IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

UNITED STATES OF AMERICA and the STATE OF IOWA, ex rel. SUSAN THAYER, Qui Tam Plaintiff/Realtor, Plaintiff, vs. PLANNED PARENTHOOD OF THE HEARTLAND, INC. (f/k/a PLANNED PARENTHOOD OF GREATER IOWA, INC.), Defendant.	No. 4:11-cv-00129-JAJ-CFB **ORDER**

This case arises from a third amended complaint ("TAC") filed by Plaintiff Susan Thayer under the Federal and Iowa False Claims Acts ("FCA" and "IFCA"). Plaintiff is an ex-employee of Defendant Planned Parenthood of the Heartland, Inc. ("PPH"). The False Claims Act imposes significant penalties on those who submit false or fraudulent claims that result in the receipt of Government money. Plaintiff alleges that Defendant knowingly claimed and received money from Title XIX-Medicaid as a result of fraudulent schemes related to Defendant's activities as a provider of reproductive healthcare services.

This matter comes before the Court pursuant to Defendant's December 5, 2014, motion to dismiss the TAC under Federal Rule of Civil Procedure 12(b)(6). [Dkt. 66]. Plaintiff responded to this motion on April 2, 2015. [Dkt. 78]. Defendant filed its reply on May 6, 2015. [Dkt. 82]. In its motion to dismiss, Defendant argues that Plaintiff's complaint fails to state a claim because Plaintiff's allegations are based on alleged regulatory violations that cannot serve as bases for liability under the FCA, Plaintiff failed to identify regulations that prohibit PPH's alleged practices, and because the applicable regulations permit the alleged conduct.

I. BACKGROUND

Plaintiff Susan Thayer served as the center manager at several of Defendant Planned Parenthood of the Heartland's clinics between 1991 and December 2008.[1] Defendant PPH provides reproductive healthcare services to patients of all income levels. PPH receives federal

[1] During this timeframe, Defendant was known as Planned Parenthood of Greater Iowa, Inc., but merged with Planned Parenthood of Nebraska/Council Bluffs, Inc. in 2009, thereafter becoming PPH.

and state funding to provide services to low-income patients through Title XIX-Medicaid. Medicaid is "a joint state-federal program in which healthcare providers serve poor or disabled patients and submit claims for government reimbursement." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 2016 WL 3317565, at *5 (June 16, 2016). In order to participate in the Medicaid program, Defendant executed an "Iowa Medicaid Provider Agreement" with the State of Iowa. This agreement explained that it was an agreement "for participation in Title XIX of the Social Security Act," and noted that Defendant agreed to "comply with all applicable Federal and State laws, rules, and written policies to the Iowa Medicaid program, including . . . the rules of the Iowa Department of Human Services and written Department policies, including but not limited to policies contained in the Iowa Medicaid provider manual." Pl. Ex. 1-A [Dkt. 75-3].[2] As a participant in the Medicaid program, Defendant submitted claims to Medicaid for reimbursement for services and supplies, and has received such reimbursement through funds provided by both the United States and the State of Iowa. Plaintiff alleges that, with each submitted claim, Defendant expressly and impliedly certified compliance with all relevant laws and regulations, in part by virtue of the Iowa Medicaid Provider Agreement, in part by part in virtue of the language of the claim form, and in part by the mere submission of the claim form.

Plaintiff alleges that between early 2006 and December 2008 Defendant participated in three "schemes" in an attempt to obtain Medicaid payments it was not entitled to. Each of these schemes is alleged in a different count, but all are alleged to violate both the FCA and the IFCA under several provisions of those laws. Count I alleges that Defendant violated numerous laws and regulations in the process of seeking reimbursement for oral contraceptive pills ("OCPs") and birth control patches it prescribed and dispensed to patients. Plaintiff alleges these claims were fraudulent because the OCPs were either 1) not properly prescribed, 2) prescribed in medically unnecessary quantities, or 3) billed for in greater than the allowed amount. Count II alleges that Defendant violated state and federal law by seeking reimbursement for services performed related to abortions without revealing that the services were performed incident to abortions. Count III alleges that Defendant improperly insisted Medicaid-eligible clients pay a portion of the cost of

[2] The Provider Agreement is necessarily embraced by the complaint and its authenticity is not questioned by either party. The Court therefore may appropriately consider this document on a motion to dismiss without converting the motion into one for summary judgment. *See Miller v. Redwood Toxicology Laboratory, Inc.*, 688 F.3d 928, 931 n.3 (8th Cir. 2012) (courts may consider "exhibits attached to the complaint whose authenticity is unquestioned"); *infra* n.4.

their services without reducing the claim submitted for the service to reflect the patient's contribution.

