UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

CIOX HEALTH, LLC 925 North Point Parkway Suite 350 Alpharetta, GA 30005 Plaintiff, v. ERIC D. HARGAN, in his official capacity as Acting Secretary of Health and Human Services 200 Independence Ave. S.W. Washington, D.C. 20201, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Ave. S.W. Washington, D.C. 20201, Defendants.	Case No. _____

CIOX HEALTH'S COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff CIOX Health, LLC ("CIOX") brings this civil action seeking declaratory and injunctive relief against defendants Eric D. Hargan, in his official capacity as Acting Secretary of Health and Human Services, and the United States Department of Health and Human Services (collectively "HHS," "the Department," or "Defendants"). In support thereof, CIOX states the following:

NATURE OF THE ACTION

1. This lawsuit seeks the entry of declaratory and injunctive relief to prevent HHS from enforcing a series of rules and regulations that unlawfully, unreasonably,

arbitrarily, and capriciously seek to restrict the fees that healthcare providers and their business affiliates (like CIOX and other medical-records providers) are entitled to charge for gathering and disseminating patient records containing individuals' protected health information ("PHI") pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936 (1996), as amended by the Health Information Technology for Clinical and Economic Health Act ("the HITECH Act"), Pub. L. No. 111-5, 123 Stat. 226 (2009), and the 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016), and as codified in relevant part at 42 U.S.C. § 17291 *et seq*.

2. As set forth below, HHS's rules are (a) impossible to square with the plain language of the controlling legislative enactments—as HHS itself conceded expressly at the time it issued them; (b) irrational, arbitrary, capricious, and absurd on their own terms; and (c) in key respects were promulgated by the Department without advance notice to the public or any opportunity to provide comment, in defiance of the Administrative Procedure Act and the most elementary requirements of good governance.

3. Most important, HHS's continued application and enforcement of these rules imposes tremendous financial and regulatory burdens on healthcare providers and threatens to upend the medical-records industry that services them. These burdens are having a severe adverse impact on already-struggling healthcare providers, including non-profit hospitals, community hospitals, academic hospitals involved in research, local clinics, and physicians' practices. And today, these rules

are being exploited by for-profit commercial businesses to shift costs they properly should bear onto healthcare providers and patients. In short, HHS's unlawful rules are forcing healthcare providers to bear costs Congress never contemplated and threaten to bankrupt the dedicated medical-records providers who service the healthcare industry by effectively—and quite deliberately—mandating that they fulfill a rapidly growing percentage of requests for PHI at a net loss.

4. At a time when the American public is clamoring to reduce healthcare costs, the rules challenged in this Complaint threaten to substantially increase costs for patients and challenge the long-term viability of the medical-records industry, which plays a critical role in facilitating healthcare providers' ability to deliver high-quality, error-free, and cost-effective healthcare services by ensuring that our Nation's healthcare professionals are able to access, share, and distribute critical patient-related information in real-time. Indeed, the vast majority of hospitals in the United States contract with medical-records providers like CIOX precisely because these companies' highly specialized services are efficient, cost-effective, and critical to the timely dissemination of key medical information, thereby allowing healthcare providers to focus their full attention on the task before them: ensuring the best possible care for patients. Left unchecked, Defendants' unlawful actions thereby threaten to disrupt the American healthcare system and increase healthcare costs for patients, with dire consequences for millions of Americans.

THE PARTIES

5. Plaintiff CIOX Health ("CIOX" or "the Company") is a business incorporated and headquartered in Alpharetta, Georgia. CIOX is a specialized medical-records

provider that qualifies as a "business associate" under HIPAA, and healthcare providers in all 50 states contract with CIOX to perform their obligations to lawfully retrieve and release individuals' PHI in accordance with both HIPAA and relevant state privacy laws. CIOX employs more than 7500 people, most of whom are stationed on-site at its clients' facilities as so-called "Release of Information" or "ROI" specialists. As a business associate under HIPAA, CIOX is subject to HHS's regulations and can be subject to civil and criminal money penalties for violations of the Department's rules. 45 C.F.R. §§ 160.402(a) and 164.500(c).

6. Defendant HHS is a federal agency whose responsibilities include the administration of HIPAA, the HITECH Act, the 21st Century Cures Act, and the enforcement of the regulations challenged in this case, including the challenged provisions located within 45 C.F.R. Part 164. HHS's principal office is located at 200 Independence Avenue, S.W., Washington, D.C. 20201, and the unlawful actions challenged in this case originated within HHS's headquarters at its subordinate division known as the Office for Civil Rights ("OCR")—which has accused CIOX of violating the unlawful regulations challenged in this litigation and indeed has threatened to take enforcement action against the Company if CIOX fails to comply with the rules and regulations challenged in this Complaint.

7. Defendant Eric D. Hargan is the Acting Secretary of HHS, is responsible for the overall administration of the Department, and is the official charged by law with administering HIPAA, the HITECH Act, and the 21st Century Cures Act. Acting Secretary Hargan, through his designees at OCR, has undertaken the unlawful

actions challenged in this case, and is sued only in his official capacity. He maintains offices at 200 Independence Ave., S.W., Washington, DC 20204.

JURISDICTION AND VENUE

8. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555, 702, and 704-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because Defendant HHS is a federal agency headquartered in the District of Columbia, because Defendant Hargan is an officer of a federal agency, and because a substantial part of the events giving rise to this complaint occurred in the District of Columbia.

RELEVANT FACTUAL BACKGROUND

10. Ensuring that healthcare providers have timely access to individual medical records is essential to the delivery of high-quality healthcare services and to the minimization of diagnostic, treatment, and other medical errors. So is enabling meaningful involvement by patients in their own course of care, which often results in better health outcomes and lower healthcare costs—particularly when it comes to managing complex diseases and chronic conditions.

11. Accordingly, and as detailed below, Congress long has promoted the development of a nationwide digital healthcare infrastructure that is designed to facilitate the timely dissemination of electronic medical records to both individual patients and the healthcare professionals responsible for guiding their treatment. Given the sensitivity of the information contained in such records, Congress likewise has taken a number of steps to protect the privacy interests that every person has in

the intimate details contained within his or her personal medical files. This case arises at the intersection of those two objectives and involves the legitimate production of individuals' PHI in accordance with the various federal and State statutes and regulations that govern such activities.

12. Producing such information in accordance with these laws is both complex and costly. Each year, hundreds of millions of lawful disclosures of PHI are made throughout the United States. The costs required to fulfill each request for a patient's PHI include not only the supplies and technology used to produce PHI to the requesting party, but also the extensive labor costs associated with receiving, compiling, verifying and processing such requests. Countless records containing PHI-containing patient histories, examination notes, discharge summaries, physicians' orders, pathology and radiology reports, images, x-rays, billing records, and other materials related to a patient's health status and course of medical care are generated or maintained in multiple media formats. And in many cases, these materials are located in multiple physical and virtual locations, which requires staff to be dispatched to physically obtain or retrieve records from an array of sources.

13. As a result, fulfilling a given request for PHI typically requires the responding party to identify, obtain, and compile records drawn from an array of disparate computer databases (including both current and legacy systems); current paper records that may be stored on-site; archived paper or electronic records that often are stored off-site or "in the cloud"; and even microfilm records that, depending on the facility at issue, might be stored either on- or off-site. This process is time-

consuming even when the information is centralized within one site; it is more complex and time-consuming when the information is located in multiple places within a single site; and it is extraordinarily complex and time-consuming where the information is located in multiple locations across multiple sites.

