UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE 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)

DEFENDANTS' MOTION TO DISMISS

In accordance with Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendants Alex M. Azar II, Secretary of Health and Human Services, *et al.*, respectfully move to dismiss Plaintiff's Complaint. In support of this Motion, Defendants respectfully refer the Court to the attached Memorandum of Points and Authorities and Proposed Order.

Dated: April 2, 2018

Respectfully submitted,

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INTRODUCTION

The Department of Health and Human Services ("HHS") has issued a rule that addresses an individual's statutory right to access their protected health information ("PHI"), as well as the corresponding obligation of "covered entities"—that is, certain healthcare providers, health plans, and healthcare clearinghouses—to provide PHI to individuals at a reasonable cost. Congress originally codified this right and obligation in the Health Information Portability and Accountability Act of 1996 (HIPAA), which HHS implemented though what is known as the "Privacy Rule." In 2009, Congress expanded the application of certain of the Privacy Rule's provisions to "business associates" of covered entities, authorized HHS to regulate business associates, and expanded the rights of individuals to access their PHI. HHS implemented these statutory changes in 2013 by amending the Privacy Rule. In 2016, HHS issued guidance that provided the public with information as to how the agency implemented the 2013 rule.

The plaintiff here, Ciox Health, LLC, alleges that HHS's 2013 rule implementing relevant statutory changes with respect to covered entities is *ultra vires* and arbitrary and capricious. Ciox further alleges that HHS's 2016 publicly-issued guidance, which provides advice and answers to frequently asked questions about the rule, (1) was improperly issued without adhering to notice and comment rulemaking procedures, (2) is *ultra vires*, and (3) is arbitrary and capricious.

Ciox, however, is not a covered entity that is subject to the rule and guidance that it challenges. Rather, as a specialized medical records provider that supplies health information management services to healthcare providers, it is defined as a "business associate" under the relevant health and privacy laws and is subject to its own separate obligations under those laws. Although Ciox can, by agreement, discharge a covered entity's obligation to provide an

individual's PHI, the Privacy Rule does not govern the payments that Ciox receives from the covered entity. Rather, Ciox and the covered entity are free to negotiate the terms of the payments that Ciox may receive for its services.

For that reason, Ciox fails to meet its heightened burden to establish Article III standing to raise its claims as a third party to the rule and guidance that it challenges; it fails to demonstrate that it has suffered a concrete and particularized injury that is fairly traceable to the 2013 rule and 2016 guidance at issue and which would be redressed through the vacatur of the rule and guidance that it seeks.

Ciox's claims are similarly unripe. It brings a challenge to (1) a rule that is anchored in a complex statutory scheme without basing the challenge on any concrete enforcement action, and (2) guidance that is non-final agency action that has no force or effect of law, as discussed below. There is not yet anything for Ciox to challenge here.

Further, Ciox lacks prudential, or statutory, standing because Ciox fails to demonstrate that it falls within the "zone of interests" of the statute anchoring its claims. That statute, like the Privacy Rule provision and the guidance, is 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.

Finally, the 2016 guidance that Ciox challenges is not final agency action, because the guidance imposes no independent legal obligations of its own. Rather, it explains HHS's current, nonbinding view of the law—which HHS has the discretion to change or depart from—and provides nonbinding suggestions for how to calculate reasonable costs that can be passed onto the individual requesters. Thus, the 2016 guidance is not subject to review under the APA.

For these reasons, as explained further below, Ciox's claims must be dismissed.

BACKGROUND

A. Legal Background

HHS's actions in this case were governed by HIPAA, the Health Information Technology for Economic and Clinical Health ("HITECH") Act, and regulations promulgated in accordance with these statutes. Congress enacted HIPAA in part to "improve portability and continuity of health insurance coverage in the group and individual markets." Health Insurance Portability and Accountability Act, Pub. L. No. 104–191, 110 Stat. 1936 (1996). The Secretary of HHS is primarily charged with enforcing HIPAA (and the subsequent legislation amending and adding to its provisions). The Secretary may attempt to resolve complaints or reports indicating non-compliance through informal means, such as the provision of technical assistance, before initiating a formal enforcement action. 45 C.F.R. § 164.524.

Section 264(c) of HIPAA required the Secretary of HHS to submit "detailed recommendations on standards with respect to the privacy of individually identifiable [health] information" within 12 months of HIPAA's enactment. "If legislation governing standards with respect to the privacy of individually identifiable health information transmitted . . . is not enacted by the date that is 36 months after" HIPAA's enactment, the statute directed that "the Secretary of Health and Human Services shall 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); *see also S.C. Med. Ass'n v. Thompson*, 327 F.3d 346, 348 (4th Cir. 2003) (describing the "two-step process to address the need to afford certain protections to the privacy of health information maintained under HIPAA"). HHS's regulations were to address at least: (1) "[t]he rights that an individual who is a subject of individually identifiable health information should have[;]" (2) "[t]he procedures that should be established for the exercise of such rights[;]" and

(3) "[t]he uses and disclosures of such information that should be authorized or required." 42 U.S.C § 264(b); *see also id.* § 264(c)(1).

HHS promulgated the Privacy Rule, the regulation containing the standards requested by Congress in 2001, after Congress failed to enact governing standards of its own.[1] U.S. Dep't of Health and Human Servs., *Standards for Privacy of Individually Identiifiable Health Information*, 65 Fed. Reg. 82,462-01 (Dec. 28, 2000); *see also Thompson*, 327 F.3d at 349. The regulation included a procedure for future modifications. *See* 45 C.F.R. § 160.104.

The Privacy Rule also included 45 C.F.R. § 164.524, titled "Access of individuals to protected health information," which is the primary provision at issue in this case. 65 Fed. Reg. 82462-01. This provision set forth an individual's right to access his or her PHI; narrow instances in which a covered entity may deny access; requirements for the form, time, and manner of PHI production; and the types of costs that can permissibly be charged to the individual for the production. 45 C.F.R. § 164.524. It applies to covered entities, which are defined as health plans, health care clearinghouses, and health providers that "transmits any health information in electronic form in connection with a transaction covered by this subchapter." 45 C.F.R. § 160.103.

