UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

CIOX HEALTH, LLC, Plaintiff, v. ALEX M. AZAR II, Secretary of Health and Human Services, *et al.*, Defendants.	Case No. 1:18-cv-00040-APM

MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND IN SUPPORT OF CIOX'S CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

To hear the government tell it, HHS's regulations do not limit the fees CIOX is able to charge when it discloses protected health information ("PHI") on behalf of "covered entities" because CIOX is a "business associate" rather than a covered entity itself, and because the challenged regulations are "solely concerned with imposing obligations upon covered entities with respect to the manner of and fees relating to the provision of PHI at an individual's request, not with imposing such obligations upon business associates like Ciox." Mot. to Dismiss ("MTD") (Dkt. 9-1) at 2. Indeed, the government claims, HHS "cannot take enforcement action against CIOX regarding the fees it charges for individual requests of PHI" because the challenged regulations don't apply to business associates at all—only covered entities. *Id*. at 14.

Those claims are astonishing. Section 13404(a) of the HITECH Act intentionally and unambiguously applied the rules governing covered entities "to business associates in the same manner as they apply to the providers and health plans for whom they are working," H.R. CONF. REP. No. 111-16, at 493 (2009), *reprinted in* 2009 U.S.C.C.A.N. 3, 86 (explaining HITECH § 13404(a)), and in a series of regulations the government never acknowledges, HHS thus mandated that business associates:

> (A) are "required to disclose [PHI] as necessary to satisfy a covered entity's obligations … with respect to an individual's request for an electronic copy of [PHI]," 45 C.F.R. § 164.502(a)(4)(ii), including the obligations to disclose PHI to commercial third parties pursuant to the challenged Third Party Directive regulation and in accordance with the challenged Patient Rate regulation, where applicable;
>
> (B) "may not use or disclose [PHI] in a manner that would violate the requirements of this subpart, if done by the covered entity," *id*. § 164.502(a)(3), such as charging more than the challenged Patient Rate regulation would allow; and

> (C) are directly liable for "a civil money penalty" if they "violate[] an administrative simplification provision," which is defined to include both the challenged Third Party Directive and Patient Rate rules. *Id.* § 160.402(a).

That is why, when HHS issued these regulations in 2013, it declared that "any Privacy Rule limitation on how a covered entity may use or disclose [PHI] ***automatically extends to a business associate***." *Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under [HITECH]—Final Rule*, 78 Fed. Reg. 5566, 5597 (2013) ("2013 Omnibus Rule").[1]

Even so, the government insists the challenged rules aren't harming CIOX because they leave the Company entirely "free to negotiate the terms of the payments [it] may receive [from covered entities] for its services." MTD at 2. That claim is dubious at best. Even if covered entities alone are subject to the challenged regulations, the notion that business associates like CIOX could "freely" negotiate with those entities outside the shadow of HHS's rules is pure fantasy. Restricting the fees covered entities can charge parties requesting PHI necessarily impacts how much those entities might be willing to pay the business associates who provide PHI on their behalf. More important, this argument's whole premise is flawed. Like most business associates, CIOX typically does not receive fees ***from covered entities*** when it fulfills their disclosure duties. Instead, CIOX's payment for such services consists of the fees it receives ***the PHI-requesting party or recipient***. Decl. of Tarun Kabaria ¶ 10 ("Kabaria Decl.") (attached as Exh. A). To the extent the government means to suggest that CIOX could mitigate the adverse impact of HHS's rules by

[1] Unless otherwise noted, all emphases are added.

renegotiating its roughly 13000 contracts and transforming its business model, that's not a jurisdictional argument; it's a recognition that the challenged rules are crushing this industry. CIOX has every right to challenge HHS's regulations.

Given the purely legal nature of CIOX's claims and the harms HHS's regulations are imposing on CIOX, there is no reason to defer a decision on the merits. Indeed, the government's motion to dismiss practically invites such a decision because its arguments are inextricably intertwined with the merits—as when it argues that HHS's 2016 Mandates are not subject to judicial review because they are interpretive rules rather than legislative ones. MTD at 23-28. After all, if this Court holds that the challenged rules were in fact legislative, CIOX would be entitled to judgment as a matter of law on its claim that the 2016 Mandates violated the APA's notice-and-comment rulemaking requirement.

With that in mind, CIOX is entitled to judgment as a matter of law on all counts. With respect to Count I, the HITECH Act's plain language bars HHS's extension of the Third Party Directive beyond PHI contained in Electronic Health Records ("EHRs"). As the Complaint explained and the government concedes, HITECH's Third Party Directive applies ***only*** where "a covered entity uses or maintains an [EHR]." MTD at 4 (quoting 42 U.S.C. § 17935(e)(1)). Yet HHS's 2013 Omnibus Rule extended the Third Party Directive to all PHI "***regardless*** of whether the designated record set [containing such PHI] is an EHR," 2013 Omnibus Rule, 78 Fed. Reg. at 5631, and indeed "***without regard to*** whether the [PHI] is in electronic or paper

form." *Id.* at 5634. Federal agencies have no authority to override conceded statutory limitations, and CIOX therefore is entitled to judgment as a matter of law.

CIOX likewise is entitled to judgment on Counts II and III. While the government repeatedly asserts that HHS's 2016 Mandates merely "paraphrase" or "clarify" its regulations and otherwise leave CIOX "free" to adopt a different view, MTD at 25, 27 n.9, it never engages with the Mandates's actual language—which deviates from the regulations HHS issued through notice-and-comment rulemaking, unambiguously declares how regulated parties must (and must not) conduct their business, expressly forbids regulated parties from taking steps to avoid the new mandates, and repeatedly threatens federal enforcement action if the new dictates are violated. Those are the hallmarks of legislative rulemaking, and CIOX is entitled to relief.

Finally, the 2016 Mandates are invalid on their own terms. To the extent they require application of the Patient Rate to Third Party Directives, they directly conflict with HITECH's explicit limitation of the Patient Rate to cases where regulated parties are "providing [the requesting] individual with a copy of [their PHI]," 42 U.S.C. § 17935(e)(3), not cases where they are "transmit[ting] such copy directly to an entity or person designated by the individual" under a Third Party Directive. *Id.* § 17935(e)(1). And where the Mandates otherwise curtail the scope of permissible charges under the Patient Rate, those limits directly conflict with HHS's prior regulations by excluding previously-authorized charges and otherwise arbitrarily constraining the "reasonable, cost-based fee" regulated entities are allowed to charge.

The Court should deny HHS's motion to dismiss and enter judgment for CIOX.

STATUTORY AND REGULATORY BACKGROUND

A. HIPAA (1996)

In 1996, Congress passed the Health Insurance Portability and Accountability Act ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, to "encourag[e] 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. § 1320(d)). To that end, HIPAA directed HHS to develop "detailed recommendations on standards with respect to the privacy of individually identifiable health information" and ordered HHS 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 should address "(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; [and] (3) The uses and disclosures of such information that should be authorized or required." *Id*. § 264(b) (same). If Congress failed timely to enact "legislation governing [such] standards" after receiving HHS's recommendations, HIPAA further authorized 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).

B. HHS's Original Privacy Rule (2000)

HHS submitted the required recommendations, but Congress did not enact legislation. HHS therefore invoked HIPAA's conditional rulemaking authority and issued its "Privacy Rule." HHS, *Standards for Privacy of Individually Identifiable*

Health Information—Final Rule, 65 Fed. Reg. 82462 (2000). That rule set uniform federal standards governing the confidentiality, privacy, and dissemination of records containing "protected health information" (or "PHI"), which was defined as "individually identifiable health information … that is … [t]ransmitted or maintained in any … form or medium." *Id.* at 82805 (codified at 45 C.F.R. § 164.501).

1. Required, Permitted, and Authorized Disclosures

Consistent with HIPAA § 264(b), the Privacy Rule then established a multi-pronged framework governing both mandatory and permissible disclosures of PHI, including disclosures of PHI to both patients and third parties:

a. Required Disclosures: The Privacy Rule generally "required" healthcare providers (called "covered entities") to fulfill an individual's request for a copy of his or her own PHI ("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")).

b. Permitted Disclosures: Outside the personal use context, the Privacy Rule generally "permitted" the disclosure of PHI ***without*** obtaining a patient's specific, prior consent in order "to carry out treatment, payment, or health care operations" or to fulfill critical public-health objectives. *Id.* (codified at 45 C.F.R. § 164.502(a)(1)(ii)-(iii)).

c. Authorized Disclosures: Finally, the Privacy Rule established a catch-all category which, as relevant here, allowed commercial third parties to obtain a patient's PHI for legitimate purposes—such as underwriting an insurance policy or pursuing legal claims. In these cases, PHI disclosures were "permitted" if, and only if, the requestor first obtained the patient's specific "authorization." *Id.* (codified at 45 C.F.R. § 164.502(a)(1)(iv)).