14. Once responsive PHI is located, it takes significant effort to fulfill a request for paper or electronic copies of patient medical records in a manner that complies with both federal law and the patchwork of applicable state privacy laws. A trained ROI specialist must: physically retrieve an individual's medical records from the various media sources and locations in which it has been discovered; review each individual request or authorization to confirm its validity and compliance with applicable legal standards; log the request and supporting details into a computer database; examine every page of the recovered materials in order to ensure compliance with both federal law and the panoply of applicable state privacy regulations (which, for example, can require the redaction of sensitive details regarding past treatment for mental health disorders, drug or alcohol abuse, domestic abuse, or HIV); review the production to ensure that another patient's private information is not erroneously included in the production; convert the records to the requestor's chosen format; physically create a digital or electronic copy of the relevant information that has been compiled; re-file the original version(s) of any retrieved information that was not originally found in a digital format; and either prepare physical copies of the as-compiled materials for mailing (if they are to be produced in paper form); copy the materials to compact disc, a USB drive, or other electronic

storage medium (if electronic copies of the records are to be mailed); or digitize the compilation of materials if they are to be sent to the requestor electronically.

15. The variable costs associated with fulfilling such requests fluctuate dramatically depending on the nature of a given request and each individual patient's unique facts and circumstances. While some routine patient requests might require the location, assessment, compilation, and production of less than 50 pages of materials and/or images (*e.g.*, when an individual is changing his or her primary physician and simply needs to send his or her most recent records to his or her new provider), other requests may seek copies of "any and all" PHI relating to a given individual—particularly when those requests are made in connection with third-party commercial activities, as when a law firm is seeking medical records in connection with the prosecution or defense of litigation or an insurer is seeking to underwrite a new life insurance policy. Such requests can be particularly challenging to fulfill where a given patient has complex or chronic conditions that require continuous treatment, since those conditions tend to generate scores of records across multiple facilities—sometimes within a single healthcare-services system, and often across multiple healthcare systems with distinct record-keeping practices. In such cases, addressing such requests can require the identification, review, compilation, copying, and production of literally thousands of pages of documents, electronic images, and films that may need to be collected from an array of distinct locations in a virtually infinite variety of formats.

16. The recent development and still-nascent adoption of federally-certified electronic health record (or "EHR") technologies pursuant to the HITECH Act (discussed in greater detail below) has not meaningfully reduced the inherent difficulties or labor costs associated with producing patient-level PHI. To the contrary, it has increased them (at least for the time being). Not only do most individuals' medical records currently reside in multiple media formats spread across multiple locations, but the various certified EHR systems now used by healthcare providers and other practitioners have been developed by different vendors using different methods, technologies, and design approaches—resulting in significant variations among health IT platforms that render such systems largely incapable of directly exchanging relevant information without substantial and time-consuming human intervention.

17. Precisely because these EHR technologies are relatively new, countless medical records that may be relevant to a given request pre-date not only the 2009 HITECH Act, the 1996 HIPAA, or the related HHS implementing rules and regulations, but also the date as of which most healthcare providers began to maintain *any* type of digital or electronic records (whether they qualify as EHRs within the meaning of the HITECH Act or not). Particularly when it comes to life-insurance-related requests and records sought in connection with litigation, literally decades of accumulated patient records can be at issue—placing a significant burden on the American healthcare system because such commercial requests almost invariably span broad expanses of time, treatment, and technology.

18. Given these complexities, most hospitals in the United States (which are called "covered entities" under the federal statutes and regulations governing PHI) have chosen to outsource the task of producing PHI to dedicated medical-records providers like CIOX (which the federal statutes and related regulations term "business associates"). In short, it is far less expensive and far more efficient for healthcare providers, who otherwise need to be focused on caring for patients, to outsource these ROI services to highly-specialized businesses like CIOX, who efficiently manage the variable costs associated with the disclosure of PHI and provide their own technological platforms, subject-matter expertise, well-developed ROI operations, and highly-trained personnel. Given their expertise, ROI specialists like CIOX typically retrieve and disclose PHI far more quickly, securely, confidentially, and cost-effectively than most healthcare providers, and outsourcing this cumbersome process to ROI professionals allows healthcare providers to focus their financial and human resources on their core mission: providing first-rate healthcare services to patients.

19. As an ROI vendor to an array of healthcare providers throughout the United States, CIOX currrently handles tens of millions of record requests per year on behalf of its healthcare provider-partners and produces literally billions of pages and images containing PHI annually. In order to ease the burden those requests otherwise might impose on the Nation's healthcare system and to help improve the delivery of healthcare services to patients, CIOX continually has invested in the development of new technologies to improve the accuracy and efficiency of the ROI process—

including proprietary technology platforms that can transmit records across provider sites that use otherwise-incompatible systems, thereby advancing interoperability between disparate locations and systems in accordance with one of Congress's primary goals under both HIPAA and the HITECH Act. *See* HIPAA § 264. Thanks to these innovative solutions, CIOX typically fulfills provider requests to access records for treatment purposes in less than 24 hours, and often can fulfill patient or third-party requests for relevant information within 5 days.

20. Individual patients' requests for copies of their own PHI currently account for approximately 4 percent of CIOX's overall volume. Because CIOX firmly believes in empowering individuals to play an active role in the management of their health and well-being, it has chosen to fulfill such requests at a significant net loss: It provides more than half of the requesting individuals with copies of their own records *free of charge* and charges the remaining minority of individuals at the HHS-mandated rate described in detail below (called the "Patient Rate")—a highly-restrictive rate which does not allow CIOX or its healthcare-provider partners to recoup the substantial costs that are associated with fulfilling such requests. CIOX therefore loses considerable sums when it fulfills these individual requests for PHI.

21. Consistent with its commitment to public health, CIOX likewise incurs substantial losses when it fulfills healthcare providers' requests for records related to a patient's continuity of care—for instance, where staff in one facility requests records relating a patient's treatment at another facility in order to supplement, augment, or assume responsibility for the patient's ongoing course of treatment. These continuity-

of-care requests account for roughly 40-to-50 percent of CIOX's total volume, and CIOX fulfills virtually all of these requests *free of charge*, even though state and federal laws otherwise would allow CIOX to charge for fulfilling such requests. Given CIOX's commitments to helping control costs across the country's sprawling healthcare infrastructure and to empowering both patients and healthcare providers, CIOX thus fulfills roughly half of the record requests it currently fulfills at a substantial net loss.

22. Given those losses, the overwhelming majority of CIOX's revenues historically have come from fulfilling patient-authorized requests for PHI from commercial third parties (such as life insurance companies and law firms) at state-regulated or independently contracted rates. The resulting revenues, derived largely from fulfilling patient-authorized requests from for-profit insurance conglomerates, incorporated businesses, and other commercial partnerships, in turn enable CIOX to provide physicians and the majority of individuals with copies of their own PHI for free (or at a significant net loss) and support CIOX's unique ability to continuously innovate ROI technologies. In short, these revenues—and these revenues alone—keep CIOX in business and enable the Company to play its vital role in: (a) containing costs that otherwise would cripple the Nation's healthcare system; (b) ensuring that healthcare providers have quick, accurate, and reliable access to continuity-of-care records; (c) preventing healthcare providers from being distracted from their patient-care responsibilities; and (d) helping empower individuals to play an active role in

managing their personal health and well-being by ensuring prompt, accurate, and often-free access to their medical records for personal use.

