

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

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v.

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Criminal Action No. 15-30032-MGM

MARGARET LUTHRA

*

a/k/a Rita Luthra,

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Defendant.

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MEMORANDUM AND ORDER REGARDING
DEFENDANT’S MOTION TO DISMISS INDICTMENT

(Dkt. No. 135)

April 13, 2018

MASTROIANNI, U.S.D.J.

I. INTRODUCTION

Before the court is Margaret Luthra’s (“Defendant”) Motion to Dismiss the superseding indictment, the government’s opposition, and Defendant’s reply. (Dkt. Nos. 135, 138, 141.) The indictment charges Defendant with three counts and she challenges each. Count 1 alleges wrongful disclosure of individually identifiable health information in violation of the Health Insurance Portability and Accountability Act (“HIPPA”), 42 U.S.C. § 1320d-6. (Dkt. No. 89 ¶¶ 11-14.) Count 2 alleges “witness tampering” in violation of 18 U.S.C. § 1512(b)(3). (*Id.* ¶¶ 15-17.) Count 3 alleges obstruction of a criminal investigation of a health care offense in violation of 18 U.S.C. § 1518. (*Id.* ¶¶ 18-21.)

Defendant argues for dismissal on numerous grounds, some levied at particular counts and some as a basis for dismissal of the entire indictment. As to Count 1, Defendant contends the government “flat out fails to state an offense” under HIPPA and that dismissal is also warranted under the doctrine of duplicity and for lack of specificity. (Dkt. No. 136 at 3.) Regarding Count 2, Defendant contends dismissal is warranted under the doctrine of duplicity and because the government failed to allege that she “corruptly persuaded” her assistant—the allegedly “tampered” witness—to withhold facts from a law enforcement officer of the United States as required by the statute. (*Id.* at 19-21.) Regarding Count 3, Defendant contends dismissal is warranted in light of the government’s failure to state an offense (i) “because of lack of mens rea and materiality . . . as count three fails to allege that [Defendant’s] statements had the ‘natural and probable effect’ of obstructing an investigation,” (ii) for lack of specificity, and (iii) under the doctrine of duplicity. (*Id.* at 25-28.) Defendant also moves for dismissal of all counts on two additional grounds: violation of her Sixth Amendment right to a speedy trial and alleged prosecutorial misconduct before the grand jury. (Dkt. No 136 at 29-39.)

The court DENIES the motion for the reasons below. Because the majority of Defendant’s arguments have been addressed and rejected in prior orders, those arguments are only briefly discussed below. The remaining arguments are addressed in turn.

II. STANDARD

Indictments must contain a “plain, concise and definite written statement of the essential facts constituting the offense charged.” Fed. R. Crim. P. 7(c)(1). Generally, “an indictment is sufficient if it, first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.” *Hamling v. United States*, 418 U.S. 87, 114, 94 (1974). “An indictment that tracks the language of the underlying statute generally suffices

to meet this standard; provided, however, that the excerpted statutory language sets out all of the elements of the offense without material uncertainty.” *United States v. Troy*, 618 F.3d 27, 34 (1st Cir. 2010) (citing *United States v. Serino*, 835 F.2d 924, 929 (1st Cir.1987)). An indictment must, nevertheless, “be accompanied [by] a statement of the facts and circumstances [sufficient to] inform the accused of the specific offence [sic], coming under the general description, with which he is charged.” *Id.* (citing *Hamling*, 418 U.S. at 117-18). “[I]n the ordinary course of events, a technically sufficient indictment handed down by a duly empaneled grand jury is enough to call for trial of the charge on the merits.” *United States v. Guerrier*, 669 F.3d 1, 4 (1st Cir. 2011) (quoting *Costello v. United States*, 350 U.S. 359, 363 (1956)). For that reason, defendants challenging the sufficiency of an indictment bear “a heavy burden,” *United States v. Perry*, 37 F. Supp. 3d 546, 550 (D. Mass. 2014) (citing *United States v. Troy*, 618 F.3d 27, 34 (1st Cir. 2010)), and courts reserve dismissal for “extremely limited circumstances” to avoid “directly encroach[ing] upon the fundamental role of the grand jury.” *Whitehouse v. U.S. Dist. Court*, 53 F.3d 1349, 1360 (1st Cir. 1995).