The FCA allows a private party to bring a claim on behalf of the Government and allows the Government an opportunity to intervene. Plaintiff filed her original complaint on March 21, 2011, and her first amended complaint on August 29, 2011. [Dkt. 10]. Following the July 5, 2012 notice of nonintervention by both the United States and the State of Iowa, the Court ordered the case unsealed and served upon Defendant. [Dkt. 17, 18]. Plaintiff then filed a Second Amended Complaint on July 26, 2012. [Dkt. 20]. Defendant filed a motion to dismiss the Second Amended Complaint on October 29, 2012. [Dkt. 31]. The Court granted that motion on Rule 9(b) grounds on December 28, 2012, finding Plaintiff had failed to allege the necessary level of specificity. Plaintiff appealed and the Eighth Circuit remanded, finding that Plaintiff had included sufficient detail to withstand dismissal pursuant to Rule 9(b), particularly in light of Plaintiff's individualized knowledge as a former PPH employee. *U.S. ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 916–20 (8th Cir. 2014). The Eighth Circuit clarified that its "holding with respect to the Rule 9(b) issue, however, should not be read as in any way expressing a view on Planned Parenthood's Rule 12(b)(6) arguments," and instructed this Court to consider whether Plaintiff's remaining allegations survive Defendant's challenges to the Complaint, including that "the complaint should be dismissed because (1) [Plaintiff's] allegations are based on alleged regulatory violations that cannot serve as bases for liability under the FCA, (2) [Plaintiff] failed to identify regulations that prohibit Planned Parenthood's practices, or (3) the applicable regulations actually permit Planned Parenthood's conduct." *Id.* at 921.

II. APPLICABLE LAW

1. Motion to Dismiss for Failure to State a Claim under Rule 12(b)(6)

Defendant moves to dismiss the TAC for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). Federal Rule of Civil Procedure 8 requires that a complaint present "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Rule 12(b)(6) allows for dismissal for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). To survive a motion to dismiss, the complaint must be grounded in enough of a factual basis to move the claim beyond the realm of mere possibility by presenting a "claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "In deciding a motion to dismiss under Rule

12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences most favorably to the complainant." *U.S. ex rel. Raynor v. Nat'l Rural Utils.*, 690 F.3d 951, 955 (8th Cir. 2012). However, Plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (*citing Papasan v. Allain*, 478 U.S. 265, 286 (1986) (on a motion to dismiss, courts "are not bound to accept as true a legal conclusion couched as a factual allegation")).

2. False Claims Act

"Enacted in 1863, the False Claims Act 'was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War.'" *Universal Health Servs., Inc.*, 2016 WL 3317565, at *4 (June 16, 2016). Though Congress has amended the FCA multiple times, "its focus remains on those who present or directly induce the submission of false or fraudulent claims." *Id.* The FCA[3] protects "the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money." *In re Baycol Prods. Litig.*, 732 F.3d 869, 874 (8th Cir. 2013) (*quoting United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 795–96 (8th Cir. 2011) (internal quotation marks omitted)). Persons who are found liable under the FCA are subject to civil penalties and treble damages. 31 U.S.C. § 3729; *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 829 (8th Cir. 2013); *Universal Health Servs., Inc.*, 2016 WL 3317565, at *5 (June 16, 2016) (*quoting Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784 (2000) (describing penalties as "essentially punitive in nature")). Under the FCA's *qui tam* provisions, private individuals are permitted "to bring a civil action in the name of the United States against those who violate the [FCA]'s provisions." 31 U.S.C. § 3729. Should the Government decline to intervene in an FCA action, as is the case here, the third party can proceed independently and is eligible to receive some of the proceeds should the action prove successful. 31 U.S.C. § 3730(d).

The FCA imposes liability "on any person who 'knowingly presents . . . a false or fraudulent claim for payment' to the government, or who 'knowingly makes a false record or statement . . . to get a false or fraudulent claim paid or approved by the government.'" *Ketroser*, 729 F.3d at 829 (*quoting* 31 U.S.C. § 3729(a)(1)(A), (B) (2008)). "The FCA attaches liability, not

[3] "Because the FCA and the IFCA are nearly identical, case law interpreting the FCA also applies to the IFCA." *U.S. ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 916 (8th Cir. 2014) (*citing Eilbert v. Pelican* (*In re Eilbert*), 162 F.3d 523, 526 (8th Cir. 1998)).

to the underlying fraudulent activity, but to the claim for payment." *Id.* (*quoting Costner v. URS Consultants, Inc.*, 153 F.3d 667, 677 (8th Cir. 1998) (internal quotation marks omitted)). "A prima facie case under the [FCA] requires that (1) the defendant made a claim[4] against the United States; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *Raynor*, 690 F.3d at 955 (*quoting United States v. Basin Elec. Power Coop.*, 248 F.3d 781, 803 (8th Cir. 2001)).

Under § 3729 subparagraph (G), the FCA also imposes penalties on people who "knowingly make[or] use[] a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[] and improperly avoid[] or decrease[] an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(G). Claims brought under paragraph (G) for failure to transmit money owed to the Government are referred to as "reverse FCA claims." *See Vigil*, 639 F.3d at 801. To establish a reverse FCA claim, a plaintiff must show that the Government

> was owed a specific, legal obligation at the time that the alleged false record or statement was made . . . . The obligation cannot merely be a potential liability: instead, in order to be subject to the penalties of the False Claims Act, a defendant must have had a present duty to pay money or property that was created by a statute, regulation, contract, judgment, or acknowledgment of indebtedness. The duty, in other words, must have been an obligation in the nature of those that give rise to actions of debt and common law for money or things owed.

United States v. Q Int'l Courier, Inc., 131 F.3d 770, 772–73 (8th Cir. 1997); *see also Vigil*, 639 F.3d at 801–02.

Finally, a person may be liable under the FCA when he "conspires to commit a violation of subparagraph (A), (B), . . . or (G)." 31 U.S.C. § 3729(a)(1)(C). Under this section, "[w]here the conduct that the conspirators are alleged to have agreed upon involved the making of a false record or statement, it must be shown that the conspirators had the purpose of 'getting' the false record or statement to bring about the Government's payment of a false or fraudulent claim." *Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672–73 (2008) (citing version of § 3729 prior to its amendment in 2009).