STATUTORY AND REGULATORY BACKGROUND

A. HIPAA (1996)

23. Congress passed HIPAA in 1996 in order to help "improve … the efficiency and effectiveness of the healthcare system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." HIPAA § 261 (codified at 42 U.S.C. § 1320d).

24. As part of those efforts, HIPAA § 264 directed HHS to develop "detailed recommendations on standards with respect to the privacy of individually identifiable health information" and ordered the Department to submit its recommendations to Congress within "12 months after the date of the enactment of this Act." *Id*. § 264(a) (formerly codified at 42 U.S.C. § 1320d-2). HIPAA further specified that the Department's recommendations to Congress "shall address at least the following: (1) The rights that an individual who is a subject of individually identifiable health information should have; (2) The procedures that should be established for the exercise of such rights; (3) The uses and disclosures of such information that should be authorized or required." *Id*. § 264(b) (same).

25. In the event Congress received HHS's recommendations but failed timely to enact "legislation governing standards with respect to the privacy of individually identifiable health information," HIPAA delegated rulemaking authority to HHS to "promulgate final regulations containing such standards not later than the date that

is 42 months after the date of the enactment of this Act." *Id*. § 264(c)(1) (same). HIPAA's grant of rulemaking authority thus was subject to two limitations: First, HHS's authority to regulate the disclosure of individually identifiable information was conditional: It was triggered only if Congress failed to enact its own legislation on this subject matter. And second, it was time-limited, authorizing the Department to promulgate regulations only within a well-defined window of time, rather than providing a perpetual delegation of authority to implement new privacy-related regulations whenever HHS deigned fit and without respect to subsequent legislative activity.

B. HHS's Original Privacy Rule (2000)

26. HHS eventually submitted its privacy recommendations to Congress under HIPAA §§ 264(a)-(b), but Congress failed to enact legislation within the 36-month window set forth in HIPAA § 264(c)(1). That failure in turn triggered HHS's conditional rulemaking authority to promulgate initial regulations regarding these issues, and, after issuing a notice of proposed rulemaking in November 1999, the Department published its final rule in 2000. *See* HHS, *Standards for Privacy of Individually Identifiable Health Information—Final Rule*, 65 Fed. Reg. 82462 (Dec. 28, 2000). For ease of reference, we call this set of regulations the "Privacy Rule."

27. HHS's Privacy Rule created the first uniform federal standards governing the confidentiality, privacy, and lawful dissemination of medical records containing an individual patient's PHI, which the regulations defined in relevant part as "individually identifiable health information … that is: (i) Transmitted by electronic media; (ii) Maintained in any medium described in the definition of electronic media

at [45 C.F.R.] § 162.103 of this subchapter; or (iii) Transmitted or maintained in any other form or medium." *Id*. at 82805 (codified at 45 C.F.R. § 164.501).

28. Consistent with HIPAA § 264(b), the Privacy Rule established a multi-pronged framework governing both *mandatory* and *permissible* disclosures of patient-level PHI, including disclosures to both individual patients and third parties seeking to access an individual's PHI for legitimate purposes: (A) disclosures that were *required* ("required disclosures"); (B) disclosures that were permitted *without* specific patient authorization ("permitted disclosures"); and (C) disclosures that were permitted *with* specific patient authorization ("authorized disclosures").

a. Required Disclosures: As relevant here, the Privacy Rule generally "required" healthcare providers to fulfill an individual's request to inspect and/or obtain a copy of his or her own medical records ("personal use requests"). *Id*. at 82805 (codified at 45 C.F.R. § 164.502(a)(2) ("A covered entity is required to disclose [PHI] … [t]o an individual, when requested under, and required by, [45 C.F.R.] § 164.524")); *see also id*. at 82823 (codified at 45 C.F.R. § 164.524(a) ("[A]n individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set.")).

b. Permitted Disclosures: Outside the personal-use context, the Privacy Rule generally "permitted" providers to disclose PHI without obtaining the patient's specific, prior consent in order "to carry out treatment, payment, or health care operations" or for certain specified categories of activities that are critical to important public health and public policy objectives. *Id*. at 82805 (codified at 45 C.F.R. § 164.502(a)(1)(ii)-(iii)).

c. Authorized Disclosures: Finally, the Privacy Rule established a catch-all category pursuant to which other disclosures are "permitted" if (and only if) such disclosures are preceded by the patient's specific, prior "authorization." *Id*. (codified at 45 C.F.R. § 164.502(a)(1)(iv)); *see also id*. at 82811 (codified at 45 C.F.R. § 164.508 (setting standards for obtaining a "valid authorization" to disclose a patient's PHI to third parties)).

29. Regardless of whether a given disclosure was required, permitted, or authorized by the Privacy Rule, however, HHS understood that the process of gathering and disclosing a patient's PHI in response to a valid request under the Privacy Rule would be both time-consuming and expensive. As we explained earlier, there might be hundreds of documents containing an individual's PHI, from an array of different healthcare providers or systems, which could have been generated and thereafter could be stored in a variety of different formats and physical or virtual locations. Just as the Privacy Rule established distinct procedures governing different categories of allowable disclosures, it established distinct cost-related rules governing these different categories of allowable disclosures.

30. With respect to requests by an individual for his or her own medical records (and for such "personal use" requests *alone*), the Privacy Rule sought to strike a balance between (A) ensuring that patients can afford to access their medical records so that they can participate in the management of their personal health, and (B) ensuring that healthcare providers would not be bankrupted by the expense of complying with their new regulatory obligation to fulfill such requests. For these personal use requests (and again, *only* these personal use requests), the Privacy Rule therefore authorized healthcare providers and their affiliates "to charge a reasonable, cost-based fee" for copying a patient's medical records, which would *include* "the labor and supply costs of copying" those records and postage for mailing those records (if the individual requested that his or her PHI be mailed), but specifically would *exclude*

most of the record provider's other costs. 65 Fed. Reg. at 82557 (emphasis added). As the Preamble to the Privacy Rule explained:

> If hard copies are made, this [reasonable, cost-based fee] would include the cost of paper. If electronic copies are made to a computer disk, this would include the cost of a computer disk. *[But providers] may not charge any fees for retrieving or handling the information [including costs relating to the storage systems and infrastructure needed to do so] or for processing the request.* If the individual requests the information be mailed, the fee may include the cost of postage. Fees for copying and postage provided under state law, but not for other costs excluded under this rule, are presumed reasonable. *If such per page costs include the cost of retrieving or handling the information, such costs are not acceptable under this rule.*

Id. (emphasis added); *see also* 45 C.F.R. § 164.524(c). For ease of reference, we shall refer to this regulatory limitation on allowable fees for servicing personal use requests as the "Patient Rate."