In 2009, Congress passed the HITECH Act, which encourages the use of electronic health records ("EHRs") and directs HHS to apply 45 C.F.R. § 164.524 such that "in the case that a [healthcare provider] uses or maintains an [EHR] with respect to [PHI] of an individual . . .

[1] Although the original regulations were enacted in 2001, more than 42 months from HIPAA's enactment, "HHS's delay in promulgating the final Privacy Rule did not deprive the agency of the power to act." *Ass'n of Am. Physicians & Surgeons, Inc. v. HHS*, 224 F. Supp. 2d 1115, 1127 (S.D. Tex. 2002), *aff'd*, 67 F. App'x 253 (5th Cir. 2003) (noting that HHS's delay, "particularly in the face of huge administrative burdens, . . . do[es] not result in the invalidation of HHS's authority to promulgate the Privacy Rule") (citing *Regions Hospital v. Shalala*, 522 U.S. 448, 459 n.2 (1998); *Brock v. Pierce Cnty.*, 476 U.S. 253, 260 (1986)).

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 . . . .” 42 U.S.C. § 17935(e)(1). Further, “any fee that the covered entity may impose for providing . . . a copy . . . if such copy . . . is in an electronic form shall not be greater than the entity’s labor costs in responding to the request for the copy.” *Id.* § 17935(e)(3). Congress defined an 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.” *Id.* § 17921.

In response, HHS modified the Privacy Rule along with other regulations. (“the 2013 Rule”). 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, 78 Fed. Reg. 5566 (Jan. 25, 2013). Three modifications bear on this case. *First*, the Privacy Rule now states that “[i]f 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). *Second*, covered entities must now “provide the individual with access to the [PHI] in the form and format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.” *Id.* § 164.524(c)(2)(i). *Finally*, the Privacy Rule states that part of the “reasonable, cost-based fee” that a covered entity may charge for complying with the individual’s request for his or her PHI includes the cost of “[l]abor for copying the protected health information requested by the individual, *whether in paper or electronic form*[,]” *Id.* § 164.524(c)(4)(i) (emphasis added). In the preamble to the final

rule, HHS "clarif[ied] that labor costs included in a reasonable cost-based fee could include skilled technical staff time spend to create and copy the electronic file, such as compiling, extracting, scanning and burning protected health information to media, and distributing the media." 78 Fed. Reg. 5636.

In 2016, HHS issued publicly available nonbinding guidance regarding 45 C.F.R. § 164.524. Guidance: Individuals' Right under HIPAA to Access Their Health Information 45 C.F.R. § 164.524 ("Guidance"), ECF No. 1-1. The guidance, in large part, takes the form of frequently asked questions ("FAQ") and answers. The guidance includes three statements that are at issue in this litigation.

First, the guidance notes in an answer to a FAQ that Section 164.524's limitations on fees that can be charged for individuals to access copies of their PHI apply "when an individual directs a covered entity to send the PHI to the third party, . . . 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)." *Id.* at 17–18 (citing 45 C.F.R. § 164.524(c)(3)(ii)). Although this guidance is not binding on any covered entity, HHS continues to hold this view about the reach of Section 164.524.

Second, the guidance provides HHS's nonbinding view that the reasonable cost of "labor for copying the PHI requested by the individual" should only include "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." *Id.* at 8, 11–13 (citing 45 C.F.R. § 164.524(c)(4)(i)). As the guidance makes clear, HHS does not interpret the regulation as

allowing covered entities to pass on the "costs associated with reviewing the request for access; or searching for and retrieving the PHI, which includes locating and reviewing the PHI in the medical or other record, and segregating or otherwise preparing the PHI that is responsive to the request for copying." *Id* at 11. As stated in the guidance, HHS reasons that "[w]hile it has always been prohibited to pass on to an individual labor costs related to search and retrieval, [HHS's] experience in administering and enforcing the HIPAA Privacy Rule has shown there is confusion about what constitutes a prohibited search and retrieval cost[,]" providing the impetus for the clarification. *Id.* Although this guidance is not binding on any covered entity and is not controlling authority, HHS continues to hold this view about the scope of the costs described in § 164.424(c)(4)(i).

Third, the guidance suggests three ways in which covered entities may calculate the "reasonable, cost-based fee" they can charge for providing PHI to individuals in accordance with 45 C.F.R. § 164.524. *Id.* at 14–16. The following methods may be used: (1) calculating the actual costs that can be recouped under the regulation; (2) calculating average costs, by using a schedule of costs for labor; and (3) using a flat fee of $6.50 for electronic copies of PHI that are also maintained electronically. *Id* at 16. The guidance does not require covered entities to use one of these options; neither does it prohibit using alternative calculations to arrive at a reasonable, cost-based fee as set forth in Section 164.524. *Id.*

B. Factual Background and Procedural History

Defendants assumes the allegations in the Complaint to be true for the purposes of this motion to dismiss. Ciox is a specialized medical-records provider that retrieves and discloses

protected health information ("PHI") for health care providers. Compl., ECF No. 1 ¶ 5. As such, Ciox is a "business associate" under HIPAA.[2] *Id.*

Ciox filed the instant lawsuit on January 8, 2018, alleging the following claims. *First*, the 2013 Rule and the 2016 Guidance's "unbounded third-party directive" requiring covered entities to provide an individual's PHI subject to the rule's other requirements regardless of whether the PHI is contained in an EHR and in the format requested by the individual, as opposed to a purely electronic format, is *ultra vires* and thus violates 5 U.S.C. § 706(2)(A) and (C). Compl. ¶ 60. *Second*, the 2016 Guidance's "binding" characterization of the allegedly new "rate-, price-, service-, cost-, and accounting-related requirements" it sets forth, *id.* ¶ 68, as well as enforcement action HHS has allegedly taken in connection with its guidance qualifies the rule as legislative and was thus unlawfully issued '"without observance of the procedure required by