[4] "Claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that . . . is presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2)(A)(i). The parties do not dispute that Defendant submitted claims seeking payment from the Government.

The FCA does not define "false" or "fraudulent." However, courts have analyzed the falsity of FCA claims under two main categories: factual and legal falsity. *See U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305–06 (3rd Cir. 2011). A claim is factually false when a provider files a claim for payment for services that were not performed or are incorrectly described. *See U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008) (*quoting Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)) ("In a run-of-the-mill 'factually false' case, proving falsehood is relatively straightforward: A realtor must generally show that the government payee has submitted 'an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.'"). In contrast, a claim is legally false when a claim certifies compliance with a particular law or regulation that constitutes a condition to governmental payment, despite the claimant not having complied with that regulation. *See Straus*, 274 F.3d at 697.

Courts have further broken down legal falsity into two sub-categories: express certification and implied certification. *See Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467–68 (6th Cir. 2011) (discussing express and implied certification); *Salina*, 543 F.3d at 1217–18. FCA actions based on an express certification theory rely on the allegedly false claim's explicit certification that it complies with a law, regulation, or standard. *Salina*, 543 F.3d at 1217 (*quoting Straus*, 274 F.3d at 698). According to the theory of implied certification, "when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim 'false or fraudulent' under § 3729(a)(1)(A)." *Universal Health Servs., Inc.*, 2016 WL 3317565, at *3 (June 16, 2016); *see also Straus*, 274 F.3d at 699 (implied certification FCA claims rely on "the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.").

The Supreme Court recently clarified the scope of the implied certification theory. In *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, the plaintiffs were parents of a teenager who had received mental health services at a clinic owned by the defendant. The young woman saw practitioners who were held out to be licensed mental health care providers. Plaintiffs' child was prescribed medication after being diagnosed with bipolar disorder. She thereafter suffered seizures, one of which resulted in her death. Plaintiffs brought an FCA claim against the facility

after discovering that practitioners at the facility were not licensed to provide mental health treatment under state law. 2016 WL 3317565, at *5–6 (June 16, 2016).

The Supreme Court held that the implied certification theory is a viable basis for liability under the FCA "when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading." *Id.* at *3 (June 16, 2016). The Court held that a violation may be actionable under the implied certification theory, "at least when two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those misrepresentations misleading half-truths." *Id.* at *9.

After holding that implied certification is a viable FCA theory in at least some circumstances, the Court went on to discuss the importance of the FCA's materiality requirement. To state a facially plausible FCA claim, a plaintiff "must plead facts raising more than a speculative possibility that [Defendant's] claims were *materially* false or fraudulent." *Ketroser*, 729 F.3d at 829 (*citing Raynor*, 690 F.3d at 956) (emphasis added). "Materially false claims" include only those claims alleging violations of conditions of payment which, had they been known by the Government, likely would have resulted in nonpayment. *See* 31 U.S.C. § 3729(b)(4) (defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"); *Universal Health Servs., Inc.*, 2016 WL 3317565, at *11–12 (June 16, 2016) (*quoting* 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)) (alteration in original) ("Under any understanding of the concept, materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation."); *Vigil*, 639 F.3d at 796 (*citing Straus*, 274 F.3d at 697) (FCA "does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions"). "The FCA may not properly be used to impose an onerous and costly burden on the healthcare system without plausible evidence that Medicare would consider [the relevant requirement] to be a material condition of payment." *Ketroser*, 729 F.3d at 832.

In determining whether a misrepresentation is "material," the Court looks beyond the mere language of the violated regulation underlying the alleged misrepresentation. The Supreme Court explained that,

> The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," *Allison Engine*, 553 U.S., at 672, or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

Universal Health Servs., Inc., 2016 WL 3317565, at *9 (June 16, 2016). While the express identification of a provision as a condition of payment is relevant to the materiality analysis, it is not dispositive. *Id.* The *Universal Health* Court repeatedly described this materiality analysis as "rigorous." *Id.* at *4, *10, *12 n.6.

Likewise, the FCA's scienter requirement is also "rigorous." *Id.* at *10. In addition to demonstrating that a claim is false and material, an FCA plaintiff must demonstrate that the defendant "knowingly" submitted the false claim. Under the FCA, a person acts knowingly when the person "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). A statement made "based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute. That is because the defendant in such a case could not have acted with knowledge that the FCA requires more before liability can attach." *U.S. ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010); *see also Ketroser*, 729 F.3d at 829, 831–32 ("Moreover, [defendant]'s reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA."). A "defendant does not act with the requisite deliberate ignorance or reckless disregard by 'tak[ing] advantage of a disputed legal question.'" *Hixson*, 613 F.3d 1186, 1190 (8th Cir. 2010) (alteration in original).

Applicable to all of Plaintiff's claims, the Iowa All Provider Manual articulates specific services that will not be paid for. It states, in relevant part:

> Payment will not be made for medical care and services:
> - That are medically unnecessary or unreasonable

- That fail to meet existing standards of professional practice, are currently professionally unacceptable, or are investigational or experimental in nature. [. . .]
- That are fraudulently claimed
- That represent abuse or overuse.

Iowa Medicaid Enterprise, All Provider Manual, Chapter I, P. 21 (March 1, 2008) (same language contained on P. 19 between July 1, 2005 and March 1, 2008) (hereinafter "All Provider Manual").[5] Plaintiff also cites several Iowa laws and regulations specific to individual claims, which are discussed further below.

