maintaining the privacy of patients' protected health information, and 5) of testing these technologies. In total, ONC estimates that initial costs of these investments would be between \$304 million and \$773 million (in 2016 dollars), and the ongoing costs of these investments would be between \$59 million and \$147 million (in 2016 dollars).²⁵

While ONC outlines a sequence of necessary tasks that must be undertaken to enable the interoperability of EHR systems, its estimates of the costs of those tasks are inherently speculative because there is no market participant that can currently provide the seamless access to EHR that ONC envisions in the Proposed Rule. Currently, the market participants that come closest to providing the comprehensive access to EHR that ONC envisions are ROI firms. As such, the costs currently incurred by ROI firms—the largest of which are technologically sophisticated firms with decades of experience in providing access to health records—provide the best estimate of the costs to providing patients and their designees with access to EHR. Based on basic economic principles, we expect that profit-maximizing ROI firms minimize their costs, and that, therefore, the firms that currently operate in the marketplace are efficient. The first assumption is a standard assumption about the operation of firms in economics: if a firm did not minimize the cost of providing a service, that firm would not be maximizing its profits. The second assumption is consistent with the observation that the ROI industry is mature, so any inefficient competitors would likely have ceased operation as more competitive firms provided services at lower costs.

To estimate the costs currently incurred by ROI providers, we use a recent survey of ROI firms, which found that the cost of producing a page of information in response to a request for health records was between \$0.18 and \$0.81 per page in 2013 dollars (with an average cost of \$0.40 per page) if the health care provider maintained at least 90 percent of its health records electronically.²⁶ (These cost estimates are generally consistent with the fees that some states

²⁵ See *infra* Tables 1-2.

²⁶ Gregory Trerotola, "Release of Information Cost Study," Prepared for HealthPort (September 2013), p. 7. The costs were higher for health care providers that maintained a smaller fraction of their health records electronically, the average cost per page being \$0.52.

permit ROI providers to charge for producing health records, which generally range from \$0.10 to \$2 per page, with some states setting a maximum fee amount per request.²⁷) We note that these estimates include the costs of labor, supplies and processing, but do not include the cost of information technology infrastructure or indirect overhead costs. That is, these are purely variable costs and exclude any fixed costs incurred by ROI firms. To be conservative in what follows, we use the lower end of the range of estimated costs per page of \$0.18 in 2013 dollars.

In 2018, Ciox produced more than 2.12 billion pages in response to requests for health records from patients and their designees. This total included 1.74 billion pages in response to requests for health records from hospitals, and 381.4 million pages in responses to requests for health records from physicians. We understand that Ciox estimates that it produces about 30 percent of the pages of health records requested in the U.S., including both those pages produced by other ROI firms and pages produced by health care providers that insource this obligation themselves. This implies that, collectively, 7.1 billion pages of health records were produced to patients and their designees in 2018.

This figure may underestimate the future volume of health records requested by patients and their designees because some ROI firms and health care providers currently charge patients and their designees for access to this information. However, the Proposed Rule would significantly limit health care providers' and ROI firms' ability to charge consumers for this information, which will likely have the effect of increasing demand.

Using the estimated lower-bound cost of \$0.18 per page and 7.1 billion pages of health records produced in 2018, we estimate that the total costs of producing these records was \$1.3 billion in 2016 dollars. This estimate, which is based on the variable costs incurred by current market participants, is substantially higher than the estimated costs project by ONC in the Proposed Rule. Tables 1 and 2 below summarize the estimated one-time and perpetual costs, respectively, outlined in the Proposed Rule. The incongruity of these estimated costs with the current structure of the ROI industry is apparent: according to ONC's calculations, with a one-time investment of no more than \$773 million and ongoing expenditures of no more than \$147 million, health care providers and ROI firms could provide patients access to their health records. Yet rather than adopting this approach, these industry participants have spent tens of billions of dollars just to implement comprehensive EHR systems, and currently spend in excess of \$1.3 billion each year just to provide this information, suggesting that either these firms are remarkably inefficient, the costs estimated in the Proposed Rule are too low, or that the approach envisioned by the ONC is not technologically feasible.