31. For the limited category of personal-use cases to which the Patient Rate applied, the Privacy Rule's strictures thus forced healthcare providers and dedicated medical-records providers like CIOX to operate at a loss—allowing them to recoup *a limited portion* of their costs, but *none* of the substantial expenses associated with data storage, infrastructure, request processing, or document retrieval and compilation—in order to ensure that every patient can afford to obtain his or her own medical records for personal use. 65 Fed. Reg. at 82557 ("If the cost [of obtaining these records] is excessively high, some individuals will not be able to obtain a copy. We encourage covered entities to limit the fee for copying so that it is within reach of all individuals.").

32. At the same time the Privacy Rule's Patient Rate required healthcare providers and their affiliates *to fulfill personal use requests* at a loss, HHS sensibly recognized that no healthcare provider should be forced to operate at *an overall* loss. As a result, the Privacy Rule self-consciously took a different tack for all other disclosures of PHI, including patient-authorized requests from an insurance company seeking to issue a life-insurance policy or from a law firm seeking medical records in connection with litigation (as well as other for-profit commercial entities). In direct contrast to the below-cost Patient Rate applicable to personal use requests, the Privacy Rule expressly declined to impose *any* limitation on the fees providers could charge for fulfilling these other permitted or authorized requests (including requests for commercial, for-profit purposes), thereby allowing hospitals, physicians, and their affiliates to recoup the substantial losses HHS's Patient Rate forced them to incur when fulfilling personal use requests by profitably fulfilling commercial requests for a patient's PHI. *See id*. ("We do not intend to affect the fees that covered entities charge for providing protected health information *to anyone other than the individual*.") (emphasis added).

33. That made sense: Again, HHS could not rationally require that healthcare providers operate at an across-the-board loss when producing records, and because these third-party disclosures typically involve the dissemination of an individual's PHI to commercial entities who themselves are engaged in profit-generating business activities, HHS recognized there was no sensible basis for making healthcare providers and their affiliates incur vast losses so that these other businesses could

generate vast profits at the expense of the healthcare system. Were it otherwise, healthcare providers—who, of course, are focused on providing high-quality healthcare to patients—effectively would be transformed into conscripted record-collection servicers for commercial parties simply to underwrite those companies' commercial profits. As the Privacy Rule therefore explained: "The proposal and the final rule establish the right to access and copy records *only for individuals, not other entities*; the 'reasonable fee' is only applicable to the individual's request. The Department's expectation is that other existing practices regarding fees, if any, for the exchange of records not requested by an individual will not be affected by this rule." *Id*. at 82754 (emphasis added).

C. The HITECH Act (2009)

34. That system worked well, and during the decade that followed implementation of HHS's original Privacy Rule, HIPAA helped modernize our Nation's healthcare system by fostering the development, deployment, and protection of digital medical record systems containing patients' PHI. During this same timeframe, however, the number of distinct digital-record formats and storage systems grew exponentially, and it became increasingly complicated to compile and transfer medical records between providers as patients moved through the healthcare system. Congress therefore passed the HITECH Act in order to further promote the "development of a nationwide health information technology infrastructure that [better] allows for the electronic use and exchange of information." HITECH Act § 3001(b) (codified at 42 U.S.C. § 300jj-11).

35. To that end, the HITECH Act encouraged healthcare providers to standardize "[t]he electronic exchange and use of health information and the enterprise integration of such information" by ensuring "[t]he utilization of an electronic health record [an "EHR"] for each person in the United States by 2014." *Id*. §§ 3001(c)(3)(A)(i)-(ii) (same). The statute in turn defined the term "EHR" as "*an electronic record* of health-related information on an individual *that is created, gathered, managed, and consulted by authorized health care clinicians and staff*"—that is, purely electronic records that are developed, deployed, and used exclusively by healthcare providers to enable the delivery of continuity-of-care services within traditional healthcare-delivery settings like a hospital or physician's office. *Id*. § 13400(5) (emphasis added) (codified at 42 U.S.C. § 17921). The statute further sought to spur healthcare providers to engage in the "meaningful use" of such digital, standard-compliant continuity-of-care records by capping the fees healthcare providers could charge federal insurance programs like Medicare if they failed to meet targets for deploying EHR technologies that complied with federal standards for the electronic exchange of continuity-of-care data (so-called "certified EHR technology"). *See id*. §§ 4101-4102.

36. Given Congress's focus on the digitization, dissemination, and disclosure of physician-generated electronic patient records using this new architecture, the HITECH Act naturally sought to ensure that there would be appropriate "privacy and security protections for the electronic exchange of an individual's individually identifiable health information [*i.e.*, their PHI]." *Id*. § 3001(c)(3)(A)(iii) (codified at 42

U.S.C. § 300jj-11). That focus in turn led Congress to do what it had not done after it received HHS's original HIPAA recommendations: It explicitly reviewed HHS's original Privacy Rule and made a series of legislative modifications that were designed for this new, EHR-based healthcare infrastructure. *See, e.g.*, HITECH Act § 13405 (codified at 42 U.S.C. § 17935 (repeatedly referencing, ratifying, or modifying various provisions of HHS's original Privacy Rule, 45 C.F.R. § 164 *et seq*.)).

37. Against a backdrop where Congress explicitly demonstrated its awareness of the original Privacy Rule's specifics, the HITECH Act made two changes that are relevant to this litigation. First, Congress sought to simplify the authorization process in a narrow category of cases. As set forth above, the prior regulatory system required an often time-consuming process which required patients to provide a written authorization to a third party, who then (and only then) could obtain the individual's PHI from a healthcare provider. To simplify that process, HITECH provided that where a provider maintains an EHR (and *only* where the provider maintains an EHR), patients now can direct the provider (or its affiliate) to "transmit" a copy of the individual's EHR as maintained by the provider directly to a designated third party in an electronic format (and *only* in an electronic format):

> In applying section 164.524 of title 45, Code of Federal Regulations [*i.e.*, the Privacy Rule], in the case that a [healthcare provider] uses or maintains an electronic health record with respect to protected health information of an individual … the individual shall have a right to obtain from such [healthcare provider] a copy of such information in an electronic format and, if the individual chooses, to direct the [provider] to transmit such copy directly to an entity or person designated by the individual, provided that any such choice is clear, conspicuous, and specific.

Id. § 13405(e)(1) (codified at 42 U.S.C. § 17935(e)(1)); *see also* 21st Century Cures Act § 4006(b)(3) (codified at 42 U.S.C. 17935(e)(2) (adding a provision for requests directed to dedicated medical-records providers like CIOX)). For ease of reference, we refer to these provisions of the HITECH and 21st Century Cures Acts as the statutory "Third Party Directive."

38. Second, and again with respect to EHRs (and *only* with respect to EHRs), the HITECH Act made a modest change to the Patient Rate for personal use cases (and, naturally, personal use cases *alone*, because the Patient Rate had never been applied to requests that were intended to serve for-profit commercial purposes). Where a provider is "providing such individual with a copy of such information" in electronic form (as opposed to when the provider is "transmit[ting] such copy directly to an entity or person designated by the individual" pursuant to a Third Party Directive), *compare* HITECH Act § 13405(e)(3) (codified at 42 U.S.C. § 17935(e)(3)) *with id*. § 13405(e)(1) and 21st Century Cures Act § 4006(b)(3) (codified at 42 U.S.C. §§ 17935(e)(1)-(2)), the HITECH Act provided that "any fee that the [provider] may impose *for providing such individual with a copy of such information* … in an electronic form … shall not be greater than the entity's labor costs in responding to the request for the copy." HITECH Act § 13405(e)(3) (codified at 42 U.S.C. § 17935(e)(3) (emphasis added)).