Here, the Court applies the implied certification theory, including the FCA's scienter and materiality requirements, as articulated in *Universal Health*. The Court therefore looks to both the language of the regulations cited in the TAC—including the Manual provisions above—and their context to determine whether submission of a claim despite noncompliance with the condition

[5] Defendant, in its motion to dismiss, and Plaintiff, in her response to Defendant's motion to dismiss, rely on various attached documents. Plaintiff moved to strike Defendant's attachments pursuant to Federal Rule 12(f) on December 22, 2014. [Dkt. 68]. The Court denied that motion as procedurally improper and instructed Plaintiff to include any objections to the attachments in her reply to Defendant's motion to dismiss. [Dkt. 72 P. 4]. However, Plaintiff declined to follow that instruction and instead filed an independent "Objection to Evidence Submitted by Defendant in Defendant's Motion to Dismiss." [Dkt. 76].

When considering a motion to dismiss under Rule 12(b)(6), "[t]he Court may consider, in addition to the pleadings, materials 'embraced by the pleadings' and materials that are part of the public record." *In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 889 (8th Cir. 2002) (*quoting Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999)). Aside from relevant provisions of the Iowa Code, the United States Code, and the Code of Federal Regulations, the TAC necessarily embraces the following items:

1. Iowa Medicaid Enterprise, Department of Human Services, Family Planning Services Provider Manual
2. Iowa Medicaid Enterprise, Department of Human Services, All Providers Manual
3. Iowa Medicaid Enterprise, Department of Human Services, Prescribed Drugs Provider Manual
4. Medicaid Provider Agreement between PPH and the State of Iowa

Each of these documents contains regulations applicable to providers of healthcare services who seek Medicaid reimbursement and is publicly available. Much of the conduct Plaintiff claims underlies PPH's alleged false reporting schemes is prohibited not by statute, but by the above handbooks. Defendant does not dispute the authenticity of these manuals. Thus, these manuals are integral to the complaint and appropriately considered on a motion to dismiss. *I. Meyer Pincus & Associates, P.C. v. Oppenheimer & Co., Inc.*, 936 F.2d 759, 762 (2d Cir. 1991); *see also Silver v. H & R Block, Inc.*, 105 F.3d 394, 396 (8th Cir. 1997) (noting that consideration of external matters is appropriate on a motion to dismiss when they form the basis of the lawsuit and their content is not disputed).

Plaintiff alleges that PPH filed false claims with federal and state Title XIX Medicaid authorities (Iowa Medicaid Enterprise and/or Iowa Family Planning Network) between "early 2006" and December 31, 2008. Therefore, laws and regulations from a time period outside of this timeframe are irrelevant. *See Landgraf v. USI Film Products*, 511 U.S. 244, 265 (1994) (*quoting Kaiser Aluminum & Chem. Corp. v. Bonjorno*, 494 U.S. 827, 855 (1990) (Scalia, J., concurring) ("[T]he legal effect of conduct should ordinary be assessed under the law that existed when the conduct took place.") (internal quotation marks omitted); *Greene v. U.S.*, 376 U.S. 149, 621–22 (1964) ("The first rule of construction is that legislation must be considered as addressed to the future, not the past.") (citations and quotation marks omitted); IOWA CODE § 4.5 (A statute is presumed to be prospective in its operation unless expressly made retrospective). The Court considers the content of these Manuals as they existed between early 2006 and December 2008. Documents from outside of the relevant timeframe will not be considered at this stage of the proceeding.

constitutes a material misrepresentation. If an alleged FCA violation stems from a practice that is not prohibited by law or regulation, or from conduct which, though a violation, would not have impacted the Government's decision to reimburse the claim, the conduct cannot form the basis of an FCA claim. *See U.S. ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998) (citation omitted) ("[C]onclusory statements that [a] defendant's claims were false, without any indications of the claims' falsity, are insufficient to entitle [a plaintiff's] section 3729 claims to survive a motion to dismiss.").

III. ANALYSIS

The TAC alleges that, "[w]ith the submittal of each reimbursement claim and as a condition of reimbursement, Defendant Planned Parenthood of the Heartland expressly and implied certified and represented that it was in compliance with all applicable federal and state laws and regulations relating to Iowa Medicaid Enterprise and its reimbursement claim requirements." TAC ¶¶ 17, 20.[6] Plaintiff argues that this express and implied certification included compliance with "the Iowa All Provider Manual and Defendant [PPH]'s Medicaid Provider Agreement." TAC ¶ 33. Plaintiff also maintains that, pursuant to Iowa Administrative Code 441–79.3(249A), Defendant "impliedly certified and represented, as a condition of reimbursement, that it had maintained and would "maintain clinical and fiscal records necessary to fully disclose the extent of services, care, and supplies furnished to Medicaid members' and [was] further required to maintain '[c]linical records'" documenting the medical necessity of the services, that the services were consistent with a client's diagnosis, and that the services are consistent with professionally recognized standards of care. TAC ¶ 28 (*quoting* All Provider Manual, March 1, 2008).