²⁷ Mike Bassett, "The Cost of Doing ROI Business," For The Record, vol. 26, no. 11. <https://www.fortherecordmag.com/archives/1114p24.shtml>.

Table 1: ONC Estimated One-Time Costs

Section	Description	Lower Bound	Upper Bound	Average
1.1	Removal of Randomized Surveillance Minimum Threshold Requirements	\$ (6,800,000)	\$ (13,700,000)	\$ (10,250,000)
1.2	Removal of the 2014 Edition From the Code of Federal Regulations	\$ (569,000)	\$ (569,000)	\$ (569,000)
1.4.2	Removal of 2015 Drug Formulary and Preferred Drug List Checks	\$ (8,963)	\$ (9,081)	\$ (9,022)
1.4.3	Removal of 2015 Smoking Status Criterion	\$ (8,963)	\$ (9,081)	\$ (9,022)
1.4.4	Removal of 2015 Patient-Specific Education Resources Criterion	\$ (1,467,080)	\$ (1,472,993)	\$ (1,470,036)
1.4.5	Removal of 2015 Secure Messaging criterion	\$ (777,837)	\$ (783,679)	\$ (780,758)
2.1	Develop support for the additional USCDI data element	\$ 103,839,940	\$ 262,332,480	\$ 183,086,210
2.2	Develop the EHI export criterion	\$ 8,744,416	\$ 87,444,160	\$ 48,094,288
2.3	Develop Application Programming Interface (API)	\$ 179,417,512	\$ 406,527,828	\$ 292,972,670
2.5	Data segmentation for privacy using API	\$ 2,306,440	\$ 7,430,748	\$ 4,868,594
2.5	Data segmentation for privacy: consent management	\$ 6,919,320	\$ 13,838,640	\$ 10,378,980
3.3	Prohibition or Restriction of Communications Costs	\$ 1,085,840	\$ 1,085,840	\$ 1,085,840
3.5	Transparency Requirements for APIs	\$ 11,379,114	\$ 11,379,114	\$ 11,379,114
	Total	\$ 304,060,741	\$ 773,494,976	\$538,777,858

Table 2: ONC Estimated Ongoing Costs

Section	Description	Lower Bound	Upper Bound	Average
1.3	Removal of the ONC-Approved Accreditor From the ONC Health IT Certification Program	\$ (4,500)	\$ (4,500)	\$ (4,500)
1.4.1	Removal of 2015 Common Clinical Data Set Summary Record Criteria	\$ (4,238)	\$ (4,238)	\$ (4,238)
1.5	Removal of Certain Certification Requirements	\$ (48,859)	\$ (48,859)	\$ (48,859)
2.2	Maintain the EHI export criterion	\$ 8,744,416	\$ 87,444,160	\$ 48,094,288
2.3	Maintain Application Programming Interface (API)	\$ 2,132,500	\$ 10,662,500	\$ 6,397,500
2.5	Data segmentation for privacy using API	\$ 17,660	\$ 17,660	\$ 17,660
3.2	Records and Information Retention	\$ 1,511,858	\$ 1,511,858	\$ 1,511,858
3.6	Real world testing	\$ 46,014,108	\$ 46,014,108	\$ 46,014,108
3.6.1	Real world testing maintenance requirements	\$ 342,565	\$ 754,220	\$ 548,393
3.8	Attestations	\$ 79,422	\$ 79,422	\$ 79,422
3.8	Attestations	\$ 209,801	\$ 209,801	\$ 209,801
4	Oversight for the Conditions and Maintenance of Certification	\$ 44,212	\$ 380,737	\$ 212,475
4	Oversight for the Conditions and Maintenance of Certification	\$ 15,858	\$ 98,672	\$ 57,265
4	Oversight for the Conditions and Maintenance of Certification	\$ 6,889	\$ 6,889	\$ 6,889
5	Information Blocking	\$ 98,192	\$ 196,384	\$ 147,288
	Total	\$ 59,159,884	\$ 147,318,814	\$103,239,349