III. ANALYSIS

A. Arguments Previously Addressed

Defendant repeats—in large part verbatim—arguments the court has previously rejected when ruling on her prior motions.¹ (*See* Dkt. No. 100 (Sept. 26, 2017 Memorandum and Order denying first motion to dismiss) and Dkt. No. 120 (Jan. 12, 2018 Electronic Order granting government’s motion to exclude delay and rejecting Defendant’s Sixth Amendment arguments); *compare* Dkt No. 88 (Def.’s Memo. of Law In Support of Mot. to Dismiss the Indictment) *with* Dkt. No. 136 (Def.’s Memo. of Law In Support of Mot. to Dismiss the Superseding Indictment).) For the sake of clarity, the relevant holdings from prior orders are repeated below.

¹ This is Defendant’s second motion to dismiss the superseding indictment. The first was denied on September 26, 2017. (*See* Dkt. No. 100.)

(1) Duplicity & Specificity

The court has already held that the doctrines of duplicity and specificity do not require dismissal of any challenged count. (Dkt. No. 100 at 205.) To quote the court's prior opinion: specificity does not merit dismissal of count 2 because "the relevant [HIPPA] allegations sufficiently track the language in 42 U.S.C. § 1320d-6 . . . and sufficiently 'inform [Defendant] of the specific offense, coming under the general description, with which [s]he is charged.'" (*Id.* at 2 (quoting *United States v. Troy*, 618 F.3d 27, 34 (1st Cir. 2010)(other citations omitted).) Likewise, "[t]he Superseding Indictment sufficiently tracks statutory language . . . [and] provide[s] sufficient notice by asserting that Defendant 'gave information she knew to be false' to United States Department of Health and Human Services ('HHS') agents who were investigating violations of 42 U.S.C. § 1320a-7b, the federal 'Anti-kickback Law.'" *Id.* at 2-3. As for the doctrine of duplicity, the court has already explained that "duplicitous counts are generally cured by jury charges requiring unanimous agreement on underlying offense(s) or by government election between different offenses contained in a single count, and not by dismissal." *Id.* at 4-5 (citing *United States v. Place*, 757 F. Supp. 2d 60, 61 (D. Mass. 2010)); *see also United States v. Robinson*, 651 F.2d 1188, 1194 (6th Cir.1981) ("dismissal of the indictment is not the proper remedy").

(2) Sufficiency of Allegations Supporting Count 3

The court has also already rejected the remaining arguments levied at Count 3: putative failures to allege "falsehoods," "Mens Rea and Materiality," and "the required nexus" purportedly required under *United States v. Aguilar*, 515 U.S. 593 (1995). (Dkt. No. 100 at 5-7.) Relevant "allegations fairly and straightforwardly imply several falsehoods, contrary to Defendant's broad construal, most obviously that Defendant misrepresented that she had been paid to write a research paper. These allegations are enough to state an offense." *Id.* "Defendant's remaining arguments all involve holdings in *Aguilar* [and progeny] that have no applicability here." *Id.* at 6, n.2. Those

holdings all concerned the broad reach of statutory “omnibus” clauses that prohibited interference with, *inter alia*, “the due administration of justice” or the “due administration of the Tax Code.” *Marinello v. United States*, -- S. Ct. --, No. 16-1144, 2018 WL 1402426, at *2-4 (U.S. Mar. 21, 2018) (citations omitted). Contrary to such omnibus clauses, 18 U.S.C. § 1518(a), under which Defendant is charged here, “more narrowly prohibits ‘attempts to . . . mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator.’” (Dkt. No. 100 at 6-7.) Thus “the concerns for breadth and ambiguity at issue in *Aguilar*” are not similarly implicated. (*Id.* at 6, n. 2.) Moreover, even if the *Aguilar* and progeny’s nexus requirement did extend to section 1518(a), there would still be no reason to impose the heightened pleading requirements urged by Defendant here. *See United States v. Ho*, 651 F. Supp. 2d 1191, 1196 (D. Haw. 2009) (rejecting the argument that *Aguilar* and *Anderson* created “additional element[s]” beyond statutory language that must be pled).

(3) Purported violations of Defendant’s 6th Amendment Speedy Trial Rights

Both this court and Magistrate Judge Robertson have already rejected Defendant’s Sixth Amendment arguments. While it is true, as Defendant contends, the argument was rejected in the context of her assertion of *statutory* speedy trial rights, the constitutional arguments she asserted in the statutory context are identical—verbatim in all material respects—to those she asserts here as a basis for dismissal. Defendant’s motion to dismiss on these grounds is therefore denied for the reasons put forward in prior orders. (*See* Dkt. Nos. 118, 120.) As Judge Robertson soundly explained, Defendant’s constitutional right to a speedy trial was not violated because Defendant in large part caused the delays complained of and has not suffered the requisite prejudice. (Dkt. No. 118.) Defendant simply repeats the same arguments previously rejected by this court and Judge Robertson. The court’s renewed analysis under *Barker v. Wingo*, 407 U.S. 514 (1972), thus inalterably leads to the conclusion that the argument still lacks merit.