Plaintiff alleges that Defendant operated three fraudulent "schemes" designed to increase its revenue by submitting fraudulent Medicaid reimbursement claims for prescriptions and services that it knew were not reimbursable under federal and state law. Plaintiff alleges that these frauds occurred from "early 2006 to December 2008." Pl. Resistance [Dkt. 78 P. 10 n.14] ("Thayer's

[6] The Supreme Court did not decide whether "all claims for payment implicitly represent that the billing party is legally entitled to payment." *Universal Health Servs., Inc.*, 2016 WL 3317565, at *8. However, in keeping with *Universal Health*, Defendant's certification of compliance with relevant law is not, alone, sufficient to state an actionable FCA claim. Plaintiff must individually establish the materiality of the alleged misrepresentations. To require this broad certification to create an actionable FCA claim would be "extraordinarily expansive." *Id.* at *13 ("For example, [i]f the Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations, then under this view [that the Government's option to decline payment is sufficient to make the misrepresentation actionable], failing to mention noncompliance with any of those requirements would always be material. The [FCA] does not adopt such an extraordinarily expansive view of liability.").

Complaint alleges that, motivated by its need to shore up declining revenues (Complaint, ¶ 57), PPH filed false claims with Iowa Medicaid between early 2006 and December 2008"); *Thayer*, 765 F.3d at 916. First, the TAC alleges that Defendant knowingly violated multiple laws and regulations in its prescription and distribution of OCPs and birth control patches, resulting in the submission of false claims and receipt of unwarranted reimbursement, as well as its failure to return money owed to the Government. Second, the TAC alleges that Defendant knowingly sought reimbursement for abortion-related services that are outside the scope of Medicaid coverage. Finally, the TAC alleges that Defendant failed to reduce its requests for reimbursement for the amount of donations Defendant solicited and received from patients.[7]

1. Fraudulent Billing of Title XIX-Medicaid for OCPs and Birth Control Patches

Count I alleges that Defendant fraudulently billed Title XIX-Medicaid for OCPs and birth control patches, in violation of 31 U.S.C. §§ 3729(a)(1)(A)-(C) and (G) and Iowa Code §§ 685.2(1)(a)-(c) and (g). Plaintiff alleges that Defendant's claims were false or fraudulent because they were:

i. dispensed by Defendant Planned Parenthood of the Heartland to clients without a valid patient-practitioner relationship, without or prior to a physician's order, or without or prior to the order of any other authorized practitioner;
ii. dispensed by Defendant Planned Parenthood of the Heartland to clients at levels not medically reasonable or necessary and/or in amounts constituting 'abuse or overuse' and/or in amounts not consistent with professionally recognized standards of care and practice;
iii. dispensed by Defendant Planned Parenthood of the Heartland to clients without any comprehensive examination by an authorized doctor or practitioner having been performed;
iv. in many cases, never delivered to the intended client; and
v. billed by Defendant Planned Parenthood of the Heartland at much higher than the allowed rate.

TAC ¶ 47a. The parties dispute whether this alleged conduct precluded Medicaid reimbursement. The Court addresses each of the above allegations in turn.

[7] The Court's ability to address the requirement that an allegedly false claim make "specific representations about the goods or services provided " is frustrated by the fact that Plaintiff neither attaches an example of a false claim or discusses specific language or codes that were allegedly false when used. However, construing the facts in the light most favorable to Plaintiff, Plaintiff has alleged that Defendant made specific representations, even though Plaintiff has failed to cite which codes were allegedly inappropriately used.

A. Valid Practitioner-Patient Relationship

Plaintiff first claims that Defendant's requests for reimbursement for OCPs and birth control patches were false *ab initio* because these contraceptives were not prescribed pursuant to a "valid practitioner-patient relationship." [Dkt. 78-1 P. 10]. Plaintiff does not explain what constitutes a "valid patient-practitioner relationship," but, as support for the requirement that one must exist, the TAC cites Iowa Code § 155A.27, Iowa Code § 147.107(7), Iowa Administrative Code 441-79.3(249A), and the Medicaid Provider Manual. TAC ¶ 28, 31. The Court first examines Plaintiff's cited laws and regulations to determine if a "valid patient-practitioner relationship" is required. *Cox*, 29 F. Supp. 2d at 1026 (citation omitted); *Ketroser*, 729 F.3d at 831–32.

The TAC claims that Iowa Code § 155A.27 requires that "each prescription drug order issued or dispensed in this state must be based on a valid patient-practitioner relationship." TAC ¶ 31. Iowa Code § 155A.27 states that, "[t]o be valid, each prescription drug order issued or dispensed in this state must be based on a valid patient-practitioner relationship, and" meet certain other requirements. However, Plaintiff fails to acknowledge that this language did not exist at Iowa Code § 155A.27 until 2009. IOWA CODE § 155A.27 (2008); 2009 Ia. Legis. Serv. Ch. 69 (H.F. 381) (WEST). During the relevant timeframe—early 2006 to December 2008—Iowa Code § 155A.27 contained no such requirement. Laws are generally applied prospectively unless it is indicated that the law is intended to apply retroactively. *See Greene v. U.S.*, 376 U.S. 149, 621–22 (1964) ("The first rule of construction is that legislation must be considered as addressed to the future, not the past.") (citations and quotation marks omitted); IOWA CODE § 4.5 ("A statute is presumed to be prospective in its operation unless expressly made retrospective"). A "valid prescription drug order" was not conditioned on the existence of a "valid patient-practitioner relationship" pursuant to § 155A.27 during the relevant timeframe. Therefore, even assuming there was no "valid patient-practitioner relationship" at the time Defendant prescribed and dispensed OCPs, that lack of relationship did not violate Iowa Code 155A.27. Similarly, Iowa Code 147.107(7) as it existed in the relevant timeframe makes no mention of a "valid patient-practitioner relationship" and therefore does not create this requirement.