2. The Patient Rate

Regardless of the basis for a given disclosure, HHS understood that gathering and disclosing records containing PHI would be time-consuming and costly. Just as the Privacy Rule set distinct rules for distinct types of disclosures, it established

distinct fee-related rules for those distinct types. As to patient requests for their own PHI (and for such "personal use" requests ***alone***), the Privacy Rule struck a balance between (A) ensuring that patients can afford to access their own PHI so that they can play a meaningful role in their own healthcare decisionmaking, and (B) ensuring that providers would not be bankrupted by the cost of fulfilling such requests. For such personal use requests (and ***only*** such requests), the Privacy Rule authorized providers "to charge a reasonable, cost-based fee" that would ***include*** "the labor and supply costs of copying" those records and postage for mailing them (if the individual requested physical copies), but ***exclude*** most other costs. 65 Fed. Reg. at 82557; *see also* 45 C.F.R. § 164.524(c). This fee limitation is known as the "Patient Rate," and for the personal use requests to which it applied, the Privacy Rule thus required providers to fulfill requests at a net financial loss in order to ensure that patients can afford to obtain their own PHI. 65 Fed. Reg. at 82557 ("If the cost [of obtaining PHI] is excessively high, some individuals will not be able to obtain a copy. We encourage [providers] to limit the fee for copying so that it is within reach of all individuals.").

At the same time the Privacy Rule required providers to fulfill personal use requests at a loss, HHS recognized it would make no sense to impose such losses when records are destined ***for commercial third parties***, such as lawyers engaged in litigation or life insurers underwriting a policy. Accordingly, the Privacy Rule expressly declined to limit the fees permitted for fulfilling such requests in response to a patient authorization. *Id*. ("We do not intend to affect the fees that covered entities charge for providing [PHI] ***to anyone other than the individual***."); *id*. at

82754 ("[T]he 'reasonable fee' is ***only applicable to the individual's request***."). The Privacy Rule thus allowed providers to recoup the losses they would incur when fulfilling personal use requests at the Patient Rate, by charging the higher commercial-use rates that more than 40 States have authorized.

3. Indirect Regulation Of Business Associates

Finally, the original Privacy Rule explained that its strictures would apply ***directly*** to healthcare providers alone—not their service-providing business associates, including medical-records specialists like CIOX—because the original HIPAA statute limited HHS's direct regulatory authority to health plans, healthcare clearinghouses, and healthcare providers. *Id*. at 82641 ("[HIPAA] limits us to regulate only those covered entities listed in [45 C.F.R.] § 160.102."). Even so, HHS expressed grave concerns that fully exempting business associates from the reach of these rules could let "covered entities … circumvent [the] rules by the simple expedient of contracting out … various functions." *Id*. at 82640.

To prevent such abuses, the Privacy Rule extended its requirements to business associates ***indirectly***: Citing HHS's authority "to regulate what uses and disclosures of [PHI] ***by covered entities*** are 'authorized,'" the Privacy Rule expressly barred covered entities from engaging service providers like CIOX to handle PHI unless the parties first executed a "business associate contract." *Id*. And, as relevant here, HHS ordered that any such contract must (A) "***not*** authorize the business associate to use or further disclose [PHI] ***in a manner that would violate the requirements of this subpart, if done by the covered entity***," and (B) obligate the business associate to "[m]ake available [PHI] ***in accordance with [45 C.F.R.] § 164.524***," which is the

regulation establishing both the personal right of access to PHI and the Patient Rate. *Id*. at 82808 (codified in 45 C.F.R. § 164.504(e)). Though the government never acknowledges it, HHS thereby imposed the Privacy Rule's strictures on business associates like CIOX indirectly, through legally-mandated contract terms.

C. The HITECH Act (2009)

Over the next decade, HIPAA spurred the development of a nationwide digital architecture for maintaining and disseminating PHI. But it also became a victim of its own success: By 2009, the number of distinct digital-record formats and storage systems had grown exponentially, making it nearly impossible to efficiently transfer records between providers. Congress therefore passed the Health Information Technology for Clinical and Economic Health Act ("HITECH"), Pub. L. No. 111-5, 123 Stat. 115, 226 (2009), to promote the "development of a nationwide health information technology infrastructure that [better] allows for the electronic use and exchange of information." HITECH § 3001(b) (codified at 42 U.S.C. § 300jj-11).

To that end, HITECH encouraged healthcare providers to standardize "[t]he electronic exchange and use of health information" by ensuring "[t]he utilization of an [EHR] for each person in the United States by 2014." *Id*. §§ 3001(c)(3)(A)(i)-(ii) (same). The statute in turn defined 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 created, maintained, and used exclusively by healthcare providers to deliver healthcare services. *Id*. § 13400(5) (codified at 42 U.S.C. § 17921).

Given Congress's focus on the digitization and exchange of physician-generated electronic patient records, HITECH naturally sought to establish 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 the Privacy Rule and ordered specific changes for this new, EHR-based infrastructure. HITECH § 13405 (codified at 42 U.S.C. § 17935).

1. The Third Party Directive

Against a backdrop where Congress explicitly demonstrated its awareness of the Privacy Rule's specifics, HITECH made three relevant changes. ***First***, it sought to simplify the "authorization" process in certain cases. Under the original Privacy Rule, commercial third parties could only secure direct access to PHI by obtaining a patient's prior written authorization and then providing that authorization to a healthcare provider. *Supra* at 6 (discussing "authorized disclosures"). In cases where a provider maintains an EHR (and ***only*** with respect to such an EHR), HITECH simplified that process by establishing a "Third Party Directive" allowing patients to direct the provider (and, by extension, its business associate) to "transmit" PHI from their EHR directly to a third party in electronic format (and ***only*** electronic format):

> ***In the case that a covered entity uses or maintains an [EHR]*** with respect to [PHI] of an individual … the individual shall have a right to obtain from such covered entity a copy of such [PHI] ***in an electronic format*** and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual.

HITECH § 13405(e)(1) (codified at 42 U.S.C. § 17935(e)(1)).

2. Modification Of The Patient Rate

Second, and again with respect to EHRs (and ***only*** EHRs), HITECH made a modest change to the Patient Rate for personal use cases (and, naturally, personal use cases ***alone***, because the Patient Rate had never applied to commercial requests). Where a covered entity is "***providing such individual*** with a copy of such information" in electronic form (as opposed to when the entity is "***transmit[ting] such copy directly to [a designated] entity***" under a Third Party Directive), *compare* HITECH § 13405(e)(2) (codified at 42 U.S.C. § 17935(e)(3)) *with id.* § 13405(e)(1) (codified at 42 U.S.C. § 17935(e)(1)), HITECH provided that "any fee that the covered entity may impose ***for providing such individual*** with a copy of such information … shall not be greater than the entity's labor costs in responding to the request for the copy." HITECH § 13405(e)(2) (codified at 42 U.S.C. § 17935(e)(3)).

3. Direct Regulation Of Business Associates

Finally, given healthcare providers' increasing reliance on business associates and HHS's long-expressed concern that it could not regulate such entities directly, *see* Privacy Rule, 65 Fed. Reg. at 82641 ("[W]e agree that there [would be] advantages to legislation that directly regulates most entities that use or disclose [PHI]."), HITECH subjected business associates to direct regulation under the Privacy Rule:

> [A] business associate may use and disclose [PHI] ***only if such use or disclosure, respectively, is in compliance with each applicable requirement of [45 C.F.R.] 164.504(e). The additional requirements of this subtitle that relate to privacy and that are made applicable with respect to covered entities shall also be applicable to such a business associate***.

HITECH § 13404(a) (codified at 42 U.S.C. § 17934(a)). In turn, cross-referenced 45 C.F.R. §§ 164.504(e)(2)(ii)(E) & (H) expressly required business associates to "[m]ake available [PHI] ***in accordance with [45 C.F.R.] § 164.524***" and to "comply with ***the requirements of this subpart that apply to the covered entity***," while "the additional requirements of this subtitle that relate to privacy" included the statute's new Third Party Directive. *See* HITECH § 13405 (codified at 42 U.S.C. § 17935).