[2] The HIPAA regulations specifically differentiate business associates from covered entities. Business associates are generally defined as a person who:

> (i) On behalf of such covered entity or of an organized health care arrangement . . . in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities . . . , billing, benefit management, practice management, and repricing; or
>
> (ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation . . . , management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

45 C.F.R. § 160.103; *see also* 42 U.S.C. §§ 17921(2), (3).

law,"' violating 5 U.S.C. § 706(2)(D). *Id.* ¶ 69 (citation omitted). *Third*, the 2016 Guidance violates 5 U.S.C. § 706(2)(A) and (C) by (1) directing "healthcare providers and their affiliates to begin applying [fee limitations] to Third Party Directives and . . .threaten[s] to take enforcement action against companies who fail[] to follow this loss-generating mandate," *id.* ¶ 74; (2) limiting the fees that can be charged to exclude "technical staff time involved in the process of searching for and retrieving" electronic PHI, *id.* ¶ 76; and (3) providing a "tripartite methodology for calculating allowable costs under the Patient Rate[.]" *Id.* ¶ 77. The complaint seeks declaratory judgment and injunctive relief.

Ciox attached a letter to the Complaint, dated March 2017. Davis Letter, ECF No. 1-2. The letter was sent from Celeste H. Davis, a Regional Manager at HHS's Office of Civil Rights, to Jared Sommers, Privacy Coordinator Officer at CHI St. Francis, which the letter identifies as a covered entity. The letter states that HHS received a complaint regarding an individual's request to CHI St. Francis for her PHI to be sent to a law firm, and states that Ciox sent an invoice to her in the amount of $224.65 for the service. *Id.* at 1. In the letter, HHS stated that in accordance "with its authority under 45 C.F.R. §§ 160.304(a) and (b)," its Office of Civil Rights ("OCR") "has determined to resolve this matter informally through the provision of technical assistance . . . . ." *Id* at 5. The letter further stated that "[s]hould OCR receive a similar allegation of noncompliance against [CHI St. Francis] in the future, OCR may initiate a formal investigation of that matter." *Id.* According to Ciox, this letter is evidence that HHS is taking enforcement action against itself and other companies over perceived violations to the 2016 guidance. Compl. ¶¶ 58, 67. Ciox alleges that the letter "inform[ed] Ciox that it had violated [the 2016 guidance] by invoicing certain allegedly excluded fees in response to a regulatory third party directive." *Id.* ¶ 58.

LEGAL STANDARDS

To survive a motion to dismiss under Rule 12(b)(1), a plaintiff must establish the Court's jurisdiction through sufficient allegations. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). When considering such a motion, the Court must accept all well-pleaded allegations as true. *See Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011). The Court need not, however, accept inferences that are unsupported by facts alleged in the complaint or that amount to mere legal conclusions. *See Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). In evaluating subject-matter jurisdiction, the court may, when necessary, look beyond the complaint to "undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

To survive a motion to dismiss under Rule 12(b)(6), a plaintiff's complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "plausibility" standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). While the Court accepts well-pleaded factual allegations as true, "mere conclusory statements" and "legal conclusion[s] couched as . . . factual allegation[s]" are "disentitle[d] . . . to th[is] presumption of truth." *Id.* at 678, 681 (citation omitted). Although the Court generally may not rely on material outside the pleadings under Rule 12(b)(6), it may consider materials incorporated into the complaint by reference, as well as judicially noticeable materials, without converting the motion into one for summary

judgment. *Abhe & Svoboda, Inc. v. Chao*, 508 F.3d 1052, 1059 (D.C. Cir. 2007).

ANALYSIS

Ciox's claims should be dismissed in full. The Court lacks jurisdiction to hear Ciox's claims because Ciox lacks Article III or third-party standing to challenge the rule and guidance and because Ciox's claims are unripe. Even if the Court had jurisdiction, Ciox fails to state a claim upon which relief may be granted. Ciox fails to establish statutory standing because its interests are outside the zone of interests of the substantive statute it seeks to protect under the APA. Further, in Counts Two and Three, Ciox does not challenge final agency action, which is required to seek APA review.

I. The Court lacks jurisdiction to hear Ciox's claims.

a. Ciox lacks Article III standing to assert its claims.

Because Ciox fails to show that it suffered an (1) injury-in-fact that is (2) fairly traceable to the complained-of conduct and (3) likely to be redressed by a favorable decision by this Court, it lacks constitutional standing to assert its claims. *Lujan*, 504 U.S. at 560. As an initial matter, the relevant portion of the 2013 rule, which is also the basis for the 2016 guidance, imposes no requirements or restrictions on business associates like Ciox. *See supra* n.2. Rather, both the challenged provision of the Privacy Rule and the guidance apply only to covered entities, a separate category of businesses. *See* 45 C.F.R. § 164.524(c)(3) (discussing the obligations of covered entities to "provide the access as requested by the individual" without mention of business associates); § 164.524(c)(4) (stating that "the covered entity may impose a reasonable, cost-based fee" for fulfilling an individual's request for a copy of his or her PHI, again without mention of business associates). When "a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*, much more is needed." *State Nat'l Bank of Big Spring v. Lew*, 795 F.3d 48, 55 (D.C. Cir. 2015) (quoting *Lujan*, 504 U.S.

at 562). "In that circumstance, causation and redressability ordinarily hinge on the response of the regulated (or regulable) third party to the government action or inaction." *Am. Freedom Law Ctr. v. Obama*, 106 F. Supp. 3d 104, 109 (D.D.C. 2015), *aff'd*, 821 F.3d 44 (D.C. Cir. 2016) (quoting *Lujan*, 504 U.S. at 562). Specifically, "[t]he existence of one or more of the essential elements of standing 'depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict."' *Id.*, 106 F. Supp. 3d at 109 (quoting *Lujan*, 504 U.S. at 562).