Plaintiff next cites Iowa Administrative Code 441-79.3(249A). Iowa Administrative Code 441-79.3(249A) is entitled "Maintenance of records by providers of service" and requires that providers "maintain complete and legible records as required in this rule." IOWA ADMIN. CODE § 441.79.3(249A) (2006). The failure to maintain these records may result in denial of requested

payment. *Id.* However, nowhere is a service provider required to maintain a record of a "valid patient-practitioner relationship." Furthermore, Plaintiff's claims are not based on any failure to maintain records.

Finally, though Plaintiff cites Iowa Administrative Code 657–8.20 in her resistance, the TAC contains no such citation. Iowa Administrative Code Chapter 657 is entitled "Pharmacy Board," and Iowa Administrative Code 657–8 is entitled "Universal Practice Standards." Iowa Administrative Code 657–8.20, entitled "Valid prescriber/patient relationship" (not "valid patient-practitioner relationship") states that

> Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, the order loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the order and any remaining refills,

subject to the pharmacist's prudent judgment. *Id.* (language the same 2006–2008). Nowhere does this code section state that a "valid patient-practitioner relationship" is required for the issuance of a prescription. Furthermore, to the extent that this code section is relevant to establishing that a patient-*prescriber* relationship is necessary to fill a prescription, the implication of this provision is that the existence of that relationship depends on a prescriber's being "available to treat the patient or oversee the patient's use of a prescription drug." Nowhere does Plaintiff allege that Defendant became unavailable to treat its patients or oversee their prescriptions. The law's allowance of a pharmacist to refuse to fill a prescription at their prudent discretion when aware that a prescriber-patient relationship no longer exists, such that the prescriber is "no longer available" to oversee the patient's prescription, does not establish a "valid patient-practitioner relationship" as a material condition to Medicaid reimbursement of a prescribed drug.

Plaintiff makes no attempt to further clarify what this amorphous "valid patient-practitioner relationship" standard means, and has failed to cite a provision requiring a "valid patient-practitioner relationship" prior to the issuance of contraceptive pills or devices. To the extent Plaintiff means to argue that contraceptives were prescribed by practitioners who were not licensed or qualified to prescribe, making the prescriptions illegal, that argument is addressed below. However, the allegation that Defendant dispensed contraception absent a "valid patient-practitioner relationship" cannot serve as the basis for Plaintiff's FCA claim. *See Cox*, 29 F. Supp. 2d at 1026 (basis for FCA claim insufficient when failure to perform conduct underlying fraud not

required by law or regulation); *Ketroser*, 729 F.3d at 831–32 (explaining that "[t]he absence of a clear requirement that a written report must underlie or support each claim for surgical pathology services means that Relators pleaded a claim of regulatory noncompliance, not a plausible claim that [Defendant] submitted false or fraudulent claims for Medicare payment" and noting that the "FCA does not create liability "without plausible evidence that Medicare would consider [conduct] to be a material condition of payment."). Furthermore, even if a valid patient-practitioner relationship were required, Plaintiff pleaded no facts indicating that this requirement would be "material." *Universal Health Servs., Inc.*, 2016 WL 3317565, at *11–13 (June 16, 2016) (discussing materiality). This conduct therefore cannot form the basis of Plaintiff's Count I.

B. Dispensing Contraception Without or Prior to a Physician or Authorized Practitioner's Order

Plaintiff also argues that prescriptions may not be dispensed without or prior to a physician's order, and that, because Defendant prescribed birth control to patients and those prescriptions were not reviewed until after the prescription was issued, the prescriptions were illegal and precluded Medicaid reimbursement for prescribed OCPs. Plaintiff cites the All Provider Manual for the proposition that "[p]rescriptions will be reimbursed only if written or approved by the primary physician." TAC ¶ 32 (*citing* All Provider Manual P. 26). On first blush, this language appears relevant to Plaintiff's claims. However, even minimal further examination reveals that this language is taken out of context.

The All Provider Manual's mandate that a prescription will only be reimbursed when written or approved by "the primary physician" applies in a narrow and specific category of cases. This language exists under a subpart detailing a "Lock-In Program," which provides that "[m]embers who use Medicaid services or items at a frequency or in an amount that is considered overuse of services may be restricted ("locked in)" [sic] to receive services from designated providers." All Provider Manual, Chapter I, P. 26 (March 1, 2008); Chap. II, P. 5 (2006 through February 2008). If a member is determined to have used services inappropriately, lock-in will follow and "is applied to an individual member." *Id.* Members in the lock-in program get their choice of designated providers, and, "[i]f the member does not designate a provider, the Department assigns a provider from those seen by the member in the past." *Id.* Medicaid providers are then urged to check the system to determine whether a member is in the lock-in program. Only after explaining this program does the manual state that, "[w]hen one of the designated providers is a physician, that doctor is the primary care physician and is responsible for providing or directing

the member's medical care and making necessary referrals to other providers. Prescriptions will be reimbursed only if written or approved by the primary physician." All Provider Manual, Chapter I, P. 26 (March 1, 2008); Chap. II, P. 5 (2006 through February 2008). The "Lock-In Program" section of the manual concludes with a brief discussion of particular forms in relationship to lock-in participants.

This is a far cry from the characterization Plaintiff makes in her TAC, where Plaintiff states:

> [A]s is relevant to Plaintiff-Relator Thayer's Complaint and the dispensing of oral contraceptive pills and birth control patches by Defendant Planned Parenthood of the Heartland, Defendant Planned Parenthood of the Heartland knew that the Iowa All Provider Manual provided that "[p]rescriptions will be reimbursed only if written or approved by the primary physician."