D. HHS's 2013 Omnibus Rule

For several years after HITECH's enactment, no one questioned the limited nature of its Third Party Directive or continued validity of the Privacy Rule's limitation of the Patient Rate to personal use requests. HHS's 2013 Omnibus Rule, however, altered both features of the regulatory regime. First, it applied the Third Party Directive to any request for PHI, ***regardless*** of whether it is in an EHR: "If an individual's request for access directs the covered entity to transmit [PHI] directly to another person designated by the individual, the covered entity must provide the copy to the person designated." 45 C.F.R. § 164.524(c)(3)(ii); *see also* 78 Fed. Reg. at 5634 (extending the Third Party Directive "without regard to whether the [PHI] is in electronic or paper form"). Moreover, the Rule required delivery of such records "in the form and format requested by the individual," even though HITECH required third-party transmission only "in an electronic format." *Compare id.* § 164.524(c)(2)(i) *with* HITECH § 13405(e)(1) (codified at 42 U.S.C. § 17935(e)(1)).

HHS did not even pretend these new regulatory mandates to transmit PHI from any form whatsoever (*i.e.*, EHR or non-EHR), in any form whatsoever (*e.g.*, paper, electronic, radiologic film, etc.) were consistent with HITECH's terms. Instead, HHS

explicitly acknowledged that its regulation was inconsistent with the statute's limited terms, and therefore invoked 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 Third Party Directive] applies by its terms ***only*** to [PHI] in EHRs. However, incorporating these new provisions in such a limited manner … could result in a complex set of disparate requirements for access to [PHI] 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 strengthen the right of access as provided under section 13405(e) of the HITECH Act*** more uniformly to all [PHI] 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.

The 2013 Omnibus Rule also made changes to the Patient Rate—most notably by allowing charges for certain previously-excluded costs. HHS explained:

> We [now] acknowledge … that the cost related to searching for and retrieving electronic [PHI] 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 [PHI] to media, and distributing the media***.

Id. at 5636. Despite this modest concession, HHS made clear that the Patient Rate would continue to bar recovery of most other costs. *Id*.

Finally, HHS amended the Privacy Rule to directly regulate business associates. In a series of new regulatory provisions, the 2013 Omnibus Rule now provided:

> (A) that once engaged by a covered entity, business associates are "required to disclose [PHI] as necessary to satisfy a covered entity's obligations … with respect to an individual's request for an electronic copy of [PHI]," *id*. at 5696 (codified at 45 C.F.R. § 164.502(a)(4));

> (B) that, in discharging this obligation, business associates "may not use or disclose [PHI] in a manner that would violate the requirements of this subpart, if done by the covered entity," *id*. at 5696 (codified at 45 C.F.R. § 164.502(a)(3)); and
>
> (C) that HHS "will impose a civil money penalty upon a covered entity or business associate [that] has violated an administrative simplification provision," *id*. at 5691 (codified at 45 C.F.R. § 160.402(a)), which was defined to include the HITECH's Third Party Directive, the Privacy Rule, and the 2013 Omnibus Rule. 45 C.F.R. § 160.103 ("Administrative simplification provision means any requirement or prohibition established by … Sections 13400-13424 of [HITECH] … or [t]his subchapter.").

Because these new requirements directly compelled business associates to comply with the same disclosure restrictions as covered entities, HHS explained:

> We note that we have not added references to "business associate" to all provisions of the Privacy Rule that address uses and disclosures by covered entities. Such additions to the Privacy Rule are unnecessary, as a business associate generally may only use or disclose [PHI] in the same manner as a covered entity. ***Therefore, any Privacy Rule limitation on how a covered entity may use or disclose [PHI] automatically extends to a business associate***.

2013 Omnibus Rule, 78 Fed. Reg. at 5597.

E. The 2016 Mandates

On February 25, 2016, HHS published, without any prior notice or opportunity to comment, a putative "Guidance" document that made dramatic changes to the Patient Rate. HHS, *Individuals' Right Under HIPAA To Access Their Health Information* (as modified May 25, 2016) (Dkt. 1-2) (the "2016 Mandates"). ***First***, the 2016 Mandates for the first time ordered application of the Patient Rate to Third Party Directives: "This [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 16. As a result, covered entities and business associates like CIOX must now locate, compile, review, and produce records to for-profit commercial entities like life insurers and lawyers at a significant financial loss, even though HHS consistently had made clear that the Patient Rate was intended only to apply to personal use requests for healthcare purposes.

Second, the 2016 Mandates dramatically curtailed the already-limited fees that can be charged under the Patient Rate. Whereas the 2013 Omnibus Rule specifically had allowed charges for "skilled technical staff time" in connection with "searching for and retrieving electronic [PHI]," 78 Fed. Reg. 5636, the 2016 Mandates now declared that such costs must be ***excluded*** from 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 <u>does not include</u> 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 … segregate, collect, compile, and otherwise prepare the responsive information***.

2016 Mandates at 11-12 (underscores in original). Moreover, the Mandates purported to limit providers to one of three options for calculating the applicable Patient Rate: (a) an "actual cost" method; (b) an "average cost" method; or (c) a $6.50 flat fee. *Id.* at 13-15. Finally, the Mandates warned that HHS "will take enforcement action" to enforce compliance with these edicts. *Id.* at 11; *see also id.* at 13.

ARGUMENT

I. THE COURT HAS JURISDICTION.

CIOX filed this lawsuit to remedy the serious adverse harms that HHS's extension of the Third Party Directive and application of the Patient Rate to such Third Party Directives are having on its business. Despite the Complaint's detail and clarity, the government nonetheless has raised an array of jurisdictional and quasi-jurisdictional objections, including arguments about Article III standing; statutory standing; and ripeness. Each is meritless.

A. CIOX Has Article III Standing.

CIOX's Complaint is straightforward and based on real harms being suffered. It alleges that CIOX is a business associate that healthcare providers across the country have engaged to release PHI on their behalf, Compl. ¶¶ 5, 18-19; that processing and responding to the tens of millions of requests CIOX handles each year for covered entities is complex, time-consuming, and costly, *id*. ¶¶ 12-19; that because CIOX historically has fulfilled roughly half the record requests it processes at or below the loss-generating Patient Rate, *id*. ¶¶ 20-21, the majority of CIOX's revenues come from the fees it charges for-profit commercial entities, at state-regulated or independently-contracted rates that generally are far higher than the Patient Rate, when fulfilling patient-authorized requests, *id*. ¶ 22; and that HHS's 2013 Omnibus Rule and 2016 Mandates now unlawfully compel CIOX to deliver PHI to such third parties (a) that HITECH does not require, since its Third Party Directive applies only to PHI drawn from EHRs, *id*. ¶¶ 42-44, 58-65; (b) in a manner HITECH does not require, since its Third Party Directive compels only electronic delivery of EHR outputs, *id*.; and (c) at

a Patient Rate that defies HITECH's text and structure and arbitrarily causes CIOX to lose significant revenues it otherwise could secure by charging the state-regulated rates which have been in place for decades. *Id.* ¶¶ 48-57, 66-77.

Even so, the government claims these allegations are "generalized, oblique, and unsubstantiated," MTD at 13, or, incredibly, "unlinked to Ciox's position as a specialized medical records provider." *Id.* at 13-14. Nonsense. These allegations are fully sufficient to discharge CIOX's pleading-stage obligation to articulate an injury that is [1] "concrete and particularized and … actual or imminent, not conjectural or hypothetical;" [2] "fairly traceable to the challenged action of the defendant;" and [3] "likely [to] be redressed by a favorable decision." *Bennett v. Spear*, 520 U.S. 154, 167 (1997). In short, the Complaint alleges [1] that CIOX is losing money when it delivers medical records to commercial third parties, because [2] the challenged rules unlawfully force it to charge only the loss-generating Patient Rate, and that [3] vacating the challenged rules would redress CIOX's injuries by allowing it to resume charging higher rates for delivering PHI to such parties. Especially at the pleading stage, no more is needed to establish standing. *Id.* at 168 ("At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim.") (internal quotation and alterations omitted); *NB ex rel. Peacock v. District of Columbia*, 682 F.3d 77, 82 (D.C. Cir. 2012) ("[A]t the pleadings stage, the burden imposed on plaintiffs to establish

standing is not onerous, and general factual allegations of injury resulting from the defendant's conduct may suffice.") (quotations omitted).[2]

Precisely because the government well understands CIOX's standing allegations, it spends most of its brief attacking CIOX's standing theory on the merits—arguing that CIOX has not shown an injury that is traceable to the challenged rules or redressable by the requested relief because the challenged rules allegedly don't regulate CIOX at all and, derivatively, because CIOX's injuries thus must be attributable only to the "independent" actions of the covered entities who concededly are subject to the challenged rules. *Id*. at 11-16. No matter which element of standing the government says these arguments implicate, they are objectively frivolous.