Here, Ciox's injury depends on the conduct of health care providers, the covered entities with whom it contracts to fulfill individual requests for PHI. "[C]ourts occasionally find the elements of standing to be satisfied in cases challenging government action on the basis of third-party conduct. These cases fall into two . . . categories." *Nat'l Wrestling Coaches Ass'n ("NWCA") v. Dep't of Educ.*, 366 F.3d 930, 940 (D.C. Cir. 2004) *abrogation on other grounds* recognized by *Perry Capital, LLC v. Mnuchin*, 864 F.3d 591(D.C. Cir. 2017). "First, a federal court may find that a party has standing to challenge government action that permits or authorizes third-party conduct that would otherwise be illegal in the absence of the Government's action." *Id.* "Second, some cases have held that plaintiffs have standing to challenge government action on the basis of injuries caused by regulated third parties where the record presented substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress." *Id.* at 941.

Ciox fails to demonstrate any of the elements of standing, let alone at the heightened standard that applies to third parties.

Injury-in-fact: First, Ciox fails to show that it is has "suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent." *Sabre, Inc. v. U.S. Dep't of Transp.*, 429

F.3d 1113, 1117 (D.C. Cir. 2005) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 180–81 (2000)); *see also Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016), *as revised* (May 24, 2016) (explaining the difference between "concrete" and "particularized" injuries and reiterating the necessity of a claimant's asserted injury meeting both definitions to satisfy the "injury in fact" requirement for standing).

Ciox does not explicitly identify the harm it has incurred or will incur as a result of HHS's complained-of actions. Rather, the passing allegations relating to harm that are scattered through the Complaint are alternately generalized, oblique and unsubstantiated. First, Ciox alleges that HHS's actions "threaten to . . . challenge the long-term viability of the medical-records industry" and "disrupt the American healthcare system." Compl. ¶ 4. This allegation is of "generalized or undifferentiated" sort that cannot support a showing of particularized injury. *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 914 (D.C. Cir. 2015) (citation omitted). Next, Ciox states that "the overwhelming majority of Ciox's revenues historically have come from fulfilling patient-authorized requests for PHI from commercial third parties," Compl. ¶ 22, but it fails to allege a concrete and particularized, and actual or imminent, harm to those revenues. *Cf. Friends of The Earth, Bluewater Network Div. v. U.S. Dep't of Interior*, 478 F. Supp. 2d 11, 22 (D.D.C. 2007) ("'In the absence of reference to past (and anticipated future)' injury tied to a specific place, 'a expression of enjoyment of all things sylvan is inadequate to show a directly affected interest.'") (quoting *Mountain States Legal Foundation v. Glickman*, 92 F.3d 1228, 1236–37 (D.C. Cir. 1996)). Finally, Ciox alleges that the 2016 guidance "*threatens to impose hundreds of millions of dollars* in costs that can be no longer recouped by healthcare providers . . ." Compl. ¶ 53, an allegation that is unanchored in any provided facts and unlinked

to Ciox's position as a specialized medical records provider. *See Advanced Mgmt. Tech., Inc. v. FAA*, 211 F.3d 633, 637 (D.C. Cir. 2000).

Ciox's attempt to inject an enforcement challenge into its Complaint fails to allege an injury-in-fact, as well. Ciox alleges that HHS threatened to "take enforcement action where necessary" to enforce the 2016 guidance and "made good on that threat by informing Ciox that it violated the 2016 [guidance] by invoicing certain allegedly excluded fees in response to a regulatory third party directive." Compl. ¶ 58. Ciox attaches a letter that HHS sent to CHI Health St. Francis (CHI St. Francis), which HHS identifies as a covered entity. *See* Davis Letter. In that letter, HHS notifies CHI St. Francis that it received a complaint from an individual alleging that CHI St. Francis violated certain regulations when that individual requested her health records from CHI St. Francis and thereafter received an invoice from Ciox charging $224.65 for fulfilling the request. *See id.* at 1. The letter, however, is not directed at Ciox. Nor does it purport to take any enforcement action against Ciox—or against CHI St. Francis, for that matter. *See generally id.* Rather, it resolved the matter by offering technical assistance to CHI-St. Francis and closed the case. *Id.* at 5; *see also* 45 C.F.R. § 160.304(b). Therefore, the letter that HHS sent to CHI-St. Francis does not establish an actual or imminent concrete injury that Ciox suffered such that would provide standing for Ciox here.

Indeed, because HHS has not and cannot take enforcement action against Ciox regarding the fees it charges for individual requests of PHI, Ciox cannot raise either an enforcement or pre-enforcement challenge to the Privacy Rule provision and guidance at issue. *See Matthew A. Goldstein, PLLC v. United States Dep't of State*, 851 F.3d 1, 4 (D.C. Cir. 2017) ("It is true that a plaintiff is not required to expose himself to liability before bringing suit to challenge the basis for an enforcement action by the government. But there is something fundamental to a pre-

enforcement challenge that is missing here. There must be some desired conduct by the plaintiff that might trigger an enforcement action in the first place.") (citation omitted).

Causation: Nor does Ciox show that HHS's complained-of actions caused any injury-in-fact. "The 'causal connection between the injury and the conduct complained of' must be 'fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court.'" *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015) (quoting *Lujan*, 504 U.S. at 561). Here, the third parties not before the Court are the covered entities with which Ciox contracts, such as CHI St. Francis. Therefore, Ciox must show that there is "little doubt" as to the "causal relationship between the government policy [under review] and the third-party conduct [that directly caused his injury][.]" *NWCA*, 366 F.3d at 941. The "substantial factor" standard may be satisfied where there is "nothing . . . indicating that the third parties whose conduct injured the plaintiffs would have had reason to continue their injurious conduct unaltered in the absence of the challenged government action." *Id.* at 943.