TAC ¶ 32 (*citing* Iowa All Provider Manual, Chap. I, p. 26); *see also* TAC ¶ 63 ("In these cases, OCPs were dispensed to Title XIX-Medicaid eligible clients without the approval of a primary physician as required by State of Iowa law and regulations.). Plaintiff dramatically overstates the import of this cited language. The All Provider Manual contains no general provision warning that "prescriptions will be reimbursed only if written or approved by the primary physician" outside the context of the lock-in program.

Plaintiff also cites Iowa Code § 147.107(7) as support for the requirement that each prescription drug order may not be dispensed without a physician's order. TAC ¶ 31. Iowa Code § 147.107(1) is entitled "Drug dispensing, supplying, and prescribing—limitations." It explains that a person "other than a pharmacist, physician, dentist, podiatric physician, or veterinarian . . . shall not dispense prescription drugs or controlled substances." Section 147.107(7) then gives family planning clinics the power to dispense birth control drugs and devices "upon the order of a physician," "notwithstanding" subsection 1. IOWA CODE § 147.107(7) (2007) ("Notwithstanding subsection 1, a family planning clinic may dispense birth control drugs and devices upon the order of a physician. Subsections 2 and 3 do not apply to a family planning clinic under this subsection."). Section 147.107(7) remained the same throughout the relevant timeframe.

Plaintiff argues that § 147.107(7)'s permission to dispense birth control "upon the order" of a "physician" requires that the OCPs be dispensed only *after* an order by a physician. The TAC alleges that pills were prescribed "before a qualified practitioner had approved the order" or "without contemporaneous approval of a qualified practitioner." TAC ¶ 90. Plaintiff also argues that "physician" here means only a physician, not any other medical professional who may be

authorized to prescribe drugs. Pl. Brief P. 11 [Dkt. 78]. Therefore, Plaintiff contends that Defendant's alleged practice of having an Advanced Registered Nurse Practitioner sign off on OCPs after the pills had already been distributed to patients violates Iowa Code § 147.107(7).

Defendant argues that the law contemplates the issuance of prescription drugs pursuant to a "physician standing order." PPH Brief P. 11 [Dkt. 67], Reply Brief P. 7 [Dkt. 82]. "A Standing Order is a routine order of a physician giving the authority for the performance of certain prescribed acts." *Lindon v. Middletown Regional Hosp.*, 1995 WL 669931, at *4 n.4 (Ohio Ct. App. Nov. 13, 1995). Though this may be a reasonable interpretation of the law, it is unsupported by the factual allegations of the TAC. At this stage of the proceeding, the Court is obligated to accept the factual allegations of the Complaint as true. *Raynor*, 690 F.3d at 955. The Complaint alleges that clients were prescribed OCPs "without the prior approval of a doctor or any other qualified healthcare practitioner." TAC ¶ 50. The TAC alleges that

> upon instructions from management, . . . [OCPs] were dispensed to Title XIX-Medicaid eligible clients by unqualified clinic personnel and later, often days after the contraceptives such as oral contraceptive pills and birth control patches had been dispensed to such clients, the disbursement of contraceptives such as oral contraceptive pills and birth control patches was approved by a qualified practitioner.

TAC ¶¶ 54, 65 (noting that an Advanced Registered Nurse Practitioner would usually sign off on prescriptions). The TAC alleges that patients, at times, never saw any practitioner or participated in any examination or consultation with a qualified practitioner prior to receiving OCPs from non-medical staff, and that the OCPs were dispensed "*without* or prior to a physician's order." TAC ¶ 47(a)(i) (emphasis added). At this stage the Court cannot assume Defendant acted pursuant to a standing order, and must draw all reasonable inferences in favor of the Plaintiff. The Court therefore finds that the facts, as alleged, arguably violate the mandate that drugs be dispensed "upon the order of a physician." Plaintiff has alleged that Defendant's conduct violated a relevant regulation.

The Court must next determine whether misrepresentation regarding compliance with this regulation would be material to the government's decision to reimburse the claim. *See Universal Health Servs., Inc.*, 2016 WL 3317565, at *11–13 (June 16, 2016); *Vigil*, 639 F.3d at 796 (*citing Straus*, 274 F.3d at 697 (the FCA "does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions")). Though the provision Plaintiff cited itself contains no explicit reference to its impact on the ability to have a

drug reimbursed by Medicaid, the Court finds that misrepresentation of compliance with licensing or prescribing requirements would likely impact the Government's decision to pay the claim. *Universal Health Servs., Inc.*, 2016 WL 3317565, at *3 (June 16, 2016) (mental health licensure requirements "so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations"). The condition in question—that a drug be prescribed by a qualified practitioner—represents the heart of prescription medication regulation. The requirement that a prescriber be licensed and qualified to prescribe drugs is central to the regulation of prescription drugs. Though explicit description of a requirement as material is unnecessary and not dispositive, it is not irrelevant. *Id.* at *9. Furthermore, multiple Medicaid-related materials support the notion that failure to meet this requirement would be material to the Government's payment decision. The Iowa Medicaid Prescribed Drugs Provider Manual explains that "[p]ayment is made for drugs prescribed by a legally qualified practitioner [including a "physician" or an "advanced registered nurse practitioner"] within the limits prescribed by law and in policies established by the department." Iowa Medicaid Enterprise, Prescribed Drugs Provider Manual, Chapter III, P. 10 (July 1, 2007) (same language present throughout relevant timeframe) (hereinafter "Prescribed Drugs Manual"); *cf* IOWA ADMIN. CODE § 441–72.2(1) ("All [outpatient] drugs are covered only if prescribed by a legally qualified practitioner (physician . . . or advanced registered nurse practitioner)."). A person reviewing a claim for reimbursement for a prescribed drug "would probably . . . conclude that the clinic had complied with core" requirements for prescribing drugs, including that the prescriber possessed the appropriate qualifications. *Universal Health Servs., Inc.*, 2016 WL 3317565, at *9 (June 16, 2016).