1. The Challenged Rules Regulate CIOX Both Directly And Indirectly.

Relying solely on the fact that 45 C.F.R. §§ 164.524(c)(3) (HHS's version of HITECH's Third Party Directive) and 164.524(c)(4) (the Patient Rate) mention covered entities but not business associates, the government first claims these regulations "impose[] no requirements or restrictions on business associates like Ciox." MTD at 11. But the HITECH Act expressly subjects business associates to 45 C.F.R. § 164.524 *via* its cross-reference to *id*. § 164.504(e): "[A] business associate

[2] Out of an abundance of caution, CIOX nonetheless directs this Court to the attached Declaration of CIOX's Executive Vice President of Operations. As the Kabaria Declaration explains in detail, the challenged rules are directly responsible for increasing the number of Third Party Directives CIOX is required to fulfill, at a Patient Rate that is far below the state-authorized rates CIOX historically has charged for disclosing PHI to third parties, and therefore are causing CIOX to lose out on significant revenues that it otherwise would be able to secure. Kabaria Decl. ¶¶ 11-17.

may use and disclose [PHI] ***only if such use or disclosure, respectively, is in compliance with each applicable requirement of section 164.504(e) of [45 C.F.R.]***." HITECH § 13404(a) (codified at 42 U.S.C. § 17934(a)); *see also* 45 C.F.R. §§ 164.504(e)(2)(ii)(E), (H) (obligating business associates to disclose PHI "in accordance with § 164.524" and to "comply with the requirements of this subpart that apply to the covered entity"). That is why the Conference Report accompanying HITECH explained that this section of the statute was intended ***precisely*** to remedy HIPAA's prior lack of direct-enforcement authority over business associates by "apply[ing] the HIPAA Privacy Rule, the additional privacy requirements, and the civil and criminal penalties for violating those standards ***to business associates in the same manner as they apply to the providers and health plans for whom they are working***." H.R. CONF. REP. NO. 111-16 at 493, 2009 U.S.C.C.A.N. at 86.

This alone forecloses the government's argument. But there's much more. Consistent with both the original HIPAA and HITECH's new § 13404(a), the Privacy Rule (as amended by the 2013 Omnibus Rule) now applies the challenged regulatory provisions ***both*** indirectly ***and*** directly to business associates, by providing that:

> **(1)** Covered entities may engage business associates like CIOX to fulfill their disclosure obligations, 45 C.F.R. § 164.502(e)(1)(i) ("A covered entity may disclose [PHI] to a business associate and may allow a business associate to create, receive, maintain, or transmit [PHI] on its behalf."), if and only if the covered entity and business associate enter into a contract which provides:
>
> > (a) that the business associate "may ***not*** … disclose [PHI] ***in a manner that would violate the requirements of this subpart, if done by the covered entity***," such as the obligation to charge no more than the Patient Rate if applicable, *id*. § 164.504(e)(2)(i);

> (b) that the business associate will "[m]ake available [PHI] ***in accordance with § 164.524***," which in turn establishes both the Third Party Directive and Patient Rate, *id.* § 164.504(e)(2)(ii)(E); and
>
> (c) that "[t]o the extent the business associate is to carry out a covered entity's obligation under this subpart, [the business associate will] ***comply with the requirements of this subpart that apply to the covered entity in the performance of such obligation***," like the Third Party Directive and Patient Rate. *Id.* § 164.504(e)(2)(ii)(H);
>
> **(2)** Once engaged pursuant to a contract containing those restrictions, business associates are legally "required to disclose [PHI] as necessary ***to satisfy a covered entity's obligations … with respect to an individual's request for an electronic copy of [PHI]***," which again includes the obligations to fulfill Third Party Directives and, where applicable, charge no more than the Patient Rate, *id.* § 164.502(a)(4);
>
> **(3)** In discharging this obligation, business associates "may ***not*** use or disclose [PHI] ***in a manner that would violate the requirements of this subpart, if done by the covered entity***," such as refusing to comply with the Patient Rate, where applicable, *id.* § 164.502(a)(3); and
>
> **(4)** allows HHS to "impose a civil money penalty upon a covered entity ***or business associate*** [that] has violated an administrative simplification provision," *id.* § 160.402(a), which includes HITECH, the Privacy Rule, and the 2013 Omnibus Rule, and thus the challenged Third Party Directive, the Patient Rate, and direct prohibitions on business associates in paragraphs **(2)** and **(3)** above, *id.* § 160.103 ("Administrative simplification provision means any requirement or prohibition established by … Sections 13400-13424 of [HITECH] … or [t]his subchapter.").

These regulations mean what they say, as HHS itself made clear when it issued them. When it promulgated the contract-based subprovisions in its original Privacy Rule [number (1) above], HHS explained they were designed to ***indirectly*** subject business associates to these rules precisely so that covered entities could not "circumvent the [Privacy Rule] by the simple expedient of contracting out the performance of various functions." 65 Fed. Reg. at 82640. And when it promulgated the direct-liability provisions in the 2013 Omnibus Rule [numbers (2)-(4) above], HHS

made clear it was doing so to ***directly*** subject business associates to the challenged rules. Indeed, HHS expressly rejected the very argument on which its brief depends:

> We note that we have not added references to "business associate" to all provisions of the Privacy Rule that address uses and disclosures by covered entities. Such additions to the Privacy Rule are unnecessary, as a business associate generally may only use or disclose [PHI] in the same manner as a covered entity. ***Therefore, any Privacy Rule limitation on how a covered entity may use or disclose [PHI] automatically extends to a business associate***.

2013 Omnibus Rule, 78 Fed. Reg. at 5597.

HHS never once acknowledges these myriad provisions. But they foreclose each of the government's standing arguments, which all depend on the demonstrably false claim that the challenged regulations do not apply to or otherwise affect business associates like CIOX and therefore cannot give rise to an injury, MTD at 11-12, that is fairly traceable to the challenged regulations, *id*. at 15-16, and which would be redressed by invalidating those regulations. *Id*. at 16-17. CIOX has standing.

2. The Government's Counter-Theory Of Injury Is Based On A False Premise And Absurd In Its Own Right.

Because the government's brief ignores the above-cited provisions, it advances a second, purely derivative argument—that CIOX's asserted injuries must be attributable not to the challenged regulations, but to the supposedly independent actions of the covered entities CIOX serves. MTD at 12 ("Ciox's injury depends on the conduct of health care providers, the covered entities with whom it contracts."); *id*. at 15 ("[T]he agreements that Ciox has negotiated with the covered entities with which it does business control the payments that Ciox receives for its services."); *id*.

at 16 ("Ciox nowhere alleges that eliminat[ing the challenged regulations] would … cause the covered entities … to refrain from inflicting whatever injury they claim.").

Again, the whole premise of this argument is incorrect: CIOX's injuries are ***directly*** attributable to the challenged regulations, which fully apply to business associates. The government therefore is wrong to invoke cases like *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, where it was undisputed that the challenged regulations did not directly apply to the plaintiffs, 366 F.3d 930 (D.C. Cir. 2004) ("*NWCA*"), or *State Nat'l Bank of Big Spring v. Lew*, where the court in fact held that the plaintiff had standing precisely because (like CIOX here) it was regulated. 795 F.3d 48, 53 (D.C. Cir. 2015) ("A regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated.").

But the government's claim would miss the mark even if it were true that CIOX's injuries derive only indirectly, through the covered entities who indisputably are subject to the challenged regulations. That is so because yet another regulation the government fails to address deems covered entities liable whenever a business associate violates HHS's rules in the course of acting on the covered entity's behalf:

> A covered entity is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, ***including a workforce member or business associate***, acting within the scope of the agency.

45 C.F.R. § 160.402(c)(1). Indeed, HHS's regulations require covered entities to either take curative action or terminate business associates who breach their contractual duties to the covered entity, *id.* § 164.504(e)(1)(ii), including the legally-mandated duties to "comply with the requirements of [the Privacy Rule] that [would] apply to

the covered entity" if it were disclosing PHI on its own. *Id*. § 164.504(e)(2)(ii)(H); *see also id*. § 164.504(e)(2)(ii)(E) (requiring business associates to act "in accordance with § 164.524"). These rules explain why HHS concededly threatened covered entity CHI Health St. Francis with enforcement action ***based on CIOX's issuance of an invoice*** that charged fees in alleged violation of the Patient Rate. *See* Dkt. 1-3.

Given these regulations and HHS's enforcement threats, it should come as no surprise that covered entities generally require CIOX to comply with the challenged regulations (including their fee restrictions) and further obligate CIOX to indemnify its covered entities from any liability based on such violations. *See* Kabaria Decl. ¶¶ 8-9. Accordingly, even if the challenged rules applied only to covered entities, their adverse impact on business associates is the natural, fully intended, and very real result of HHS's vicarious-liability rules and enforcement threats. Were CIOX were forced to rely on a derivative-harm theory, there is "little doubt" regarding the "causal relationship between the government policy [CIOX is challenging] and the [harmful] third-party conduct." *NWCA*, 366 F.3d at 941-42 (citing *Tozzi v. HHS*, 271 F.3d 301 (D.C. Cir. 2001) and *Block v. Meese*, 793 F.2d 1303 (D.C. Cir. 1986)). That's enough to demonstrate each element of CIOX's standing. *See, e.g.*, *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 & n.1 (D.C. Cir. 2017) (explaining that in "performing that inherently imprecise task of predicting or speculating about causal effects, common sense can be a useful tool," and observing that where "government action causes an injury, enjoining the action usually will redress that injury").