Here, the agreements that Ciox has negotiated with the covered entities with which it does business control the payments that Ciox receives for its services. The Complaint is bereft of *any* allegations specifically linking HHS's complained-of conduct with the actions of covered entities and the effects of those actions on Ciox. *See generally* Compl. Nor does HHS's letter to CHI-St. Francis demonstrate any causal relationship between the Privacy Rule provision and guidance at issue and Ciox's asserted injuries (to the extent they are properly asserted). Although HHS notes in its letter that "all of the access requirements that apply with respect to PHI held by the covered entity (e.g., an individual may be charged only a reasonable, cost-based fee that complies to 45 C.F.R. § 164.524(c)(4)) apply with respect to PHI held by the business associate," that fact does not foreclose Ciox from receiving higher payments from the covered entity. Davis

Letter at 3. 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 to a business associate. Therefore, Ciox fails to allege in the Complaint how the 2013 Rule and the 2016 guidance are substantially likely to harm Ciox. *NWCA*, 366 F.3d at 944 ("Abstract theory and conjecture are not enough to support standing . . . ."); *see State Nat'l Bank of Big Spring v. Lew*, 795 F.3d 48, 55 (D.C. Cir. 2015) (finding that the plaintiff, a bank, lacked standing to challenge the Financial Stability Oversight Council's "too big to fail" designation authority because the plaintiff did not allege that it was subject to that authority and because its theory of causality was "simply too attenuated and speculative to show the causation necessary to support standing").

Redressability: Finally, Ciox fails to establish that to the extent it has demonstrated an injury, the injury could be redressed by a favorable decision from the Court. For Ciox to successfully allege redressability, the facts alleged must "be sufficient to demonstrate a substantial likelihood that the third party directly injuring the plaintiff would cease doing so as a result of the relief the plaintiff sought." *Renal Physicians Ass'n v. United States HHS*, 489 F.3d 1267, 1275 (D.C. Cir. 2007). Here, Ciox nowhere alleges that elimination of the relevant portions of the 2013 Rule and the 2016 guidance would be substantially likely to cause the covered entities with which they contract to refrain from inflicting whatever injury they claim. While Ciox generally alleges that "the overwhelming majority of Ciox's revenues historically have come from fulfilling patient-authorized requests for PHI from commercial third parties . . . . derived largely from fulfilling patient-authorized requests from for-profit insurance conglomerates, incorporated businesses, and other commercial partnerships," Compl. ¶ 22, it

does not connect this statement to an allegation demonstrating how the "nonagency activity" that affects them—*i.e.*, the activity of the covered entities—"will be altered or affected by the agency activity they seek to overturn." *Chesapeake Climate Action Network v. Exp.-Import Bank of the United States*, 78 F. Supp. 3d 208, 225 (D.D.C. 2015) (citation omitted). In the absence of that connection, Ciox does not demonstrate redressability.[3]

For these reasons, Ciox's Complaint should be dismissed for want of Article III standing.[4]

b. Ciox's claims are unripe.

Even if Ciox had standing, this court should not exercise jurisdiction over its claims because they are unripe. *See Chlorine Inst., Inc. v. Fed. R.R. Admin.*, 718 F.3d 922, 927 (D.C. Cir. 2013). The ripeness requirement exists "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs v. Gardner*, 387 U.S. 136, 148–49 (1967), *abrogated on other*

[3] And as to Ciox's challenges to the guidance in Counts Two and Three, Ciox fails to establish how HHS's rescission of the guidance would redress any properly-pleaded injury. As explained in more detail *infra*, the guidance does not work a change in the law; rather, the guidance merely explains HHS's understanding of the rule and provides options for how covered entities can calculate their costs in accordance with the rule. Therefore, HHS's rescission of the guidance would not alter the legal regime for Ciox. *E.g.*, *Nat'l Multi Hous. Council v. Jackson*, 539 F. Supp. 2d 425, 431-32 (D.D.C. 2008) (concluding that because the challenged-guidance "by its own terms does not create any new obligations . . . . the relief plaintiffs seek would not redress their claimed injury").

[4] Further, even if Ciox met the "constitutional minimum of standing" flowing from Article III's case-and-controversy requirement, it appears that Ciox is attempting to assert claims on behalf, not of itself, but of the covered entities with which it contracts. However, Ciox fails to allege that those entities are unable to protect their own rights. *See generally* Compl; *see also Kowalski v. Tesmer*, 543 U.S. 125, 129–30 (2004). Thus, Ciox does not meet the criteria to bring its claims as a third party.

grounds by *Califano v. Sanders*, 97 S. Ct. 980 (1977). In applying the ripeness doctrine, courts consider two factors: "the fitness of the issues for judicial decision" and "the hardship to the parties of withholding court consideration." *Id.* at 149; *accord Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998).

Ciox's claims fail to meet either prong. First, Ciox's claims are unfit for adjudication. Under the fitness prong of the ripeness test, courts consider "whether the agency action is final; whether the issue presented for decision is one of law which requires no additional factual development; and whether further administrative action is needed to clarify the agency's position[.]" *Action Alliance of Senior Citizens of Greater Phila. v. Heckler*, 789 F.2d 931, 940 (D.C. Cir. 1986). The existence of "final agency action" is "'a crucial prerequisit[e]' to ripeness[.]" *Sprint Corp. v. FCC*, 331 F.3d 952, 956 (D.C. Cir. 2003) (citation omitted). But even where there is final agency action and the challenge raises issues of law, the dispute "still may not be fit for review where the agency retains considerable discretion to apply the new rule on a case-by-case basis, particularly where there is a complex statutory scheme [.]" *Id.* In such cases, judicial review "is likely to stand on a much surer footing in the context of a specific application" of the agency's policy than it would "in the framework of [a] generalized challenge." *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158, 164 (1967).