39. For this narrow class of cases (again, involving personal use requests but *not* Third Party Directives), and in these limited circumstances (again, involving the electronic transmission of an EHR but *not* the transmission, whether electronic or

physical, of any records other than EHRs), this change effectively barred providers from charging patients for ancillary supply or postage costs that otherwise had been permitted under the Privacy Rule's original Patient Rate. This limitation was fully rational since, by definition, the electronic transmission of an EHR to an individual patient (as opposed to the physical mailing of records in paper form or a digitized version of non-EHRs on, for instance, a compact disc or flash drive) requires no ancillary supply or postage costs.

40. Apart from these two changes, however, the HITECH Act: (a) did *not* alter the longstanding regulatory division between required disclosures, permitted disclosures, or authorized disclosures; (b) did *not* alter the longstanding rule that the Patient Rate applies *only* to personal use requests but *not* to disclosures of PHI to for-profit commercial entities; and (c) did *not* alter any of the other provisions relevant here except as to the narrowly-defined category of EHRs (which, again, are "electronic record[s] of health-related information on an individual that [are] created, gathered, managed, and consulted by authorized health care clinicians and staff," HITECH Act § 13400(5) (codified at 42 U.S.C. § 17921), rather than paper records, digitized records, or any other compilations of records that may be "gathered," "managed," or stored outside of the typical healthcare-practice setting.

D. HHS's 2013 Omnibus Rule

41. For the first several years after the HITECH Act's enactment, no one questioned the limited nature of the statute's EHR-delimited Third Party Directive or the continued vitality of the Privacy Rule's longstanding proviso that its Patient Rate applies *only* where a healthcare provider or its business associate was

responding to personal use requests from individual patients rather than delivering patient-level PHI to for-profit commercial enterprises like life insurers or lawyers.

42. On January 25, 2013, however, HHS promulgated a new set of regulations (which we refer to as the "2013 Omnibus Rule") that dramatically—and unlawfully—expanded the Third Party Directive beyond the HITECH Act's EHR-delimited confines. *See* HHS, *Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the [HITECH] Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules—Final Rule*, 78 Fed. Reg. 5566 (Jan. 25, 2013). In direct conflict with the plain language of the HITECH Act, these new regulations purportedly required healthcare providers and their affiliates to fulfill patient requests to transfer their PHI directly to a third party *regardless* of whether the underlying PHI was or was not contained in an EHR: "If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual." 45 C.F.R. § 164.524(c)(3)(ii). Moreover, HHS's new regulations required providers to deliver those records in *any format* the patient requested, even though the HITECH Act specified that the statutory Third Party Directive created only a limited right to direct the transmission of EHRs "in an electronic format." *Compare id.* § 164.524(c)(2)(i) *with* HITECH Act §§ 13405(e)(1) and 21st Century Cures Act § 4006(b)(3) (codified at 42 U.S.C. §§ 17935(e)(1)-(2)).

43. HHS did not even pretend that its creation of unbounded regulatory mandate that providers transmit patient PHI, from any form whatsoever (*i.e.*, EHR or non-EHR), in any form whatsoever (*e.g.*, paper, electronic, radiologic film, etc.), to any third party (including profit-seeking commercial parties like insurers and lawyers) was consistent with the HITECH Act's language. Instead, the Department explicitly acknowledged that its regulation was *inconsistent* with the plain terms of the HITECH Act, and therefore sought to invoke the conditional and time-limited rulemaking authority it had been granted under HIPAA § 264(c)(1). In HHS's words:

> Section 13405(e) [*i.e.*, the HITECH Act] applies by its terms *only* to protected health information in EHRs. However, incorporating these new provisions in such a limited manner in the Privacy Rule could result in a complex set of disparate requirements for access to protected health information in EHR systems versus other types of electronic records systems. As such, the Department proposed to use its authority under section 264(c) of HIPAA to prescribe the rights individuals should have with respect to their individually identifiable health information *to strengthen the right of access as provided under section 13405(e) of the HITECH Act* more uniformly to all protected health information maintained in one or more designated record sets electronically, *regardless of whether the designated record set is an EHR*.

2013 Omnibus Rule, 78 Fed. Reg. at 5631 (emphasis added). But the Department made no effort to explain how it lawfully could invoke rulemaking authority that had expired well over a decade *before* HHS even proposed (much less promulgated) the 2013 Omnibus Rule and which in any event was conditioned on a lack of legislative activity in the area—much less how it could exercise that authority in a manner that directly overrode the explicit limitations set forth in Congress's subsequent and specific HITECH Act restrictions.

44. As if to underscore its contempt for the HITECH Act's textual limitations, HHS then expressly refused to define the statutory term EHR for regulatory purposes on the ground that its boundless regulatory version of the statute's otherwise-limited Third Party Directive effectively had rendered Congress's carefully written text irrelevant: "Because we are not limiting the right of electronic access to EHRs, we do not believe there is a need to define or further clarify the term at this time." *Id*. at 5632.

45. The 2013 Omnibus Rule also made certain changes to the Patient Rate's cost structure—most notably by allowing providers to begin charging individuals for at least a portion of the costs that previously had been excluded by the Patient Rate. As the Department explained:

> We [now] acknowledge … that the cost related to searching for and retrieving electronic protected health information in response to requests [is] not … negligible, as opposed to what we had anticipated [when we first promulgated the Privacy Rule], particularly in regards to designated record set access that will require more technically trained staff to perform this function. We clarify that labor costs included in a reasonable cost-based fee could include skilled technical staff time spent to create and copy the electronic file, such as compiling, extracting, scanning and burning protected health information to media, and distributing the media. This could also include the time spent preparing an explanation or summary of the protected health information, if appropriate.

Id. at 5636. Despite this modest concession, HHS nonetheless made clear that it would continue to bar healthcare providers from recovering the sizeable costs associated with compiling and storing the underlying data: "Fees associated with maintaining systems and recouping capital for data access, storage and

infrastructure are not considered reasonable, cost-based fees, and are not permissible to include under this provision." *Id*.

46. Finally, the 2013 Omnibus Rule made no changes to the Privacy Rule's clear statement that the Patient Rate applied only to personal use requests, and not to requests in which a patient's PHI was being delivered to for-profit third parties (whether *via* authorization under the original Privacy Rule's still-intact provisions at 45 C.F.R. §§ 164.502(a)(1)(iv) and 164.508 or *via* the new unbounded version of a third-party directive that HHS had promulgated in open defiance of the HITECH Act's explicit textual limitations).

E. HHS's 2016 Evisceration Of The Patient Rate Rules

47. On February 25, 2016, HHS pivoted again, stunning the medical-records industry by publishing, without any prior notice to the public or any opportunity for comment, a putative "Guidance" document that not only made dramatic changes to the Patient Rate but expressly threatened to initiate enforcement action against healthcare providers and their affiliates if they failed to comply with the putative "Guidance" document's newly issued edicts. *See* HHS, *Guidance: Individuals' Right Under HIPAA To Access Their Health Information* (attached as Exh. A, as modified May 25, 2016). We refer to this new set of regulatory directives as the "2016 Mandates."