Because the government well understands that the challenged rules necessarily "flow through" to business associates, it ultimately asserts that if CIOX doesn't like the way HHS's rules are impacting it, it can simply renegotiate its contracts with the covered entities it serves: "Ciox confuses the limited fee that an individual may be charged with the compensation it can receive from the covered entity for its services. Ciox remains free to negotiate its compensation with covered entities seeking to outsource the fulfillment of requests for PHI." MTD at 16. But this argument completely misunderstands CIOX's business model. CIOX typically is not paid by covered entities for fulfilling Third Party Directives or patient-authorized requests from commercial entities. CIOX instead is compensated by the fees it receives from the requestor or recipient, and does not receive a separate service fee from the covered entity on whose behalf it is acting. Compl. ¶ 22; *see also* Kabaria Decl. at ¶ 10.

Given that the government effectively is asserting that CIOX remains "free" to fundamentally transform its business model and renegotiate its roughly 13000 contracts with providers across the United States, its argument only serves to underscore CIOX's standing. After all, the effort, disruption, and expense of doing so is itself a legally cognizable harm sufficient to confer standing on tis own. *See, e.g.*, *Airline Serv. Providers Ass'n v. Los Angeles*, 873 F.3d 1074, 1078 (9th Cir. 2017) (holding that "[t]he time spent in [unwanted] negotiations is itself a concrete injury"). And, of course, the government cannot evade the fact that the challenged regulations are harming CIOX by telling CIOX that it is "free" to suffer these other harms instead. For standing purposes, the relevant inquiry is not whether CIOX conceivably could

do something—however impractical and costly—to solve its problem besides suing HHS. All that matters is that the challenged regulations are hurting CIOX's business right now and removing those regulations would fix the problem. That's true whether CIOX is directly regulated by the challenged rules or whether those provisions harm it indirectly. CIOX has standing.

B. CIOX's Claims Are Ripe.

The government next claims CIOX's claims are not ripe because adjudicating them "would benefit from a more concrete setting." MTD at 18. But the government never explains ***why*** "a more concrete setting" would be helpful or ***what*** "additional factual development" might facilitate the resolution of CIOX's purely legal claims. *Action Alliance of Senior Citizens of Greater Phila. v. Heckler*, 789 F.2d 931, 940 (D.C. Cir. 1986). That's because there is no such explanation. The statute either allows HHS to extend the Third Party Directive beyond EHRs, or it doesn't. It either allows HHS to require physical delivery of records in connection with Third Party Directives, or it doesn't. It either allows HHS to apply the Patient Rate to Third Party Directives, or it doesn't. And the 2016 Mandates either were issued unlawfully, or they weren't. Those purely legal questions are "presumptively suitable" for review. *Shays v. FEC*, 414 F.3d 76, 95 (D.C. Cir. 2005) (quoting *AT&T Corp. v. FCC*, 349 F.3d 692, 699 (D.C. Cir. 2003) and citing *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 479 (2001)).

The government nonetheless claims these purely legal questions are unfit for review because they arise under "a complex statutory scheme." MTD at 19 (quoting *Nat'l Abortion Fed'n v. Ashcroft*, No. 03 Civ. 8695, 2004 WL 555701, at *2 (S.D.N.Y. Mar. 19, 2004), for the proposition that HIPAA "is 'complex'"). But the legal issues

CIOX has raised are not themselves complex, *see infra* § II, and "The statute has a lot of parts!" isn't a legitimate reason to defer review anyway. Ignoring CIOX's Complaint won't make the statute any less "complex," and "complexity" matters only if there is a sound reason to think that further developments might make the case easier to resolve in the future. *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164 (1967). Again, the government has not offered any reason to think that is so here.

Finally, the government claims CIOX has not shown it would face any "hardship [from] deferring review unless and until HHS takes enforcement action." MTD at 20. But as set forth in the Complaint and detailed above, the challenged regulations are costing CIOX vast sums both directly (because CIOX is subject to the challenged rules) and indirectly (because CIOX's covered-entity partners are legally obligated to both mandate and police CIOX's compliance with those rules). The government in any case cites no significant institutional interest in deferring the resolution of these purely legal questions—much less one that warrants the continued imposition of those harms on CIOX. *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 440 F.3d 459, 465 (D.C. Cir. 2006) ("Where there are no significant agency or judicial interests militating in favor of delay, hardship cannot tip the balance against judicial review.") (alterations omitted); *see also AT&T*, 349 F.3d at 700. The case is ripe.

C. CIOX Has Statutory Standing.

Finally, the government claims CIOX lacks statutory standing because its "interests do not fall within the scope of the HITECH Act provision [that] anchor[s] its claims." MTD at 20. But the modest standard for statutory standing "forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with

the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (quotation omitted).

CIOX easily meets this easy-to-meet standard. Once again, the government argues that the HITECH provisions CIOX invokes apply only to covered entities, not business associates. MTD at 21-22. And once again, that claim is foreclosed by HITECH's plain text, which expressly subjects business associates to both the statutory provisions CIOX invokes and the regulations it challenges. *Supra* at 18-19 (discussing HITECH § 13404(a) (codified at 42 U.S.C. § 17934(a)).

The government at least acknowledges this section of HITECH. Yet it claims this section ***supports*** the government's statutory standing argument because it "appl[ies] two sets of regulations and one set of statutes to business associates, none of which include 42 U.S.C. § 17935(e) or 45 C.F.R. § 164.524." MTD at 29. That is true—but only if you don't bother to check § 13404(a)'s cross-references. ***First***, by subjecting business associates to "each applicable requirement of [45 C.F.R. §] 164.504(e)," HITECH § 13404(a) directly applies 45 C.F.R. § 164.524's restrictions to business associates. *See* 45 C.F.R. § 164.504(e)(2)(ii)(E) (requiring business associates to "[m]ake available [PHI] in accordance with § 164.524"); *id*. § 164.504(e)(2)(ii)(H) ("To the extent the business associate is to carry out a covered entity's obligation under this subpart, [it is required to] comply with the requirements of this subpart that [would] apply to the covered entity in the performance of such obligation.").

Second, by subjecting business associates to "[t]he additional requirements of this subtitle that relate to privacy and that are made applicable with respect to covered entities," this section subjects business associates to 42 U.S.C. § 17935(e)(1)'s Third Party Directive—which was the very next subsection of HITECH (§ 13405(e)(1)), in Subtitle D of the statute (titled "Privacy"), and is the basis for CIOX's lawsuit. Again, that's why HITECH's Conference Report explained in no uncertain terms that HITECH § 13404(a) now applies the relevant statutes and regulations directly "to business associates in the same manner as they apply to the providers and health plans for whom they are working." H.R. CONF. REP. NO. 111-16 at 493, 2009 U.S.C.C.A.N. at 86.[3] CIOX has statutory standing.

[3] Contrary to the government's apparent belief, CIOX's claims do not depend on 42 U.S.C. § 17935(e)(2), and that provision does not undermine the foregoing analysis. MTD at 22. While it is true that this provision does use "permissive language with respect to business associates[']' options for providing PHI to individuals," *id.*, this provision applies ***only*** to Third Party Directives that are made directly "***to a business associate*** for access to [PHI] about the individual." 42 U.S.C. § 17935(e)(2). We fully agree with the government that the plain text of this provision does not obligate CIOX to fulfill requests received directly from patients (much less charge the Patient Rate if it chooses to do so). CIOX's claims therefore focus instead on cases where, pursuant to HITECH § 13405(e)(1) (codified at 42 U.S.C. § 17935(e)(1)), an individual issues a Third Party Directive ***to a covered entity*** that, pursuant to the statutory and regulatory regime, has engaged CIOX to fulfill such requests on its behalf. As set forth above, both HITECH § 13404(a) (codified at 42 U.S.C. § 17934(a)) and HHS's regulations unambiguously subject business associates to the same rules as covered entities when discharging those entities' responsibilities under HITECH § 13405(e)(1) (codified at 42 U.S.C. § 17935(e)(1)), and CIOX therefore has statutory standing to challenge HHS's unlawful extension of the Third Party Directive and application of the Patient Rate to that context.

II. CIOX IS ENTITLED TO SUMMARY JUDGMENT.

A. HHS's Extension Of The Third Party Directive Beyond EHRs Violates HITECH's Plain Language And Exceeds HHS's Authority.