B. COUNT 1 – Failure to State Offense Due to “Express” Authorization

Defendant also contends the superseding indictment fails to state an offense under section 1320d-6 of HIPPA because certain regulations promulgated by the Secretary of HHS expressly allow the disclosures she is alleged to have made. (Dkt No. 136 at 7.) The court disagrees and holds the government has sufficiently stated an offense under section 1320d-6.

As relevant to Count 1, the indictment alleges as follows. Many insurance companies, including those from whom Defendant receives payments, list covered prescription drugs in a “formulary.” (Dkt. No. 89 ¶ 9.) If a drug is not listed in the formulary, insurers will not pay for it (or will pay less) unless the prescribing physician first completes a “Prior Authorization Form” (“PA”) certifying that the drug is “medically necessary” for the insured patient. (*Id.* ¶ 10.)

In January 2011, Warner Chilcott launched Atelvia, a medication to which cheaper generic alternatives were readily available. (*Id.* ¶ 12.) In light of those alternatives, Atelvia was not included in most insurer formularies. (*Id.*) After receiving “numerous” denials for Atelvia prescriptions, Defendant asked the Warner Chilcott sales representative to assist her medical assistant with PAs. (*Id.* ¶ 14.) The sales representative agreed and assisted by filling out the PAs directly; during that process he “had access” to and “used” Defendant’s patient’s protected health information to fill out the PA forms. (*Id.*) On the basis of those allegations, count 1 charges Defendant with aiding and abetting a violation of 42 U.S.C. § 1320d-6. Specifically, Count 1 charges that Defendant:

did knowingly and without authorization disclose protected individually identifiable health information relating to an individual, that was maintained by a covered entity, as defined in C.F.R. § 160.103, to another person, to wit: Warner Chilcott Sales Representative # 1.

(Dkt. No. 89 ¶ 12.)

Section 1320d-6 makes it a crime to knowingly disclose “individually identifiable health information to another person” without proper authorization. 42 U.S.C. § 1320d-6(a). Whether any given disclosure violates HIPPA is generally governed by HIPAA “privacy regulations” promulgated

by the HHS. 42 U.S.C. §§ 1320d-1, 1320d-6, 1320d-9; *see also Citizens for Health v. Leavitt*, 428 F.3d 167, 172 (3d Cir. 2005)(describing enactment, implementation, and challenge of regulatory “privacy rule”). Defendant contends that several of these regulations expressly permit the disclosures she is alleged to have aided and abetted. Each argument is addressed and rejected below for similar reasons. In each instance, Defendant essentially invokes heightened charging standards and makes factual contentions not properly addressed in this posture.

1. 45 C.F.R. §§ 164.502(a)(1)(ii) & 164.506(c)

45 C.F.R. § 164.502 generally imposes HIPPA’s “privacy rule” in providing “[a] covered entity or business associate may not use or disclose protected health information, except as permitted or required” elsewhere in the regulations. 45 C.F.R. § 164.502(a). Subsection (a)(1)(ii) of 164.502 permits disclosure “[f]or treatment, payment, or health care operations, as permitted by and in compliance with § 164.506” of the same Part. Subsection (c)(1) of section 164.506, in turn, provides that a covered entity “may use or disclose protected health information for its own treatment, payment, or health care operations.” Subsection (c)(3) similarly states that a covered entity “may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.” Defendant argues that these provisions provide three distinct “express authorizations” for her alleged disclosures.

First, she contends that “pursuant to § 164.506(c)(1), [she] was expressly allowed to disclose the information, as it was part of her own treatment of her patients.” (Dkt. No. 136 at 8.) Second, Defendant contends the same section “also expressly authorized [her] to disclose the information as the disclosures were part of her own ‘health care operations.’” (*Id.* at 8.) Finally, Defendant contends that subsection (c)(3) permitted disclosure to the pharmaceutical salesperson because his employer, “a drug company, Warner Chilcott was a health care provider under HIPPA regulations.” (Dkt. No 136 at 9.)

The court finds none of these arguments establish a basis for dismissal. Defendant's contention that she was authorized to disclose information because it related to her "treatment" and "payment" operations reads subsection (c)(1) quite broadly. It is not clear that such a broad reading is appropriate, nor is it clear how that broad reading could result in dismissal.