Providing Access to Health Records at Zero Cost Is Not Feasible

In the Proposed Rule, ONC envisions a scenario in which health IT developers invest substantial amounts—between \$304 and \$773 million initially—in developing an infrastructure that provides access to health records at relatively low costs. In addition to these one-time investments, the ONC recognizes that there will also be ongoing costs of between \$59 and \$147 million annually to maintain and update the systems that allow consumers to access their health records. ONC acknowledges that it is important to have a mechanism by which industry participants can recover the costs reasonably incurred in providing consumers access to their health records:

[U]nless we establish [a cost recovery] exception, actors may be unable to recover costs that they reasonably incur to develop technologies and provide services that enhance interoperability. This could undermine the ultimate goals of the information blocking provision by diminishing incentives to invest in, develop, and disseminate interoperable technologies and services that enable more robust

access, exchange, and use of EHI. Therefore, we propose to establish an exception that would permit the recovery of certain costs that we believe are unlikely to present information blocking concerns and would generally promote innovation, competition, and consumer welfare, provided certain conditions are met.²⁸

We emphasize here that ONC correctly recognizes that fostering firms' ability to recover their costs and earn a reasonable profit on their investment provides "incentives to invest in, develop, and disseminate interoperable technologies" and can "promote innovation, competition, and consumer welfare" in certain circumstances.

Despite an acknowledgement of the importance of allowing firms to recover reasonable costs, the Proposed Rule proposes an exception that would prevent firms from recovering their reasonable costs by preventing "the actor [from] charg[ing] a fee based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual's EHI."²⁹ The Proposed Rule does not provide a justification for this exception to firms' ability to recover their reasonable costs. However, it may be based on the ONC's belief that the incremental costs of providing electronic access to EHI is zero, coupled with the assumption that firms should price their services at their incremental costs in competitive markets.³⁰

But the "competitive" (or "reasonable") price for providing electronic access to EHI cannot be zero for at least two reasons. First, as we described earlier, the incremental cost of providing electronic access to EHI is likely much greater than zero. ONC envisions the costless provision of this information using technology that has not yet been developed, but the best information about the costs of providing patients with access to their health records is based on the costs currently incurred by firms in providing those records. And, as we described earlier, the variable costs associated providing patients access to their health records were likely in excess of \$1.3 billion in 2016 dollars. Second, and more importantly, even if the incremental cost of providing patients or their designees access to the patients' EHI electronically were truly zero, the competitive price for the provision of that information cannot be zero because it would not allow firms to recover their fixed costs. And to set prices in such a way that did not allow firms to recover their total costs would remove any economic incentive for firms to participate in the market. While fixed costs that have already been incurred will not affect a firm's decision to operate in the short run, if a firm cannot cover both its fixed and variables costs with the revenue it earns from operations (*i.e.*, earn a non-negative profit), it will choose not to participate in the market at all.³¹

²⁸ Proposed Rule, p. 7538.

²⁹ Proposed Rule, p. 7540.

³⁰ David G. Luenberger, *Microeconomic Theory* (1995), New York: McGraw-Hill, Chapter 3.4.

³¹ Hal R. Varian, *Microeconomic Analysis* (Third Edition), New York: W.W. Norton & Company, Chapter 13.5.

The practice of pricing above incremental cost is evident in how prices are determined for goods or services for which the incremental production cost is zero. For example, most computer software can be disseminated to or downloaded by users at almost no incremental costs, yet software companies such as Microsoft routinely charge for the use of their products. Similar examples can be found in industries as diverse as video streaming services that offer content owned by the service provider like Netflix or Disney+, live professional sporting events or entertainment (e.g., theater, opera, or concerts), and parking garages. In all of these industries, competitive prices are significantly higher than the incremental cost of providing access to consumers.

If prices for these competitive services were set by regulation to be zero, the firms that currently compete to offer the services would have no economic incentive to continue to do so, and they would certainly lack any incentive to innovate or improve their products to the betterment of consumers. By reducing choice and stifling innovation, such a regulation would clearly reduce consumer welfare. For the same reason, a Proposed Rule that does not allow ROI firms or healthcare providers to recover the reasonable costs of providing electronic access to EHIs—but instead mandates that such services be provided at a price of zero risks harming consumers “by diminishing incentives to invest in, develop, and disseminate interoperable technologies and services that enable more robust access, exchange, and use of EHI.”³²