CIOX is entitled to summary judgment on Count I, which challenges the 2013 Omnibus Rule's extension of the Third Party Directive beyond EHRs because it (1) conflicts with HITECH's plain language and (2) exceeds HHS's lawful authority. Compl. ¶¶ 63-65 (citing 5 U.S.C. §§ 706(2)(A), (C)); *see also Pub. Employees Ret. Sys. v. Betts*, 492 U.S. 158, 171 (1989) ("[A]gency interpretations must fall to the extent they conflict with statutory language."); *Michigan v. E.P.A.*, 268 F.3d 1075, 1081 (D.C. Cir. 2001) ("If [the agency] lacks authority under the [the statute], then its action is plainly contrary to law and cannot stand.").

This isn't a close question. Prior to HITECH's enactment, neither HIPAA nor the Privacy Rule allowed individuals to compel the delivery of their PHI directly to commercial third parties, like life insurers or trial lawyers. Instead, such parties could obtain those records only by delivering a valid patient "authorization" to the PHI's custodian, who then and only then could disclose the PHI to the third party. Privacy Rule, 65 Fed. Reg. at 82805 (codified at 45 C.F.R. § 164.502(a)(1)(iv)). HITECH established a carefully-circumscribed exception to that process. Its Third Party Directive applies only to "***an [EHR]*** with respect to [PHI] of an individual," HITECH § 13405(e) (codified at 42 U.S.C. § 17935(e)); grants individuals "a right to obtain" only "***a copy of such information in an electronic format***," *id.*; and merely allows 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 [the

designated] entity or person." *Id.* The Third Party Directive thus applies by its plain terms only to PHI ***in EHRs***—not to PHI in any other records—and compels delivery of such PHI to designated third parties ***only in electronic format***.

The 2013 Omnibus Rule nonetheless expanded the Third Party Directive by compelling covered entities and their business associates to (A) fulfill Third Party Directives ***regardless*** of whether the requested PHI comes from an EHR, and (B) deliver the responsive PHI ***in any format requested***, not just electronically. 45 C.F.R. § 164.524(c)(2)(i); *id.* § 164.524(c)(3)(ii). Indeed, HHS candidly admitted that its new rules were inconsistent with HITECH's limited terms when it issued them:

> Section 13405(e) [*i.e.*, HITECH's Third Party Directive] applies by its terms ***only*** to [PHI] in EHRs. However, incorporating these new provisions in such a limited manner … could result in a complex set of disparate requirements for access to [PHI] in EHR systems versus other types of electronic records systems. As such, the Department [will] ***strengthen the right of access as provided under section 13405(e) of the HITECH Act*** more uniformly to all [PHI] 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.

That was impermissible. Federal agencies don't get to "strengthen" statutes because the law Congress actually passed might "result in a complex set of disparate requirements," *id.*, or because they think Congress should have applied the law "more uniformly" than it did. *Id.* Instead, "[d]isagreeing with Congress's expressly codified policy choices isn't a luxury administrative agencies enjoy." *Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016); *see also Jordan v. Sec'y of Educ.*, 194 F.3d 169, 171-72 (D.C. Cir. 1999) (rejecting agency's attempt to "add an obligation that is not in the statute" because agencies "may not rewrite the statute").

The 2013 Omnibus Rule did not pretend it was doing otherwise—for instance, by asserting that some "ambiguity" in HITECH authorized it to "interpret" the statute as establishing a broader Third Party Directive.[4] Instead, the ***only*** basis HHS cited for its conscious disregard of HITECH's admittedly limited "terms" was its alleged "authority under section 264(c) of HIPAA to prescribe the rights individuals should have with respect to their individually identifiable health information." 2013 Omnibus Rule, 78 Fed. Reg. at 5631. There are three problems with that assertion.

First, it exceeds the limitations of § 264(c). *Burwell*, 827 F.3d at 73 ("Agencies may act only when and how Congress lets them.") (citing *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)). Congress expressly conditioned HHS's ability to exercise § 264(c) authority on the absence of pertinent legislation. HIPAA § 264(c), 110 Stat. at 2033 (formerly codified at 42 U.S.C. § 1320d-2) (authorizing HHS to issue "final regulations … [i]f legislation governing … the privacy of individually identifiable health information … is not enacted"). That predicate for HHS's exercise of § 264(c) authority dissolved once Congress enacted such legislation. HHS's construction of § 264(c)'s conditional authority as a boundless mandate that allows it to create new rights regardless of Congress's actions defies clear congressional intent.

Moreover, § 264(c) expired ***in 2000***—over a decade before HHS issued the 2013 Omnibus Rule. HIPAA § 264(c), 110 Stat. at 2033 ("[HHS] shall promulgate final regulations … ***not later than the date that is 42 months after the date of the enactment of this Act***"). For that reason, HHS's § 264(c) rulemaking authority no

[4] HHS therefore cannot argue so now. *SEC v. Chenery Corp.* 318 U.S. 80, 95 (1943).

longer is codified in the U.S. Code; it has been relegated to a "historical note." The 2013 Omnibus Rule thus treated § 264(c) not only as a wandering mandate to create new rights without apparent regard to subsequent congressional action (in conflict with Congress's original premise for granting such authority), but as authority to do so for all eternity (in conflict with the limits Congress attached to that authority). This Court should reject HHS's *Night of The Living Dead* approach to § 264(c).

Second, it in any event is axiomatic that a federal agency "cannot rely on its general authority" to trump "a specific statutory directive." *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1119-20 (D.C. Cir. 1995) (citing *NRDC v. Reilly*, 976 F.2d 36, 41 (D.C. Cir. 1992); *Sierra Club v. EPA*, 719 F.2d 436 (D.C. Cir. 1983)); *see also RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) ("The specific governs the general. That is particularly true where Congress has deliberately targeted specific problems with specific solutions.") (alterations omitted); *Gilbert v. United States*, 640 F.3d 1293, 1308 (11th Cir. 2011) (*en banc*) ("An ambiguous or general statutory provision enacted at an earlier time must yield to a specific and clear provision enacted at a later time."). HHS defied that rule here: Claiming HITECH did not go as far as it should, HHS blew past the statute's specific limits based solely on its supposed general authority to establish brand new rights.

Finally, even if HHS could exercise § 264(c)'s authority in this zombie-like fashion, § 264(c) itself almost violates the non-delegation doctrine. While that rule does not bar Congress from "obtaining the assistance of its coordinate Branches," it must at least "lay down … an intelligible principle to which the person or body

[exercising delegated authority] is directed to conform." *Panama Refining Co. v. Ryan*, 293 U.S. 388, 420 (1935) (quotation omitted). HIPAA § 264(c), however, provided no "policy or standard that would serve to confine [HHS's] discretion." *Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989). Instead, it granted HHS *carte blanche* to "promulgate final regulations containing … standards with respect to the privacy of individually identifiable health information," without offering any guidance regarding how to select appropriate standards; when they should be applied; or the manner in which they should be enforced. HIPAA § 264(c), 110 Stat. at 2033. At the very least, the grave constitutional concerns raised by HHS's exercise of this apparently boundless authority to create new rights are reason alone to reject the legitimacy of its invocation. *See, e.g.*, *Public Citizen v. DOJ*, 491 U.S. 440, 466 (D.C. Cir. 1989). CIOX is entitled to summary judgment on Count I.

B. HHS's 2016 Mandates Are Procedurally Invalid.

CIOX likewise is entitled to summary judgment on Count II, which challenges HHS's 2016 Mandates as legislative rules for which notice-and-comment rulemaking was required but not conducted. Compl. ¶¶ 66-69 (citing 5 U.S.C. §§ 551(4), 553(b)-(c), 706(2)(D)). In particular, the Complaint alleges the 2016 Mandates: (A) imposed rate-, price-, service-, and cost-related restrictions—including rules ordering the application of the Patient Rate to Third Party Directives and setting new methods for calculating it—in binding, rather than discretionary, terms; (B) deviated from both the statute and HHS's prior legislative rules (which, in contrast, were issued via notice-and-comment rulemaking); and (C) threatened "enforcement action" for

violations. *Id*. (quoting 2016 Mandates). Those are the hallmarks of legislative rulemaking, and there is no reason to delay the entry of judgment in CIOX's favor.

1. This Claim Is Appropriately Resolved On Summary Judgment.

The government does not deny that HHS issued the 2016 Mandates without notice and comment or that they (1) apply the Patient Rate to Third Party Directives and (2) restrict the fees CIOX otherwise would be able to charge. Instead, the government concedes each of those points, *see, e.g.,* MTD at 25, but claims that Count II's procedural challenge to the Mandates (and by extension Count III's substantive challenge) fails to state a valid claim because the Mandates are merely interpretive rules that are immune from review. *Id*. at 23-28.