48. Two sets of changes are particularly notable here. *First*, in a dramatic reversal from more than a decade of precedent; in defiance of Congress's understanding of the Privacy Rule at the time it enacted the HITECH Act; and in direct conflict with the HITECH Act's plain text, HHS announced that it henceforth

would require application of the Patient Rate beyond the personal use context, including in response to regulatory third party directives ordering healthcare providers to deliver patient records to for-profit commercial entities. *Second*, the 2016 Mandates compounded the impact of that announcement by dramatically curtailing the permissible charges and fees under the Patient Rate, in direct conflict with both the HITECH Act and its own 2013 Omnibus Rule.

1. Application of the Patient Rate to Third Party Directives

49. Though it had been clear for more than a decade that the Patient Rate was intended only to ensure that individuals *themselves* could afford to obtain their medical records for personal use and, thus, that the Patient Rate would not apply to the delivery of records to anyone except the individual, *supra* at ¶¶ 30-32 (collecting quotations), the 2016 Mandates for the first time announced that providers now would be required to deliver records to commercial third parties at the Patient Rate:

> This [fee] limitation [*i.e.*, the Patient Rate] applies *regardless* of whether the individual has requested that the copy of the PHI be sent to herself, or has directed that the covered entity send the copy directly to a third party designated by the individual (and it doesn't matter who the third party is).

2016 Mandates at p.16 (emphasis added).

50. Thus, when a for-profit law firm or life insurance company submits a request that is framed as a regulatory third party directive, the 2016 Mandates now obligate providers—under threat of administrative prosecution—to gather and produce any volume of records sought at the loss-generating Patient Rate, effectively forcing healthcare providers and dedicated medical-records providers like CIOX to subsidize

those businesses' profits and threatening to impose massive costs on the American healthcare system.

2. Further Constriction Of The Patient Rate

51. Adding further injury, the 2016 Mandates then made dramatic changes to the component terms of the Patient Rate—substantially curtailing the already-limited fees that providers previously had been allowed to charge for fulfilling individuals' record requests for their own personal use and now would be forced to charge for-profit commercial entities as well.

52. As set forth above, the 2013 Omnibus Rule specifically had provided that medical-records providers like CIOX would be entitled to begin charging requestors for "skilled technical staff time" involved in the process of "searching for and retrieving electronic protected health information in response to requests" because those costs far exceeded HHS's original assumption that such costs would be "negligible." *Supra* at ¶ 45 (quoting 2013 Omnibus Rule, 78 Fed. Reg. at 5636). Despite the plain terms of the 2013 Omnibus Rule, however, the 2016 Mandates suddenly declared that such costs must be *excluded* from any "reasonable, cost-based fee" calculated under the Patient Rate:

> Labor for copying <u>includes only</u> labor for creating and delivering the electronic or paper copy in the form and format requested or agreed upon by the individual, *once the PHI that is responsive to the request has been identified, retrieved or collected, compiled and/or collated, and is ready to be copied*….
>
> In contrast, labor for copying does *not* include labor costs associated with*: Reviewing the request for access [or s]earching for, retrieving, and otherwise preparing the responsive information for copying. This includes labor to locate the appropriate designated record sets about the individual, to review the records to identify*

> *the PHI that is responsive to the request and to ensure the information relates to the correct individual, and to segregate, collect, compile, and otherwise prepare the responsive information for copying*.

2016 Mandates at p.12 (emphasis added).

53. It would be hard to overstate the consequences of that change in the third-party directive context, particularly where commercial records requests are at issue. Again, such requests frequently seek "any and all" PHI relating to a given individual and therefore require the identification, review, compilation, copying, and production of literally thousands of pages of documents, electronic images, and films that may need to be collected from an array of distinct locations in a virtually infinite variety of formats. The 2016 Mandates' exclusion of the exhaustive labor and associated costs of "locat[ing] the appropriate designated record sets about the individual," "review[ing] the records to identify the PHI that is responsive to the request and to ensure the information relates to the correct individual," and "segregate[ing], collect[ing], compil[ing], and otherwise prepar[ing[the responsive information for copying," *id*., thus threatens to impose *hundreds of millions of dollars* in costs that no longer can be recouped by healthcare providers—all so that for-profit insurers and lawyers can make bigger profits from their purely commercial activities.

54. Beyond this unlawful, unexplained and irrational departure from the 2013 Omnibus Rule, the 2016 Mandates also purported to require providers to choose from one of three new options for calculating the permissible fees for producing PHI under the Patient Rate: (a) an "actual cost" method that is impossible to apply in practice; (b) an "average cost" method that fails sensibly to account for the relevant costs

associated with fulfilling requests for patients' PHI; or (c) a $6.50 flat fee that was drawn from thin air and bears no rational relationship to the actual costs associated with processing such requests.

> 55. **Actual Cost***:* The "actual cost" option would require providers to calculate the actual labor cost and actual supply cost for each and every request it fulfills, which in CIOX's case is tens of millions of records per year. To perform these millions of calculations, the provider would have to compute, for each and every request, the precise length of time it take the entity's ROI specialists to copy and send the record in the form and format requested by the individual and then "multiply the time by [the employee's] reasonable hourly rate." *Id*. at p.14. Moreover, the 2016 Mandates would require providers like CIOX to calculate the employee's "reasonable hourly rate" differently depending on the type of request: "What is reasonable for purposes of an hourly rate will vary depending on the level of skill needed to create and transmit the copy in the manner requested or agreed to by the individual (e.g., administrative labor level to make and mail a paper copy versus more technical skill needed to convert and transmit the PHI in a particular electronic format)." *Id*. Given the tens of millions of requests that companies like CIOX process annually, it is impossible as a practical matter for an entity like CIOX to employ this method—as CIOX would have explained to HHS in written comments had HHS provided the public with notice of and an opportunity to comment on this absurdly impractical proposal.

> 56. **Average Cost**: The "average cost" option would require providers to "develop a schedule of costs for labor based on average labor costs to fulfill standard types of access requests, as long as the types of labor costs included are the ones which the Privacy Rule permits to be included in a fee (e.g. labor costs for copying but not for search and retrieval) and are reasonable." *Id*. That option is no more rational, because the effort required to process any individual request varies dramatically depending on the patient's medical history, the number of forms and locations where the patient's records are located, the number of pages of the records produced, the length of time for which records are sought, and a variety of other highly-individualized factors that are entirely independent of whether a given request can be shoehorned into a "standard type." HHS sought to address that obvious deficiency in its methodology by permitting providers to calculate "average labor rates" on a per-page basis, but *only* when the record was originally created in a paper

> medium and the individual requests a paper copy, or when the individual requests that an original paper copy be scanned into an electronic file, and *not* in determining the appropriate charge for providing records that are maintained in an electronic medium. *Id*. Yet there is no rational basis for this limitation, which ignores that most records maintained electronically were produced by converting paper records into PDF format "pages" of electronically stored media and, likewise, that there is no way for patients to receive records directly from an EHR in those cases where the request implicates not only electronically-stored information but information that is stored within a statutory EHR.
>
> 57. **The $6.50 Flat Fee**: Given the absurdity of the two other methodologies set forth in the 2016 Mandates, HHS ultimately authorized providers to charge a flat fee, not to exceed $6.50, for fulfilling a given request for records. But the Department made no effort to explain why $6.50 was an appropropriate measure of the extraordinary costs associated with providing such records; that fee bears no rational relationship to the actual cost of fulfilling these requests; and it is not remotely tailored to the rationale for having a Patient Rate in the first place. Ultimately, this fee limitation threatens to impose hundreds of millions of dollars on the American healthcare system.