Here, as will be explained below, the guidance that Ciox challenges is not final agency action, and HHS retains the discretion to modify or rescind the guidance. Ciox does also challenge the 2013 Rule in Count One, which is a final agency action. But neither the challenge to the rule nor the challenge to the guidance is fit for review because Ciox's challenge would benefit from a more concrete setting. *See Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1204 (D.C. Cir. 1998). Ciox has provided no substantiated allegations alleging that HHS

could or would exercise its discretionary enforcement authority against business associates like Ciox; thus, the impact of the rule on Ciox is, at best, purely speculative at this point. *See Am. Servicemen's Union v. Mitchell*, 54 F.R.D. 14, 17 (D.D.C. 1972) (courts "should not consider . . . claims that are abstract, speculative and of no pressing immediacy"); *see also Ctr. For Sci. In The Pub. Interest v. Food & Drug Admin.*,CIV.A.03-1962 RBW, 2004 WL 2011467, at *4 (D.D.C. 2004) (concluding that "since there is only an alleged procedural violation and because the effects" of the action at issue "have not yet been felt by the plaintiffs, this case is not ripe for review"). Further, there is a complex statutory scheme under HIPAA and the HITECH Act, the laws that govern a covered entity's statutory duties to provide an individual's PHI, and further complexities are raised where a business associate such as Ciox seeks to litigate the extent of a covered entity's duties. *See, e.g.*, *Nat'l Abortion Fed'n v. Ashcroft*, No. 03 CIV. 8695 (RCC), 2004 WL 555701, at *2 (S.D.N.Y. Mar. 19, 2004) (analyzing the same part of the HIPAA providing the basis for HHS's regulations and noting that the legislation is "complex"); *cf. AARP v. United States Equal Employment Opportunity Comm'n*, 267 F. Supp. 3d 14, 19 (D.D.C. 2017), *on reconsideration*, No. CV 16-2113 (JDB), 2017 WL 6542014 (D.D.C. Dec. 20, 2017) (noting the "complex regulatory and statutory framework" created in part by the HIPAA as amended by a subsequent statute). Those complexities warrant "the context of a specific application" of the agency's policy to be ripe for adjudication here. *Toilet Goods Ass'n*, 387 U.S. at 164; *see also Sprint Corp.*, 331 F.3d at 956. Ciox fails to allege such a specific application of HHS policy.

Second, Ciox does not demonstrate that the Court's immediate intervention is necessary to prevent hardship. Under the hardship prong, courts consider the detriment to the parties from deferring judicial review. Where the court or the agency has an institutional interest in deferral, that interest will only be outweighed if deferral would "impose a hardship on the complaining

party that is immediate, direct, and significant." *State Farm Mut. Auto. Ins. Co. v. Dole*, 802 F.2d 474, 480 (D.C. Cir. 1986). Such hardship must consist of "'adverse effects of a strictly legal kind[.]"' *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 809 (2003) (quoting *Ohio Forestry Ass'n*, 523 U.S. at 733). Sufficient hardship is not present when a party faces "mere uncertainty as to the validity of a legal rule[.]" *Id* at 811.

As explained *supra*, Ciox has not even identified its injury-in-fact with sufficient concreteness and particularity, and it is thus difficult to discern from the Complaint what, if any, hardship Ciox faces in deferring review unless and until HHS takes enforcement action. In the absence of such information, Ciox's claims do not meet the hardship prong of the ripeness analysis.

For these reasons, Ciox's claims should be dismissed for lack of jurisdiction as unripe.

II. Ciox fails to state a claim upon which relief may be granted.

a. Ciox lacks statutory standing to bring its claims.

Even if Ciox met the jurisdictional standing and ripeness requirements, Ciox lacks prudential, or statutory, standing to bring this lawsuit. That is because Ciox's interests do not fall within the scope of the HITECH Act provision in which it seeks to anchor its claims. When a plaintiff brings a claim under the APA as a party allegedly "aggrieved" by some agency action that violated a substantive statute, *see* 5 U.S.C. § 702, that suit may not proceed unless the interest asserted by the plaintiff is "arguably within the zone of interests to be protected or regulated by the statute that he says was violated." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 132 S. Ct. 2199, 2210 (2012) (quoting *Ass'n of Data Processing*

Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 153 (1970)).[5] Although the prudential-standing test "is not meant to be especially demanding," a plaintiff lacks prudential standing if his "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." *Id.* at 2210(citation omitted).

Ciox claims that HHS's actions violate 42 U.S.C. § 17935(e). *See* Compl. ¶¶ 62, 72. But Ciox's interests do not fall within the zone of interests to be protected or regulated by that statutory provision. Section 17935(e) is titled "Access to certain information in electronic format," and sets forth an individual's right to obtain PHI in an EHR. 42 U.S.C. § 17935. This subsection has three components, none of which impose any requirements upon business associates.

The first component, § 17935(e)(1), provides individuals with a right to obtain from covered entities that maintain an individual's PHI in an EHR "a copy of such information 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 . . . ." 42 U.S.C. § 17935(e)(1). It makes no mention of business associates. The second component, § 17935(e)(2), and the only one that mentions business associates, merely states that "if the individual makes a request to a business associate for access to, or a copy of, [PHI] about the individual" or requests a business associate to "grant such access to, or transmit such copy directly to, a person or entity designated by the individual," the business associate "*may* provide the individual with such access or copy

[5] The Supreme Court has clarified that, although this test has been called "prudential standing," that phrase is a "misnomer;" rather, "[w]hether a plaintiff comes within the zone of interests is an issue that requires us to determine, using traditional tools of statutory interpretation, whether a legislatively conferred cause of action encompasses a particular plaintiff's claim." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1387 (2014) (citation omitted); *see also Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1302 (2017) ("The question is whether the statute grants the plaintiff the cause of action that he asserts.").

. . . or grant or transmit such access or copy to such person or entity designated by the individual." *Id.* § 17935(e)(2) (emphasis added). The copy "*may* be an electronic form . . . ." *Id.* (emphasis added). The third component, § 17935(e)(3), creates limitations on what covered entities may charge for providing an individual's PHI in an EHR; it states that "any fee that the covered entity may impose for providing such individual with a copy of such information . . . if such copy . . . is in an electronic form shall not be greater than the entity's labor costs in responding to the request for the copy . . . ." *Id.* § 17935(e)(3). Again, this component does not impose a fee limitation on what business associates can charge—for example, it imposes no limitations on what business associates can charge covered entities for their services.