This claim should be resolved on summary judgment because the government's jurisdictional claims are inseparable from the merits. In short, if this Court agrees that the 2016 Mandates are legislative rules that required notice-and-comment rather than interpretive rules that did not, then Count II not only states a valid claim but CIOX is entitled to judgment as a matter of law. *Mendoza v. Perez*, 754 F.3d 1002, 1025 (D.C. Cir. 2014) ("[P]laintiffs are entitled to entry of summary judgment in their favor [because the challenged guidances] are legislative rules"); *General Elec. Co. v. EPA*, 290 F.3d 377, 385 (D.C. Cir. 2002) (vacating putative guidance document held to be a legislative rule).

2. The 2016 Mandates Are Legislative Rules.

The government's basic argument is that the 2016 Mandates are non-reviewable interpretive rules or policy statements because they merely "paraphrase" or "clarif[y]" the Patient Rate and Third Party Directive, MTD at 25, and thus are "at most,

interpretive, non-final guidance in part." *Id*. at 26. But incanting those words doesn't make them true, *Chamber of Commerce v. OSHA*, 636 F.2d 464, 468 (D.C. Cir. 1980) ("We do not classify a rule as interpretive just because the agency says it is."), and there is a reason why the government relies entirely on self-serving characterizations instead of the Mandates' actual text. Consistent with the Mandates' telling lack of ***either*** a general disclaimer of intent to regulate ***or*** a specific disclaimer that any of the challenged provisions do so, the Mandates set forth commands in binding terms that leave no room for disagreement. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (rejecting even a general disclaimer as mere "boilerplate"); *cf*. *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 252-53 (D.C. Cir. 2014) (crediting specific disclaimers only because "the caveats run throughout the document" and "repeatedly state[] that it 'does not impose legally binding requirements'").

Indeed, despite the government's naked denial, the 2016 Mandates are just "like a ukase. It commands, it requires, it orders, it dictates." *Appalachian Power*, 208 F.3d at 1023. Take their directive applying the Patient Rate to Third Party Directives. Though the Privacy Rule declared that the Patient Rate "do[es] ***not*** … affect the fees … for providing [PHI] to anyone other than the individual," 65 Fed. Reg. at 82557, the 2016 Mandates begin by issuing an unqualified countermand:

> This limitation [the Patient Rate] ***applies regardless*** of whether the individual has requested that the copy of 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 16. The Mandates then expressly forbid regulated parties from trying to evade the fee limitations imposed by this new directive:

> We note that a covered entity (or a business associate) ***may not circumvent the access fee limitations*** [*i.e.*, the Patient Rate] by treating individual requests for access like other HIPAA disclosures—such as by having an individual fill out a HIPAA authorization when the individual requests access to her PHI (including to direct a copy of the PHI to a third party).

Id. at 17. These commands leave no room for deviation. They do not say regulated parties ***may*** or ***should*** charge the Patient Rate when fulfilling Third Party Directives; they flatly declare that "[t]his limitation ***applies***." They emphasize that regulated parties are ***not*** allowed to consider a third party's commercial character in determining whether the Patient Rate should apply: "[I]t ***doesn't matter*** who the third party is." They expressly declare that regulated parties "***may not***" attempt to evade the new mandate. And they cannot sensibly be described as "paraphrasing" the Privacy Rule or Omnibus Rule; precisely because these commands are unprecedented, they are not accompanied by any citation to those Rules. This is the stuff of legislative rules. *See, e.g.*, *General Electric*, 290 F.3d at 383 ("[T]he mandatory language of a document alone can be sufficient to render it binding.").

That equally is true of the Mandates' new rules for calculating the Patient Rate, which begin by expressly barring charges for the costs of preparing requested PHI for copying: "[L]abor for copying does not include labor costs associated with … preparing the responsive [PHI] for copying. This includes labor to … segregate, collect, compile, and otherwise prepare the responsive [PHI] for copying." 2016 Mandates at 12 (emphasis in original); *see also id*. at 10 (similar). Given the compulsory language of

these underscored prohibitions, the government never denies that this directive is indeed a binding command from which regulated parties cannot deviate. Instead, it baldly asserts that this command simply "clarifies HHS's position about what 45 C.F.R. § 164.524(c)(4)(i) has always meant." MTD at 25. Not so. HHS took exactly the opposite position when it issued the 2013 Omnibus Rule:

> We acknowledge commenters' assertions that the cost related to ***searching for and retrieving electronic [PHI] in response to requests*** would be not be negligible, as opposed to what we had anticipated, 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 [PHI] to media, and distributing the media***.

78 Fed. Reg. at 5631.

The government offers two responses. It first claims this Mandate is consistent with the 2013 Omnibus Rule, because the Rule merely said these activities "***could be viewed as*** included labor costs" but did not ***have to be***. MTD at 26 n.8 (emphasis modified; citing 78 Fed. Reg. at 5636). But that claim ignores the surrounding language and context, which readily shows HHS intent to authorize the inclusion of these costs in calculating the applicable Patient Rate. That is why the 2013 Omnibus Rule took pains to confess that the original Privacy Rule had erred in assuming such costs would be "negligible," and rather than declare "Tough luck!," instead "clarif[ied] that labor costs included in a reasonable cost-based fee could include skilled technical staff time." 78 Fed. Reg. at 5636. If the government were right that the 2013 Omnibus Rule merely acknowledged a conceivable interpretation of the prior

regulations without actually adopting it, its confession of error and accompanying discussion of skilled technical staff time wouldn't have "clarif[ied]" anything at all.

As a result, the government ultimately asserts that the Omnibus Rule's preamble is irrelevant. MTD at 26 n.8. But while it's true that a preamble does not control if it is "inconsistent with the plain language of the regulation," *Barrick Goldstrike Mines, Inc. v. Whitman*, 260 F. Supp. 2d 28, 36 (D.D.C. 2003), this preamble was fully consistent with the language of the 2013 Omnibus regulation and so is strong "evidence concerning contemporaneous agency intent." *Wyoming Outdoor Council v. U.S. Forest Service*, 165 F.3d 43, 53 (D.C. Cir. 1999). HHS thus cannot claim credibly that its new Mandates simply "clarif[y] what [the regulation] has always meant." MTD at 25. They eviscerated it. *Sprint Corp. v. FCC*, 315 F.3d 369, 374 (D.C. Cir. 2003) ("[W]hen an agency changes the rules of the game … more than a clarification has occurred. To conclude otherwise would intolerably blur the line between when the APA notice requirement is triggered and when it is not.").

The 2016 Mandates' new tripartite framework for calculating the applicable Patient Rate fares no better. 2016 Mandates at 13-15 (establishing "actual costs," "average costs," and $6.50 "flat fee" methods for calculating the appropriate Patient Rate). At least on this point, the government does not pretend that these new methods merely "clarify" or "paraphrase" HHS's pre-existing regulations. Instead, it claims the Mandates merely "suggest[] three ways" for calculating the applicable rate and are "expressly permissive," because they "use … language like 'may' and 'can.'" MTD at 25-26 (citing 2016 Mandates at 15).

This argument has only surface appeal. While the 2016 Mandates do say these three "methods may be used," Mandates at 14, the key point here is that they allow CIOX to choose ***only*** from these three methods and expressly bar CIOX from charging the traditional state-authorized rates it would prefer. *Id.* at 15-16. That is classic legislative rulemaking activity, and the D.C. Circuit's decision in *General Electric* is directly on point. The challenged guidance document in that case likewise gave regulated parties multiple options, but the appellate court had no trouble recognizing that such optionality does not make a guidance any less mandatory:

> [E]ven though the Guidance Document gives applicants the option of calculating risk in either of two ways (assuming both are practical) it still requires them to conform to one or the other, that is, not to submit an application based upon a third way…. To the applicant reading the Guidance Document the message is clear: in reviewing applications [EPA] will not be open to considering approaches other than those prescribed in the Document.

290 F.3d at 384. Particularly given the Mandates' repeated threats of enforcement action, 2016 Mandates at 11 ("We will continue to monitor whether the fees that are being charged to individuals are creating barriers to this access [and] will take enforcement action where necessary."); *see also id.* at 13, that equally is true here.