58. Finally, the 2016 Mandates ominously threatened that the Department "will take enforcement action where necessary" to enforce compliance with these new edicts. *Id*. at p.11. Defendants later made good on that threat by informing CIOX that it had violated the 2016 Mandates by invoicing certain allegedly excluded fees in response to a regulatory third party directive. *See, e.g.*, Letter from HHS to J. Sommers, OCR Transaction No. 17-259171, at 3 ("The fee may not include costs associated with verification; documentation; searching for and retrieving the PHI; maintaining systems; recouping capital for data access, storage or infrastructure; or other costs not listed above even if such costs are authorized by State law…. The specifics … are set forth in the OCR guide entitled 'Individuals' Right under HIPAA to Access the Health Information.'") (attached as Exh. B).

FIRST CAUSE OF ACTION
(Violation of 5 U.S.C. § 706(2)—2013 Omnibus Rule and 2016 Mandates)

59. CIOX repeats and incorporates by reference the allegations contained in paragraphs 1 through 58 above.

60. The 2013 Omnibus Rule is final agency action within the meaning of 5 U.S.C. § 704 and therefore is subject to immediate judicial review. As outlined both previously and hereinafter, its creation of an unbounded third-party directive is both "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id*. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id*. § 706(2)(C).

61. Prior to the HITECH Act's enactment in 2013, neither HIPAA nor the Privacy Rule contained any mechanism by which individuals could direct healthcare providers or their affiliates to deliver PHI to third parties. Instead, the only mechanism for third-party delivery under the Privacy Rule required the third party to deliver a valid "authorization" from the individual whose PHI was being requested. *See* Privacy Rule, 65 Fed. Reg. at 82805 (codified at 45 C.F.R. § 164.502(a)(1)(iv)); *id*. at 82811 (codified at 45 C.F.R. § 164.508 (setting standards for obtaining a "valid authorization" to disclose a patient's PHI, including to commercial third parties)).

62. By its plain terms, the HITECH Act's Third-Party Directive applies only to "*an electronic health record* with respect to [PHI] of an individual," HITECH ACT § 13405(e) (codified at 42 U.S.C. §§ 17935(e) (emphasis added)); grants individuals "a right to obtain" only "*a copy of such information in an electronic format*," *id*.(emphasis added); and, with respect to the Third-Party Directive, merely authorizes the

individual "to direct the covered entity to transmit *such copy* [*i.e.*, the "copy of such information in an electronic format," *id.*] directly to [a designated] entity or person." *Id*. (emphasis added). By its plain terms, the HITECH Act's statutory Third Party Directive therefore applies exclusively to PHI that is contained in EHRs—not to any other records that happen to contain a person's PHI—and further requires that healthcare providers and their affiliates like CIOX can be compelled to deliver such information to the individual's Third-Party designee *only* in electronic format.

63. As HHS openly conceded when it promulgated the 2013 Omnibus Rule, its unbounded regulatory version of a third-party directive directly conflicts with the HITECH Act's textual restrictions both (a) by requiring providers to deliver an individual's PHI to third parties *regardless* of whether that information is derived from an EHR, and (b) by requiring providers to deliver that information to third parties *in any format* demanded by the requestor (not just in electronic format, as the HITECH Act expressly provided). *See* 2013 Omnibus Rule, 78 Fed. Reg. at 5631; *see also* 45 C.F.R. § 164.524(c). It therefore is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id*. § 706(2)(C).

64. HHS's only alleged basis for its conceded disregard of the HITECH Act's explicit statutory limitations is its claim that the Department somehow was authorized to exercise "authority under section 264(c) of HIPAA to prescribe the rights individuals should have with respect to their individually identifiable health

information to strengthen the right of access as provided under section 13405(e) of the HITECH Act." 2013 Omnibus Rule, 78 Fed. Reg. at 5631. But HHS's rulemaking authority under HIPAA § 264(c) was conditioned on Congress's failure to enact pertinent legislation. *See* HIPAA § 264(c) (formerly codified at 42 U.S.C. § 1320d-2). Once Congress spoke to this issue in the HITECH Act, that basis for action dissolved. Moreover, HHS's rulemaking authority under HIPAA § 264(c) in any event expired in 2000—nearly a decade before Congress passed the HITECH Act, and well over a decade before HHS even proposed the 2013 Omnibus Rule (much less promulgated it). Indeed, precisely because HHS's § 264 rulemaking authority lapsed ages ago, it no longer is codified in the U.S. Code; it has been relegated to a "historical note" because it no longer is extant. And even if HHS's conditional and otherwise time-limited rulemaking authority under HIPAA § 264(c) somehow could survive those glaring defects, it is well-settled that federal agencies like HHS cannot use an earlier grant of general rulemaking authority to override the specific limitations of later-enacted statute like the HITECH Act.

65. The unbounded version of the third-party directive set forth in the 2013 Omnibus Rule and 2016 Mandates is thus *ultra vires*, *see* 5 U.S.C. § 706(2)(A), (C), and CIOX is entitled to both declaratory and injunctive relief barring both its enforcement and enforcement of any related provisions of the 2016 Mandates. *Id.* § 706(2); *see also* 28 U.S.C. § 2201(a); *id.* § 2202.

SECOND CAUSE OF ACTION
(Violation of 5 U.S.C. § 706(2)(d)—2016 Mandates)

66. CIOX repeats and incorporates by reference the allegations contained in paragraphs 1 through 65 above.

67. The APA requires federal agencies, including HHS, to publish a "notice of proposed rulemaking" (or "NPRM") in the Federal Register and to provide the public with an opportunity to comment on the NPRM before promulgating any substantive "rules," 5 U.S.C. § 553(b), which include any agency action or actions relating to the "approval or prescription for the future of rates, … prices, … services or … costs, or accounting, or practices bearing on any of the foregoing." *Id.* § 551(4).

68. Though HHS deemed the 2016 Mandates a "Guidance," they actually are legislative rules within the meaning of the APA and represent "final agency action for which there is no other adequate remedy." *Id.* § 704. Among other things: (A) the 2016 Mandates characterize the rate-, price-, service-, cost-, and accounting-relating requirements they set forth in binding, rather than precatory, discretionary, policy, or interpretive terms; (B) they expressly threaten the parties that are subject to their requirements (including non-profit hospitals, community hospitals, physicians, clinics, and dedicated medical records providers like CIOX) with "enforcement action" for violations; (C) the rules they impose deviate from more than a decade of previously-enacted regulatory requirements that themselves had been promulgated through notice-and-comment rulemaking; and (D) HHS indeed has taken enforcement action against CIOX (and, on information and belief, others) based expressly on provisions of the new substantive rules first established by the 2016

Mandates—including the 2016 Mandates' unprecedented and previously undisclosed edict that the Patient Rate must be applied whenever patient-level PHI is delivered to for-profit commercial entities pursuant to the unbounded regulatory version of the HITECH Act's Third Party Directive, and the new methods by which hospitals, physicians, and their affiliates must calculate fees associated with fulfilling requests for PHI under the 2016 Mandates.