Because the statute only imposes requirements on covered entities, while using purely permissive language with respect to business associates options for providing PHI to individuals, *id.* § 17935(e)(2), without including business associates in its fees limitation component, this provision does not encompass business associates in its zone of interests such that would sustain Ciox's lawsuit challenging the provision's requirements for covered entities. Prudential standing can be satisfied only by a plaintiff's "own legal rights and interests," not "the legal rights or interests of third parties." *See Valley Forge Christian Coll. v. Ams. United for Separation of Church and State*, 454 U.S. 464, 474 (1982).

This conclusion is further borne out by the structure of the statute at issue and its neighboring provisions. 42 U.S.C. § 17935 is preceded by two sections that specifically delineate which relevant laws must be extended to business associates, and the fee and format requirements in 42 U.S.C. § 17935(e) and 45 C.F.R. § 164.524 are not among those listed. *See* 42 U.S.C. § 17931 (stating that sections "164.308, 164.310, 164.312, and 164.316 of title 45, Code of Federal Regulations, shall apply to a business associate of a covered entity in the same

manner that such sections apply to the covered entity"); *id.* § 17934 (applying 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). Thus, Ciox is not liable for failure to comply with the provision at issue.

For these reasons, Ciox's asserted interests do not fall within 42 U.S.C. § 17935's zone of interests and, thus, the Complaint must also be dismissed on lack of prudential or statutory standing.

b. Counts Two and Three challenge agency action that is not final under the APA.

In Counts Two and Three, Ciox challenges HHS's 2016 guidance, alleging that the guidance violates the APA because it (1) was improperly crafted without notice and comment, and (2) is both *ultra vires* and arbitrary and capricious. The 2016 guidance, however, is not final agency action, and, thus, is not subject to judicial review under the APA. Therefore, these claims should be dismissed for failure to state a claim. Fed. R. Civ. P. 12(b)(6); *see also Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003).

Judicial review under the APA is limited to "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court[.]" 5 U.S.C. § 704. The Supreme Court defines final agency action as action (1) that marks the "consummation of the agency's decisionmaking process" and (2) by which "rights or obligations have been determined, or from which "legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citation omitted). The D.C. Circuit has provided "complementary" factors to assess along with the test in *Bennett. CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011) (examining whether the "agency had taken a definitive legal position concerning its statutory authority[,]" whether "the case presented a purely legal question of

statutory interpretation[,]" and whether "the agency's letter imposed an immediate and significant practical burden" on the agency)(citation omitted).

As a general matter, this Circuit has stated that general statements of policy are categorically non-final agency action and, thus, precluded from judicial review. *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) (citing *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 809–11 (2003)). "An agency action that merely explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule—is a general statement of policy." *Id.* at 252. Further, "interpretative rule[s] . . . generally do not qualify" as final agency action "because they are not finally determinative of the issues or rights to which they are addressed." *Am. Tort Reform Ass'n v. Occupational Safety & Health Admin.*, 738 F.3d 387, 395 (D.C. Cir. 2013) (citation omitted); *see also Sierra Club v. Envtl. Prot. Agency*, 873 F.3d 946, 951 (D.C. Cir. 2017). An interpretive rule "merely interprets a prior statute or regulation, and does not itself purport to impose new obligations or prohibitions or requirements on regulated parties." *Nat'l Min. Ass'n*, 758 F.3d at 252. To distinguish between these types of agency actions and a legislative rule, which would be subject to judicial review, this Circuit has analyzed the following factors: (1) "the actual legal effect (or lack thereof) of the agency action in question on regulated entities"; (2) "the agency's characterization of the guidance"; and (3) "whether the agency has applied the guidance as if it were binding on regulated parties. *Id.* at 252–53; *Sierra Club*, 873 F.3d at 951.

This court should not treat HHS's guidance as the "consummation" of its decisionmaking or as imposing rights, obligations, or legal consequences; it is not final agency action.[6] *See Bennett*, 520 U.S. at 177–78. Ciox has challenged three aspects of the guidance, but none of the agency statements that it disputes is final agency action. The first challenged portion of the guidance paraphrases or, at most, clarifies HHS's position regarding the effect of the 2013 rule by noting that the rule's fee limitation for individual requests for PHI, 45 C.F.R. § 164.524(c)(4), continues to apply when an individual's request for PHI directs the PHI to be sent to a third-party in accordance with 45 C.F.R. § 164.524(c)(3)(ii). Guidance at 17–18. The second portion publicly clarifies HHS's position about what 45 C.F.R. § 164.524(c)(4)(i) has always meant by allowing covered entities to charge labor costs for copying. Guidance at 8, 11–13. "[T]he case law is clear" that such agency action is unreviewable and non-final "where an agency merely expresses its view of what the law requires of a party, even if that view is adverse to the party."[7] *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 808 (D.C. Cir. 2006) (citation omitted). The third challenged portion of the guidance suggests three ways in which covered entities may calculate their limited fee under Section 164.524(c)(4). Guidance at 14–16. That portion of the guidance is expressly permissive and merely provides options for covered

[6] Defendants concede that its issuance of the guidance constitutes "agency action" under the APA. *See* 5 U.S.C. § 551(4).