Finally, the government seeks refuge in claims that it could change its mind down the road. *See, e.g.*, MTD at 8 ("HHS retains the discretion to modify or rescind the guidance."); *id.* at 27 n.9 ("[C]overed entities … are free to interpret the regulations in a different lawful way than the agency interpretation."). Those claims are hard to credit given the government's elsewhere-repeated statements that HHS stands fully behind the challenged rules. *See, e.g.*, *id.* at 6 ("HHS continues to hold this view."); *id.* at 7 (same). More important, there's no need for this Court to be distracted by the

government's self-serving claims. Agencies make these same representations every time they refuse to conduct notice-and-comment rulemaking, and the courts reject those claims just as often. *CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003) ("[T]he agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the 'force of law,' but the record indicates otherwise.") (citing *General Electric*, 290 F.3d at 383-85; *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 95-96 (D.C. Cir. 2002)).

C. The 2016 Mandates Are Substantively Invalid.

Finally, CIOX is entitled to summary judgment on Count III, which challenges the 2016 Mandates as substantively incompatible with both HHS's prior regulations and the HITECH Act, and otherwise arbitrary and capricious. Indeed, these defects only underscore the procedural shortcomings in the 2016 Mandates. *See, e.g.*, *United Steelworkers v. FHA*, 151 F. Supp. 2d 76, 89-90 (D.D.C. 2015) (Mehta, J.) (proceeding to determine that challenged rules were arbitrary and capricious even after determining they were invalid for want of notice-and-comment rulemaking, and "for much the same reason"). Given the relationship between CIOX's procedural and substantive challenges to the 2016 Mandates; the Mandates' repeated enforcement threats; and the government's representation that HHS continues to stand by the challenged rules, it is particularly important to address these issues now.

1. The 2016 Mandates' Application Of The Patient Rate To Third Party Directives Conflicts With HITECH's Plain Language.

As we previously explained, HHS's original Privacy Rule made clear that its below-cost Patient Rate applied solely to personal use requests—not requests seeking

the disclosure of PHI to commercial third parties. 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***."). That was so because the Patient Rate was intended solely to ensure that individuals could afford to access their own medical records in order to participate meaningfully in their own healthcare decisions; as HHS originally explained, "[i]f the cost is excessively high, some individuals would not be able to obtain a copy. We would encourage covered plans or providers to make efforts to keep the fee for copying within reach." *Standards for Privacy of Individually Identifiable Health Information—Proposed Rule*, 64 Fed. Reg. 59918, 59984 (1999). Because those concerns do not apply where a commercial party intends to use a patient's records for profitmaking purposes, the Privacy Rule thus fully allowed regulated parties to charge state-authorized rates for delivering PHI to third parties that, generally speaking, exceed the Patient Rate. Privacy Rule, 65 Fed. Reg. at 82754 ("The proposal and the final rule establish the right to access and copy records ***only for individuals, not other entities***.").

Congress was well aware of that backdrop when it passed HITECH, but took no steps to alter this longstanding distinction between the fees allowed for fulfilling personal use requests and those allowed where PHI is transmitted to third parties. HITECH's plain language instead ratifies and reaffirms this distinction. It first sets forth two distinct access rights using two distinct textual formulations: one by which the patient herself may "***obtain … a copy*** of [her PHI from an EHR] in an electronic format," HITECH § 13405(e) (codified at 42 U.S.C. § 17935(e)(1)), and the other by

which the patient may "direct the covered entity [and, by virtue of *id*. § 13404(a) (codified at 45 C.F.R. § 17934(a)), its business associate] ***to transmit such copy*** directly to an entity or person designated by the individual." *Id.* HITECH then expressly addresses application of the Patient Rate to these distinct rights: With express reference to the existing Privacy Rule, it declares that the Patient Rate applies where the regulated party is "providing ***such individual with a copy of such [PHI]***," *id*. § 13405(e)(2) (codified at 42 U.S.C. § 17935(e)(3)), but not also where it is "***transmit[ting] such copy directly to [a] designated [third party]***." *Cf. id*. § 17935(e)(1). Congress thus expressly distinguished between an individual's right to "obtain" 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 the former—not the latter.

The 2016 Mandates' unprecedented extension of the Patient Rate to Third Party Directives cannot be squared with the statutory text. When a covered entity sends PHI directly ***to a third party***, it is not "providing ***[the] individual*** with a copy of [her PHI]." HITECH § 13405(e)(2) (codified at 42 U.S.C. § 17935(e)(3)). It's sending the PHI to someone else. And when Congress wanted to address that scenario, it knew how to do so: As set forth above, it talked about "transmit[ting] such copy directly to [a] designated [third party]." *Cf. id*. § 13405(e)(2) (codified at 42 U.S.C. § 17935(e)(1)). The usual rule is that "where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal

quotation omitted). And where Congress knows how to say something but fails to do so, it likewise presumed to act intentionally. *Touche Ross & Co. v. Redington*, 442 U.S. 560, 572 (1979).

To be sure, these presumptions can be overcome if there is good reason to think Congress meant otherwise. But HHS offered no such reason here, and there is none. Again, the Patient Rate exists solely to ensure that individuals can afford to access to their own PHI for personal use because "[i]f the cost [of obtaining PHI] is excessively high, some individuals will not be able to obtain a copy." Privacy Rule, 65 Fed. Reg. at 82557. Those concerns simply do not apply where commercial third parties want a patient's PHI in order to make money, which is why the Privacy Rule repeatedly explained that the Patient Rate was ***not*** designed "to affect the fees … for providing [PHI] ***to anyone other than the individual***." *Id*. at 82557. HITECH did not alter the commonsense basis for that longstanding approach, and the 2016 Mandates conflict with it.

2. The 2016 Mandates' Cost Methods Are Arbitrary and Capricious.

The Mandates' tripartite approach to calculating the applicable Patient Rate fares no better. It allows an "actual costs" method that would require CIOX to compute its costs on a case-by-case basis for each of the tens of millions of requests it completes each year, 2016 Mandates at 14; an "average costs" model that expressly prohibits "per page fees" for electronically maintained PHI and instead would require the creation of a "schedule of costs … to fulfill standard types of access requests," *id*.; or otherwise limits CIOX to a "flat fee" model, "provided the fee does not exceed $6.50, inclusive of all labor, supplies, and any applicable postage." *Id*. at 15.

Those options are totally arbitrary, and the 2016 Mandates utterly failed to grapple with their defects. *See United Steelworkers*, 151 F. Supp. 3d at 89 (explaining that an agency "has acted in an arbitrary and capricious manner" where it has "entirely failed to consider an important aspect of the problem") (internal quotation omitted). The "actual costs" method is completely impractical for all but the smallest medical-records providers. For a company like CIOX, which handles tens of millions of individual requests each year, calculating the "actual" per-request costs based on a "reasonable hourly rate" for each "person copying and sending the PHI" would require minute-by-minute, employee-by-employee tracking on a per-request basis; require CIOX to then perform literally hundreds of millions of calculations per year; and subject CIOX to incessant disputes over the reasonableness of the resulting charges. *Id*. at 14. The 2016 Mandates, however, make no effort to explain how or why that is a practical approach, much less a reasonable one.

The "average costs" model is equally impracticable and just as unjustifiable. As the Complaint explained, there is no such thing as a "standard" request for PHI, because the time, effort, and skill required to process a given request fluctuates dramatically depending on each patient's unique medical history and the myriad forms and locations in which relevant records might be located. Compl. ¶¶ 12-17. Indeed, that is why the Privacy Rule expressly eschewed the use of such fee schedules. 65 Fed. Reg. at 82735 ("We are not specifying a set fee because copying costs could vary significantly."). But HHS never acknowledged its departure from the Privacy Rule's explicit rejection of that approach—much less provided a reasoned explanation

for it. *See ANR Pipeline Co. v. FERC*, 71 F.3d 897, 898 (D.C. Cir. 1995) ("[W]here an agency departs from established precedent without a reasoned explanation, its decision will be vacated as arbitrary and capricious.").

That leaves only the Mandates' $6.50 option, which—precisely because of the foregoing defects in the other methods—is for all intents and purposes the only option available. But HHS drew its $6.50 figure from whole cloth: The Mandates offer no basis for selecting $6.50, and it does not remotely approximate the costs necessary to fulfill requests for PHI. That is improper. The most basic requirement of administrative law requires that agencies "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983) (quotation omitted). But in this case, nothing in the 2016 Mandates (or anywhere else in the record) "explains how or why Defendants selected [$6.50]. The number quite literally appears to have been pulled out of thin air." *United Steelworkers*, 151 F. Supp. 3d at 90. Given their complete failure to grapple with the foregoing issues, the 2016 Mandates represent the epitome of arbitrary and capricious decisionmaking and cannot stand.

CONCLUSION

For the foregoing reasons, this Court should deny the government's motion to dismiss and grant CIOX's cross-motion for summary judgment.

Dated: May 2, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 2nd day of May, 2018, he caused the foregoing MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND IN SUPPORT OF CIOX'S CROSS-MOTION FOR SUMMARY JUDGMENT to be served upon the following via this Court's ECF system:

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