We conclude this section by noting that, in other contexts, the federal government recognizes the importance of covering both the fixed and variable costs in the health care industry. For example, in assessing the adequacy of Medicare payments to hospitals for inpatient and outpatient care, the Medicare Payment Advisory Commission (MedPAC) considers whether Medicare payment rates are high enough to ensure hospitals’ access to capital. As MedPAC notes, hospitals “must have access to capital to maintain and modernize their facilities and to improve their capability to deliver patient care.”³³ Indeed, the base rate used to determine hospital rates explicitly includes both operating and capital cost components.³⁴ Setting Medicare payment rates to reimburse hospitals only enough to cover the marginal costs of providing care to Medicare beneficiaries would not ensure access to capital, and MedPAC notes that Medicare payments rates to hospitals are intentionally set above the incremental costs that hospitals incur to provide care to beneficiaries: “[MedPAC] examines whether Medicare payments cover the variable cost of treating an additional Medicare patient, meaning the costs that vary with volume. On average, the marginal profit across hospital service lines was approximately 8 percent in 2017.”³⁵ In 2017, Medicare payments to hospitals under the Medicare fee-for-service program

³² Proposed Rule, p. 7538.

³³ MedPAC, *Report to the Congress: Medicare Payment Policy* (March 2019), p. 57.

³⁴ MedPAC, *Hospital Acute Inpatient Payment System: Payment Basics*. (October 2019). http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_19_hospital_final_v2_sec.pdf?sfvrsn=0

³⁵ MedPAC, *Report to the Congress: Medicare Payment Policy* (March 2019), p. 78.

were \$190.1 billion,³⁶ implying that CMS made payments to hospitals in 2017 that were \$15 billion higher than the variable costs of providing care to Medicare patients. Similarly, Medicare's payments for physician services reflect both the cost of providing each service (the physician work required) as well as the fixed costs of maintaining a practice and covering professional liability insurance.³⁷

ONC Overstates the Benefits of Providing Access to Electronic Health Information

ONC estimates the total benefits associated with its Proposed Rule under the assumption that, by mandating the provision of electronic health information at no incremental cost to patients and their designees, "the safety, quality, and effectiveness of care provided to patients...[and] progress towards reforming health care delivery and payment" will be enhanced.³⁸ ONC estimates that these potential benefits range from \$3.1 billion to \$9.2 billion (in 2016 dollars) annually in a steady state.³⁹

ONC posits that benefits from the adoption of APIs will result from three effects: 1) reduced provider burden associated with locating patient data, 2) reduced costs related to reductions in duplicate testing, avoidable hospitalizations and readmissions, emergency room (ER) visits, and adverse drug events, and 3) an increase in the number of individuals with access to their health information.⁴⁰ It is likely that the benefits associated with each of these factors is overstated.

Much has been written about the role that EHRs have played in enhancing physician "burnout." For example, a Stanford Medicine survey of over 500 surveyed primary care physicians found that 71 percent of surveyed physicians believe that "EHRs contribute greatly to physician burnout."⁴¹ Similarly, a report issued by the Harvard T.H. Chan School of Public Health in conjunction with the Massachusetts Hospital & Health Association and the Massachusetts Medical Society, found that "[t]here is broad consensus that a major contributor to physician

³⁶ MedPAC, *Report to the Congress: Medicare Payment Policy* (March 2019), Table 3.1.

³⁷ MedPAC, *Payment Basics: Physician and Other Health Professional Payment System: Payment Basics*. (October 2019). http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_19_physician_final_sec.pdf?sfvrsn=0

³⁸ Proposed Rule, p. 7584.

³⁹ Proposed Rule, § XIV.C. 2, p. 7586.

⁴⁰ Proposed Rule § XIV.C. 2, p. 7572.