[7] Indeed, if HHS were to issue guidance saying that the rule allows for costs associated with search and retrieval of an individual's PHI to fall within "labor for copying" costs, as Ciox appears to prefer, such guidance would appear to impose additional obligations on *requestors* beyond those set forth in the regulation, since copying is a separate task from search and retrieval, and therefore would appear to constitute final agency action under the APA. *E.g.*, *Nat'l Min. Ass'n v. Jackson*, 768 F. Supp. 2d 34, 44 (D.D.C. 2011) (concluding that the challenged agency action amounted to final action because the agency appeared to impose "an additional step to the permitting process that is not contemplated or set forth in the [prior] guidelines").

entities, as evidenced by its use of language like "may" and "can." *E.g.*, Guidance at 15 ("The following methods *may* be used . . . ."); *see Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta*, 785 F.3d 710 (D.C. Cir. 2015) (relying on similarly permissive language as evidence that "the provisions that follow are meant to be precatory, not mandatory") (citation omitted). HHS takes the position that covered entities may calculate their fees in different ways so long as they comply with Section 164.524(c)(4). None of these aspects of the guidance alters the legal regime under which the relevant regulated parties operate,[8] and an agency action will only be final where its effect is "a certain change in the legal obligations of a party[.]" *Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 8, 15 (D.C. Cir 2005). Further, HHS retains complete discretion to rescind or change this guidance, which HHS concedes has no force or effect of law and does independently not bind any covered entity.

Indeed, the guidance amounts to no more than a general statement that explains HHS's current understanding of the relevant law or, at most, interpretive, non-final guidance in part. .

[8] Ciox's allegation that these statements constitute "dramatic changes" to the legal framework are unsubstantiated. *See* Compl. ¶ 51; *see also id.* ¶ 48. These bare assertions are undercut by the language in 45 C.F.R. § 164.524 as well as the guidance itself.

The only portion of the guidance for which Ciox attempts to substantiate this claim is the guidance regarding the "labor for copying" costs that may be passed to the individual. There, Ciox relies on language in the preamble to the final rule to argue that the guidance works a change. *See* Compl. ¶ 52. Ciox's reliance on this language is misplaced. The preamble mentions that "compiling, extracting, scanning, and burning" the PHI *could* be viewed as included labor costs. 78 Fed. Reg. at 5636. Those tasks are distinct from "locating, reviewing, . . . and segregating or otherwise preparing" the PHI that the guidance clarifies to be outside the scope of the 2013 rule's "labor for copying" language. Even if the language were somehow inconsistent, it is well-settled that a rule's preamble is not binding. *See Nat'l Wildlife Fed. v. EPA*, 286 F.3d 554, 569–70 (D.C. Cir. 2002) ("The preamble to a rule is not more binding than a preamble to a statute. 'A preamble no doubt contributes to a general understanding of a statute, but it is not an operative part of the statute and it does not enlarge or confer powers on administrative agencies or officers.'") (quoting *Ass'n of Am. R.Rs. v. Costle*, 562 F.2d 1310, 1316 (D.C. Cir. 1977)).The guidance notes that HHS has always applied the "labor for copying" language to exclude costs for search and retrieval.

Huerta, 785 F.3d at 719 (concluding that the challenged agency action was not final, regardless of whether it was found to be a general statement of policy or an interpretive rule, because it was "nonbinding guidance that does not conflict with existing regulations"); *see also, e.g.*, *Sec. Indus. & Fin. Markets Ass'n v. United States Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 425 (D.D.C. 2014).

To be sure, it is possible for documents styled as guidance to amount to final agency action if the guidance has an independently binding and legally consequential effect. *See Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000). Here, however, "there has been no 'order compelling the regulated entity to do anything.'" *McCarthy*, 758 at 253 (quoting *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004)). "[T]he document itself would [not] be given any weight at all in [subsequent] proceedings." *Molycorp, Inc. v. EPA*, 197 F.3d 543, 546 (D.C. Cir. 1999), because the source of authority for any potential enforcement activity undertaken by HHS flows from the 2009 statute and the 2013 Rule, not the guidance.[9] *See generally* Davis Letter; *see also* 42 U.S.C. § 17935; 45 C.F.R. § 164.524.

Accordingly, this is not a situation in which the challenged document "reads like a ukase" that "commands[,]" "requires[,]" and "dictates." *Appalachian Power Co.*, 208 F.3d at 1023. To

[9] Using the factors provided by the D.C. Circuit for differentiating between general statements of policy and legislative rules, this court should not consider the guidance to be a legislative rule. *McCarthy*, 758 F.3d at 252-53 (considering (1) "the actual legal effect (or lack thereof) of the agency action in question on regulated entities"; (2) "the agency's characterization of the guidance"; and (3) "whether the agency has applied the guidance as if it were binding on regulated parties."). First, HHS considers the guidance as having no legal effect, as it contains no independently and not binding on any covered entities, which are free to interpret the regulations in a different lawful way than the agency interpretation. Second, Ciox has not substantiated its allegations that HHS has applied the guidance as binding. *See generally* Compl. The letter it attaches merely refers CHI St. Francis to the guidance (1) for further explanation regarding the various methods that may be used to calculate a reasonable, cost-based fee for the provision of PHI at the behest of an individual request and (2) for "material explaining the [regulatory] provisions related to Access to Medical Records[.]" Davis Letter at 4, 5.

the extent that the guidance contains mandatory language, it is clear from context that the agency does not believe that the guidance *itself* requires regulated parties to do anything; HHS is instead expressing its nonbinding view that other legal authorities require particular actions in certain circumstances. *See, e,g.*, Guidance at 8, 11–13 (explaining HHS's views about what tasks are included under "labor for copying" under 45 C.F.R. § 164.524(c)(4)(i)).

Therefore, in the event that this Court concludes that it has jurisdiction to hear Ciox's claims, Counts Two and Three should be dismissed under Fed R. Civ. P. 12(b)(6) for failure to challenge a final action under the APA.

CONCLUSION

For the foregoing reasons, Ciox's Complaint should be dismissed.

Respectfully submitted,

Dated: April 2, 2018

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF THE 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)

[PROPOSED] ORDER

The Court having considered Defendants' Motion to Dismiss and the parties' submissions relating thereto, it is hereby

ORDERED that the Motion is GRANTED. It is further

ORDERED that the Complaint is DISMISSED.

SO ORDERED.

_____
Date

_____
Amit P. Mehta
United States District Judge