69. Despite the fact that the 2016 Mandates therefore qualify as legislative rules, HHS issued those rules without providing the public with any notice of its intention to do so and without providing the public with any opportunity to comment on the Department's historically unprecedented proposals, in direct violation of 5 U.S.C. §§ 553(b)-(c). Given HHS's failure to comply with the APA's rulemaking strictures, the 2016 Mandates were unlawfully issued "without observance of procedure required by law," *id*. § 706(2)(D), and CIOX is entitled to both declaratory and injunctive relief barring Defendants from taking any action to enforce any provision or provisions of the 2016 Mandates. *Id*. § 706(2); *see also* 28 U.S.C. § 2201(a); *id*. § 2202.

THIRD CAUSE OF ACTION
(Violation of 5 U.S.C. § 706(2)—2016 Mandates)

70. CIOX repeats and incorporates by reference the allegations contained in paragraphs 1 through 69 above.

71. From the inception of the Privacy Rule in 2000, HHS made clear that its below-cost Patient Rate applied solely to personal use requests for PHI—that is, requests in which individuals requested the delivery of their own PHI to themselves

for their own health treatment—and not to requests in which such information would be delivered to a for-profit commercial entity like a life insurance company or law firm for their own profit-making purposes. 65 Fed. Reg. at 82557 ("We do not intend to affect the fees that covered entities charge for providing protected health information *to anyone other than the individual*.") (emphasis added); *see also id.* at 82754 ("The proposal and the final rule establish the right to access and copy records *only for individuals, not other entities*."). Instead, the Privacy Rule and subsequent decade of practice allowed the States to develop, implement, and enforce their own cost-based structures for such services.

72. Congress was well aware of that backdrop when it passed the HITECH Act in 2009 but took no steps to alter this longstanding regulation or its deference to State regulation of PHI by third parties. To the contrary, it expressly ratified that longstanding rule when it addressed cost structures in the new legislation, by distinguishing between the costs applicable where an individual seeks to obtain his or her own PHI for personal use and the costs applicable where such information is to be transmitted to third parties. In particular, the HITECH Act's Third Party Directive established two distinct rights: One pursuant to which individuals could "obtain from [a] covered entity a copy of [their PHI] in an electronic format," 42 U.S.C. § 17935(e)(1), and the other pursuant to which individuals could direct the covered entity "to transmit such copy directly to an entity or person designated by the individual," *id.* § 17935(e)(1), or ask a business associate to "grant or transmit such

access or copy to such person or entity designated by the individual." *Id.* at § 17935(e)(2).

73. In expressly addressing the permissible fees for fulfilling statutory Third Party Directives, however, Congress made clear that the Patient Rate fee limitations under "paragraph (c)(4) of … section 164.524 of title 45, Code of Federal Regulations" would apply only where the records provider was "providing *such individual* with a copy of such information," *id.* § 17935(e)(3) (emphasis added), but not where the records provider was "transmit[ting] such copy directly *to an entity or person designated by the individual*." *Cf. id.* §§ 17935(e)(1), (e)(2) emphasis added). Congress thus expressly distinguished between the individual right to "obtain" or "access" his or her own PHI and the individual's right to direct its "transmi[ssion]" to a Third Party, but applied the Patient Rate *only* to cases where the individual was "obtain[ing]" or "access[ing]" his or her own information and *not* in cases where the individual was directing the "transmi[ssion]" of PHI to a third party. That is clear evidence that Congress did not intend to apply the Patient Rate to Third Party Directives. After all, where Congress uses distinct language in different provisions of the same statutory scheme, its choice is presumed to be deliberate. And where Congress knows how to say something but fails to do so, it likewise presumed to act intentionally in the disparate inclusion or exclusion of the pertinent language.

74. Despite Congress's clear textual distinction between the fees that may be charged for personal use requests and those that may be charged in connection with Third Party Directives, the 2016 Mandates (a) gutted the longstanding distinction

Congress had relied upon in passing the HITECH Act; (b) flouted the HITECH and 21st Century Cures Acts' maintenance of those distinctions; (c) disregarded HHS's own rationale for having limited the Patient Rate to personal use requests for the preceding 15 years (namely, its concern with whether individuals could afford to access their own records for personal use, rather than whether for-profit businesses had to pay market rates in order to access their customers' records when carrying out profitable commercial activities); and (d) articulated no rational basis for reversing its longstanding regulatory distinction between categories of record requests, by directing healthcare providers and their affiliates to begin applying the Patient Rate to Third Party Directives and by expressly threatening to take enforcement action against companies who failed to follow this loss-generating mandate. Incredibly, HHS published the 2016 Mandates and upended decades of practices without proposing those changes, soliciting comments on them, or addressing any comments on them.

75. That decision thus is both "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C). CIOX is entitled to both declaratory and injunctive relief barring Defendants from taking any action to enforce any provisions of the 2016 Mandates that would require them to charge the loss-generating Patient Rate to any request for transmission of patient-level PHI pursuant to a statutory Third Party Directive

(or HHS's otherwise and independently unlawful regulatory version of a third party directive). *Id*. § 706(2); *see also* 28 U.S.C. § 2201(a); *id*. § 2202.

76. At the same time the 2016 Mandates flouted the HITECH Act's continued limitation of the Patient Rate to personal use requests, their exclusion of skilled technical staff time involved in the process of searching for and retrieving electronic protected health information directly conflicts with the 2013 Omnibus Rule's explicit inclusion of such costs in the Patient Rate. But federal agencies cannot take actions that conflict with their own regulations, and this aspect of the 2016 Mandates thus likewise is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id*. § 706(2)(C). CIOX is therefore entitled to both declaratory and injunctive relief barring Defendants from taking any action to enforce this exclusion.

77. Finally, and for the reasons detailed above, the 2016 Mandates' tripartite methodology for calculating allowable costs under the Patient Rate—wherever that rate must be applied—is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id*. § 706(2)(A), because there is no colorable basis, and because HHS failed to offer any credible rationale, for imposing the impractical, absurd, and irrational cost methodologies that the 2016 Mandates forced on providers without prior notice or any opportunity to comment on these facially irrational mandates. Once again, CIOX therefore is entitled to both declaratory and injunctive

relief barring Defendants from taking any action to enforce these provisions of the 2016 Mandates.

PRAYER FOR RELIEF

WHEREFORE, CIOX prays that this Court:

A. **DECLARE AND HOLD** that the 2013 Omnibus Rule's unbounded version of the HITECH Act's Third Party Directive is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id.* § 706(2)(C);

B. **DECLARE AND HOLD** that the 2016 Mandates were unlawfully issued "without observance of procedure required by law," *id.* § 706(2)(D), are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2)(A), and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id.* § 706(2)(C).

C. **VACATE, SET ASIDE, AND PERMANENTLY ENJOIN** Defendants from taking any action to enforce the 2013 Omnibus Rule's unbounded version of the HITECH Act's Third Party Directive;

D. **VACATE, SET ASIDE, AND PERMANENTLY ENJOIN** Defendants from taking any action to enforce the 2016 Mandates; and

E. **GRANT** such further relief as the Court may deem just and proper.

Dated: January 8, 2018

Respectfully submitted,

By: /s/ Michael D. Shumsky

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 8th day of January, 2018, he caused the foregoing COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF to be served upon the following via messenger and/or electronic mail:

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