⁴¹ Stanford Medicine, "How Doctors Feel About Electronic Health Records: National Physician Poll by the Harris Poll." (2018). <http://med.stanford.edu/content/dam/sm/ehr/documents/EHR-Poll-Presentation.pdf> (hereinafter, Harris Survey), p. 5. A recent white paper by Stanford Medicine summarizing this survey and a symposium of health care industry professionals concluded that "EHRs, with their cumbersome user interfaces and onerous billing requirements, have become a burden to doctors and nurses, contributing to burnout and information overload among physicians, and degrading patient care." Stanford Medicine. "White Paper: The Future of Electronic Health Records." September 2018. <http://med.stanford.edu/content/dam/sm/ehr/documents/EHR-White-Paper.pdf> [hereinafter, Stanford White Paper.] See also, Atul Gawande, "Why Doctors Hate Their Computers." *New Yorker* (November 12, 2018). <https://www.newyorker.com/magazine/2018/11/12/why-doctors-hate-their-computers> "...I've come to feel that a system that promised to increase my mastery over my work has, instead, increased my work's mastery over me."

burnout is dissatisfaction and frustration with EHRs.”⁴² Physicians see “monolithic EHRs as inefficient data entry and storage platforms with outdated interfaces that require excessive mouse clicks to perform what should be simple tasks.”⁴³

While physicians and other health care providers may believe that greater interoperability of EHRs could promote improved patient care, the features that they cite as leading to burnout will not be remedied by greater interoperability. Rather, the improvements they seek revolve around lessening the burden that the data entry associated with EHR maintenance currently imposes on them.⁴⁴ A related issue arises from Medicare and Medicaid reporting standards that require physicians to document every action they take on behalf of a patient.⁴⁵

The Proposed Rule also suggests that patients would benefit from greater interoperability because they will have greater access to their own records. Yet, analyses of patients’ use of systems such as electronic portals to access their own medical information indicates that few patients take advantage of the opportunities available. One study found that while 95 percent of Medicare patients discharged from a hospital between 2014 and 2016 that had complied with Stage 2 of Meaningful Use stay were provided access to “view, download, and transmit their information... only 10 percent of those with access used it.”⁴⁶ Similarly, a recent General Accounting Office (GAO) study of DHHS data found that while 88 percent of hospitalized patients and 87 percent of patients with outpatient physician encounters had access to their records electronically, only 15 and 30 percent, respectively, actually did access their records.⁴⁷ These results indicate that many patients already have ready access to their online records, but the vast majority choose not to use the information. Moreover, even among patients who do access their health records electronically, it is not clear that patient usage of portals to access

⁴² Harvard T.H. Chan School of Public Health in conjunction with the Massachusetts Hospital & Health Association and the Massachusetts Medical Society. “A Crisis in Health Care: A Call to Action on Physician Burnout.” (2018). (Hereinafter, Harvard Report) <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/21/2019/01/PhysicianBurnoutReport2018FINAL.pdf>

⁴³ Ed Corbett. “Physician Burnout and the EHR: Addressing Five Common Burdens.” *Health Catalyst* (May 22, 2019) <https://www.healthcatalyst.com/insights/physician-burnout-EHR-addressing-5-top-burdens>

⁴⁴ Specifically, surveyed physicians noted a desire to “improve [the] EHR interface design to eliminate inefficiencies and reduce screen time, shift more data entry to support staff, and use...highly accurate voice recording technology that acts as a scribe during patient visits.” Harris Survey, p. 11. See, also, Philip Kroth et al., Association of Electronic Health Record Design and Use Factors with Clinician Stress and Burnout.” *JAMA Network Open.*, 2019. 2(8) e199609. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2748054>

⁴⁵ Stanford White Paper.

⁴⁶ Sunny Lin et al., “Are Patients Electronically Accessing Their Medical Records? Evidence from National Hospital Data.” *Health Affairs* 38 (2019): 1850-1857, p. 1850.

⁴⁷ General Accounting Office. “Health Information Technology: HHS Should Assess the Effectiveness of Its Efforts to Enhance Patient Access to and Use of Electronic Health Information.” (March 2017). GAO-17-305 <https://www.gao.gov/assets/690/683388.pdf>

their own information has a significant positive effect on medical outcomes, although usage does appear to enhance medication compliance and contact with physicians.⁴⁸