"Treatment" is elsewhere defined as:

the provision, coordination, or management of health care and related services by one or more health care providers, **including the coordination or management of health care by a health care provider with a third party**; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

45 C.F.R. § 164.501 (emphasis added). "Payment" has a more complex definition. It is defined in relevant part as "[t]he activities undertaken by . . . [a] healthcare provider . . . to obtain or provide reimbursement for the provision of health care" so long as those activities "relate to the individual to whom health care is provided and include," but are not limited to:

- (i) Determinations of eligibility or coverage . . . ;
- (ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;
- (iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance . . . and related health care data processing;
- (iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
- (v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and
- (vi) Disclosure to consumer reporting agencies

45 C.F.R. § 164.501.

Defendant does not address how either definition results in dismissal. Rather, she quotes and underscores the operative language from section 164.506 allowing for disclosure for a covered entity's "own treatment [or] payment" and concludes without elaboration that the section "expressly

allowed” her to disclose protected information to a salesperson because it “was part of her own treatment of her patients.” (Dkt. No. 136 at 8 (emphasis in original).) When the indictment is considered upon a motion to dismiss, where Defendant faces a “heavy burden,” *Perry*, 37 F. Supp. 3d at 550, and courts reserve dismissal for “extremely limited circumstances,” *Whitehouse*, 53 F.3d at 1360, asserting the disclosed information is, in some sense, related to *payment for treatment* does not mandate dismissal under § 164.501. To the extent Defendant suggests the alleged disclosure was made for the purpose of “coordinat[ing] or manag[ing] of health care . . . with a third party,” 45 C.F.R. § 164.501, she at best makes a factual argument not properly considered here.

Second, Defendant contends that § 164.506(c)(1) also permitted disclosure because it was disclosed for her own “health care operations.” Section 164.501 defines “health care operations” as “any of the following activities of the covered entity to the extent that the activities are related to covered functions:”

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, **development or improvement of methods of payment or coverage policies**; and

45 C.F.R. § 164.501 (emphasis added).² In highlighting the bolded language, Defendant appears to contend the alleged disclosures were permitted because they allowed for the development and improvement of methods of payment for Atelvia. This does not satisfy Defendant’s “heavy burden” in seeking dismissal. Simply highlighting language and concluding, without exposition, that the court must be dismissed is plainly insufficient. Defendant at most makes an implicit factual argument not properly considered in this posture.

Third, Defendant contends that section 164.506(c)(3) permitted disclosure because Warner Chilcott is “another . . . health care provider” and the disclosure was made “for the payment activities of the entity that receives the information.” (Dkt. No 136 at 9.) Her argument derives from the definition of “health care provider” and “health care.” “Health care provider” is defined as a “provider of . . . health services . . . and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.” 45 C.F.R. § 160.103. The definition of “health care,” Defendant notes, includes the “[s]ale or dispensing of a drug . . . or other item in accordance with a prescription.” *Id.* Thus, Defendant argues, “since the definition of ‘health care’ includes the sale of a drug in accordance with a prescription, Warner Chilcott was a ‘health care provider’ under the regulations, as it furnished, billed, or was paid for health care (. . . the sale of its drug Atelvia) “in the normal course of business. (Dkt. No. 136 at 9-10 (quoting 45 C.F.R. § 164.506(c)(3)).) The court rejects this contention as well. Defendant provides no authority for her claim that a pharmaceutical company filling out PAs for the purpose of inclusion on formulary lists acts “in accordance with a prescription.” Again, this argument is factual and does not warrant dismissal.

² 45 C.F.R. § 165.501 was amended in January of 2013. *See* 78 FR 5695 (Jan. 25, 2013). None of the apparent changes have relevance here, and the substance of the prior version quoted in Defendant’s brief is identical to that quoted here.

2. 45 C.F.R. § 164.502(e)(1)

Defendant also contends that § 164.5-2(e)(1) expressly permitted the alleged disclosures. At the time of the activities in question, that section provided:

A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

45 C.F.R. § 164.502(e)(1)(i) (as published by 67 FR 53181-01, 2002 WL 1840541 (Aug. 14, 2002)).

“Business associate” was defined elsewhere in the regulations as “with respect to a covered entity, a person who:”

(i) On behalf of such covered entity or . . . performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, **billing, benefit management, practice management, and repricing;** or

(B) **Any other function or activity regulated by this subchapter**

45 C.F.R. § 103 (as published by 65 FR 82462-01, 2000 WL 1875566 (Dec.28, 2000)) (emphasis in

Defendant’s brief). According to Defendant, the above language expressly authorized her alleged

disclosure to Warner Chilcott. In her own words, Defendant asserts that Warner Chilcott was:

a business associate of [Defendant] as it performed, or assisted [her] in the performance of “claims processing or administration . . . billing, benefit management, practice management, repricing,” and “any other function or activity” of [Defendant’s] “regulated by Subchapter C,” which included those activities of hers regulated under Subchapter C: her treatment of patients, her prescribing of drugs; and her conduct of health care operations.