The Proposed Rule also spends substantial effort estimating the potential cost savings attributable to interoperability's supposed ability to reduced various forms of medical utilization (including testing, hospitalization, ER visits and adverse drug events). Without going into a detailed critique of the bases for these estimates, it is worth noting that ONC's estimates are based on a variety of assumptions (e.g., that the historic rates of IT adoption and switching are good proxies for future provider behavior and effects of interoperability) and on a limited number of studies of the cost impacts of the utilization thought to be potentially reducible through enhanced interoperability. Balancing this research are other studies that provide reasons to be skeptical of the general net effects of health information technology. For example, one study of early adoption of health IT found it was associated with a 1.3 percent increase in billed charges and no evidence of savings or quality enhancement after five years.⁴⁹

Finally, there are several potentially offsetting costs that are not considered in the proposed rule. Two documented examples are the enhancement of providers' ability to capture revenue and an increase in malpractice litigation leading to greater practice of costly defensive medicine. Regarding the first point, one recent article promotes interoperability as a means to generate revenue through the connection of different services to "creat[e] new profit centers of revenue through reimbursements by CMS and private insurers."⁵⁰ A recent economic analysis of hospital adoption of EHR systems is associated with reduced coding costs and associated increased billing ability. The authors estimate that reduced coding costs may increase inpatient Medicare costs by about \$1 billion annually.⁵¹

On the second point, a potential increase in the practice of "defensive medicine" and its associated costs can occur if greater access to electronic records leads to an increase in (even unfounded) malpractice litigation. Many studies have demonstrated the significant role that malpractice litigation has in raising health care costs by fostering medically unnecessary

⁴⁸ Elske Ammenwerth et al. "The Impact of Electronic Patient Portals on Patient Care: A Systematic Review of Controlled Trials." *Journal of Medical Internet Research* 2012 Nov-Dec; 14(6): e162; Clement Scott Kruse et al., The Effect of Patient Portals on Quality Outcomes and Its Implications to Meaningful Use: A Systematic Review. *Journal of Medical Internet Research* 2015 Feb; 17(2): e44.

⁴⁹ Leila Agha. "The Effects of Health Information Technology on the Costs and Quality of Medical Care." *Journal of Health Economics* 34 (2014): 19-30.

⁵⁰ Donald Voltz. "Hospital and Clinic Revenue Drivers for 2018-the Interoperability of Wellness, Chronic Care and Service Care Transitions." *Health Care Business Today* (November 17, 2017). <https://www.healthcarebusinesstoday.com/hospital-and-clinic-revenue-drivers-for-2018/> See, also, Donald Voltz. "How data integration can enhance revenue for providers." *Health Data Management* (December 28, 2017.) <https://www.healthdatamanagement.com/opinion/how-data-integration-can-enhance-revenue-for-providers>, which notes that "technology has the potential to bridge this divide [between billing and care delivery workflows] by automating and integrating the revenue capture with the care delivery component."

⁵¹ Gautam Gowrisankaran, Jianjing Lin and Keith Joiner. "How do Hospitals Respond to Payment Incentives?" NBER Working Paper No. 26455 (November 2019.)

defensive practices. For example, one recent study found total health care expenditures to be between four and five percent higher because of the threat of malpractice litigation, with no measurable difference in quality of care.⁵² Even a small proportion of such costs (which amount to approximately \$140-\$175 billion annually of the \$3.5 trillion in U.S. health spending in 2017) swamp the total benefits that the Proposed Rule suggests might result from enactment, which, as explained above, may be too high.

The Costs of Providing EHRs to Patients will be Passed on to Consumers, Regardless of What Fees are Permitted in the Proposed Rule

Even if API developers or ROI firms cannot pass their costs on directly to patients, a large portion of any costs that they charge providers will be passed onto patients indirectly. As explained above, the proposed rule “establishes a general prohibition on API Technology Suppliers imposing fees associated with API technology” with limited exceptions that are intended “to allow API Technology Suppliers [to] recover the full range of reasonable costs associated with developing, deploying, and upgrading API technology over time...and earn a reasonable return on their investments....”⁵³ The Proposed Rule also states that “any unreasonable fees associated with a patient’s access to their EHI may be suspect under the information blocking provision.”⁵⁴ However, for all the reasons provided above, in defining “reasonable costs” the Proposed Rule does not contemplate the full costs of providing true interoperable EHI, nor who will bear these costs.

The Proposed Rule’s concern about the reasonableness of the fees stems from a realization that any fees levied by an API Technology Supplier to a provider “would likely be passed on directly to patients, creating a significant impediment to their ability to access, exchange and use their EHI, without special effort....” Furthermore, ONC notes that “in our view, patients have effectively paid for this information” because the costs associated with initially documenting electronic health information while providing care have likely already been incurred (and passed on to patients or their health plans). This argument ignores at least three fundamental principles.

First, to the extent that, as the Proposed Rule contemplates, API Developers pass on at least those costs that the Proposed Rule deems as “reasonable” to providers, it is likely that providers will in turn pass these costs onto patients just as they have passed on the costs of initially collecting the EHI. Even if providers are not allowed to charge patients *directly*, that does not mean that they will not recover these costs through other mechanisms, such as increased charges

⁵² Michael Frakes and Jonathan Gruber. “Defensive Medicine: Evidence from Military Immunity.” National Bureau of Economic Research Working Paper 24846. (July 2018). The authors compared the experience of active duty military personnel treated in military facilities, whose treatment is protected by liability immunity, with various control groups and settings. See, also, Daniel Kessler. “Evaluating the Medical Malpractice System and Options for Reform.” *Journal of Economic Perspectives* 2011 25(2): 93-110 for a review of other studies that reach qualitatively similar findings.

⁵³ Proposed Rule, § XIV.C. 3, pp. 7487-89.

⁵⁴ Proposed Rule, § XIV.C. 3, p. 7490.

for the medical services they provide to patients. Nearly one third of all hospitals currently earn negative operating margins; as a result, they cannot afford *not* to pass on any additions to their costs.⁵⁵

Moreover, we understand that only a small minority—approximately 5 percent—of the requests that Ciox processes on behalf of health care providers are from patients, with the remainder stemming from various third parties. As a result, if health care providers are forced to pass on the costs of complying with these requests by increasing their fees for medical services, patients and health insurers will end up indirectly bearing the costs of responding to these third-party requests.

Second, if, as we argue, ROI service providers no longer service hospitals and other providers because they cannot recover their reasonable total costs following the enactment of the Proposed Rule, hospitals will need to find other ways to comply with patients’ (and their designees’) requests for their EHRs. To the extent that they have previously found it most efficient to utilize ROI firms to comply with EHR requests, they will be forced to utilize less efficient mechanisms and incur greater costs (which will, in one way or another, also be passed on to their patients).

Third, if the Proposed Rule allows patients and their designees to request and receive comprehensive EHR information for less than its cost, this subsidization will encourage them to request more EHR information than they would when paying full cost, *i.e.*, more than is economically efficient. Indeed, a recent analysis shows that following the release of guidance concerning individuals’ right to access their medical records by the Office of Civil Rights in 2016, there has been a large increase in attorney (third-party) requests submitted as patient directed requests (PDRs) in order to qualify for lower rates. Significantly, the number of pages requested through the PDRs was sometimes more than double those submitted directly as legal requests, demonstrating the effect on demand of reduced fees.⁵⁶ Unless patients’ access to their EHR is below societally optimal levels at the true cost of providing that access, such subsidization can result in “excess demand” for EHR. This is of particular concern with respect to the Proposed Rule’s inclusion of patient designees in its provision. For example, such designees can include plaintiffs’ attorneys seeking fodder for malpractice litigation, which as discussed above, leads to costly, but not quality enhancing, defensive medicine.

Conclusion

As we have outlined in these comments, ONC’s Proposed Rule that is intended to comply with various portions of the 21st Century Cures Act to foster increased interoperability fails to take account of various critical considerations. These include the true cost of developing and operating truly interoperable systems, the incentives created by preventing cost-based pricing of

⁵⁵ American Hospital Association, TrendWatch Chartbook 2018. Table 4.1.

⁵⁶ Beth Anne Jackson et al., “Misuse of Patient Directed Request for Copies of Medical Records.” AHIOS. 2019. http://ahios.org/images/files/ahios-pdr-wp-9-20-19_final.pdf For three provider organizations, the average increase in pages per request via PDRs relative to attorneys ranged from 86 to 556 percent. (page 4).

EHR transmission services, and various considerations that relate to the beneficial (and less beneficial) potential effects of ONC's proposal.