(Dkt. No. 136 at 9-10 (brackets omitted).) She further contends that she did not need to obtain

“satisfactory assurance” from Warner Chilcott that it would “appropriately safeguard the

information” because Warner Chilcott was a “health care provider.” (*Id.*) In this manner Defendant again asserts another factual argument not suitable for resolution on a motion to dismiss.

C. COUNT 1 – Failure to State Offense Due to Absence of Mens Rea Allegations

Defendant contends the indictment fails to state an offense because it does not allege facts showing she “knowingly” disclosed information in violation of HIPPA. Specifically, she contends the government at most “allege[s] that [Defendant] asked Sales Representative # 1 for help with prior authorizations, and that ‘in the course of helping,’ Sales Representative # 1 had such access.” (Dkt. No. 136 at 14.) She cites no authority justifying dismissal in support of this argument.

An indictment is sufficient if it apprises the defendant of the elements of the offenses charged, and enables the defendant to plead an acquittal or conviction in bar of future prosecutions for the same offense. *Hamling v. United States*, 418 U.S. 87, 117 (1974). The indictment here adequately apprises Defendant of the *mens rea* element. Specifically, it charges her with “knowingly and without authorization” disclosing protected information to a pharmaceutical sales representative. (Dkt. No. 89 ¶ 12.) In support of that charge, the indictment alleges she disclosed information for the purpose of having the representative complete PA forms and later told investigators that no such disclosure took place and twice directed her medical assistant to repeat that misrepresentation. (*Id.* at ¶¶ 9-14, 17.) It further alleges she told the assistant, “in sum and substance, that there is a HIPPA law and there would be hefty fines for them both if people found out they shared medical records.” (*Id.* ¶ 17.) This is sufficient to allege a knowing violation.

D. COUNT 2 – Failure to State Offense Regarding “Corruptly Persuaded”

Defendant contends count 2 fails to state an offense because the factual allegations do not establish that she “corruptly persuaded” her medical assistant to “hinder, delay, or prevent the communication of information relating to the commission of a federal offense” to federal investigators as required by 18 U.S.C. § 1512. (Dkt. No. 136 at 19.) These arguments are factual in

nature and involve either challenges to the facts alleged or inferences not reasonably drawn from the allegations as a whole. To the extent Defendant suggests she is alleged to have “persuaded Medical Assistant # 1 to exercise her Fifth Amendment right by refraining from revealing information to the . . . investigators,” she clearly misreads the complaint. No fair reading of the relevant allegations involves an invocation of privilege, whatever legal import such invocation may have had. To the extent Defendant suggests the government has not alleged facts establishing she “corruptly” persuaded her employee to misinform investigators, she makes the same error. In short, the indictment fairly apprises her of the charge against her and alleges more than sufficient facts in support of the charge.

E. ALL COUNTS – Alleged Misconduct before the Grand Jury

Finally, Defendant argues the entire superseding indictment must be dismissed because of the government’s misconduct before the grand jury. (Dkt. No. 136 at 31-36.) The purported misconduct involves the presentation to the grand jury of “swaths of testimony” concerning charges present in the original indictment but omitted in the superseding indictment. (*Id.* at 32.) According to Defendant, none of the testimony in question (filed under seal on the instant docket) “related in the slightest to the current allegations” made against her in the superseding indictment. (*Id.*) She further contends that the “prosecutor used the [same] testimony . . . to provide false legal instructions, testimony, and argument to the grand jury.” She goes on to suggest the same conduct was intended to convey “bad character” arguments to the grand jury in violation of ethical standards published by the ABA and case law from courts outside of the First Circuit. (*Id.* at 37.)

After reviewing the sealed materials in question, this court is not persuaded that introduction of the testimony at issue was made in bad faith, for the purpose of making propensity arguments, or in violation of ethical standards. As the government has amply conveyed in filings opposing both the instant and prior motions, the challenged testimony was relevant to and established context for

the remaining charges. Defendant has shown neither misconduct nor prejudice and her arguments on these grounds are therefore rejected.

IV. CONCLUSION

For the reasons above Defendant's Motion to Dismiss is DENIED in its entirety. (Dkt. No. 135.)

It is So Ordered.

/s/ Mark G. Mastroianni

MARK G. MASTROIANNI

United States District Judge