The Court finds the circumstances of the requirement sufficient to suggest that Medicaid would not reimburse the cost of a drug that was prescribed absent authority from a legitimate prescribing source. Therefore, the Court finds that "a misleading half-truth" regarding this requirement would be material to the Government's decision to pay the claim. *Id.* at *9 (misleading half-truths are actionable omissions that can form the basis for an FCA claim). The Court also finds that the facts as alleged are sufficient to plead the requisite scienter at this stage of the proceeding. Because the Court accepts the Complaint's factual allegations as true and draws all reasonable inferences from those allegations, the Court finds that Plaintiff has pleaded an FCA claim for prescription of OCPs "without or prior to the authorization of a physician or . . . any

other authorized practitioner." TAC ¶ 47(a)(1). The existence of any actions pursuant to a standing order is a question of fact inappropriate for resolution on a motion to dismiss.

C. Automatic C-Mail Refill Program

Plaintiff alleges that Defendant's C-Mail program resulted in the filling of prescriptions for OCPs in medically unnecessary quantities or in quantities that represent abuse or overuse. "At the heart of Count I of Thayer's Complaint is the allegation that PPH, through its C-Mail scheme, 'created a medically unnecessary surplus of at least 120.96 doses [of OCPs] for each client each year, resulting in overcharges to the [Iowa Medicaid] of at least $113.70 per client." [Dkt. 78 P. 20] (*citing* TAC ¶¶ 68, 85). The Iowa Medicaid Enterprise Prescribed Drugs Provider Manual in effect between early 2006 and 2008 explains that prescriptions may be refilled, "generally, after ¾ of the previous supply is used." Prescribed Drugs Manual P. 7 (2006–2008) (using "75%" rather than "3/4" as of July 28, 2008). The parties agree that the law in effect at the time allowed for a prescription to be refilled when 75% of the "previous supply" of the prescription "is used."

Plaintiff alleges that Defendant mailed clients "a three-menstrual-cycle supply of OCPs (i.e., a total of eighty-four [84] OCPs, since each OCP package provides for twenty-eight days per menstrual cycle) every sixty-three (63) days for at least one full year." TAC ¶¶ 67, 68. Plaintiff alleges that this practice violates the All Provider Manual's prohibition on payment for medical care and services that are "medically unnecessary or unreasonable" or "represent abuse or overuse." All Provider Manual, Chap. I, P. 19 (2006) (language found on P. 20 as of March 1, 2008). In this circumstance, the Court finds that the "medical necessity" analysis may constitute a cognizable FCA claim. *Contrast infra* Part III.1.E; *see Straus*, 84 F. Supp. 2d at 431; *U.S. v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1155 (W.D. Mo. 2000). The issue here is not whether a recommended course of treatment meets a subjective "standard of care," or whether the prescription of OCPs itself was a "medically necessary" course of treatment. Instead, the question is whether the prescription of a daily pill in a fashion that creates an exponentially growing surplus of those daily pills constitutes a "medically unnecessary" quantity. Furthermore, Plaintiff's claim does not rest solely on the argument that these quantities are "medically unnecessary." It also relies on violation of the 75% rule, which is articulated in the Prescribed Drugs Manual. Given the factual allegations and regulations underlying this conduct, Plaintiff has therefore pleaded sufficient facts to demonstrate that this claim is "false" for purposes of the FCA. Furthermore, the Court assumes, without deciding, that failure to disclose this practice constitutes a material misrepresentation.

In addition to pleading sufficient allegations that a claim is false, Plaintiff must also plead sufficient allegations that the Defendant acted with knowledge that the claim was false. The FCA's knowledge requirement is "rigorous." *Universal Health Servs., Inc.*, 2016 WL 3317565, at *10. Knowledge can come in the form of "actual knowledge of the information," "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). "[I]nnocent mistakes and negligence are not offenses under the Act." *U.S. ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 767 (8th Cir. 2002) (*quoting U.S. ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464–65 (9th Cir. 1999) (internal quotation marks omitted)).The TAC alleges that "[d]espite its knowledge that due to its own prior early automatic refills a client had a growing surplus of OCPs, such that including these excess OCPs the client had not yet reached the required percentage to permit a refill, [PPH] continued to refill client OCPs and bill them to Medicaid." TAC ¶ 68. The Court finds that this factual allegation may be sufficient to withstand a motion to dismiss on the issue of whether Defendant knowingly violated the prescription refill guidelines.

However, a claim is not made with "knowledge" under the FCA when the allegedly false statement made in the claim is "based on a reasonable interpretation of a statute . . . if there is no authoritative contrary interpretation of that statute." *Hixson*, 613 F.3d at 1190; *U.S. v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) (citations omitted) ("[C]laims are not 'false' under the FCA when reasonable persons can disagree whether the service was properly billed to the Government."). Defendant argues that distributing prescription refills every 63 days adhered to the allowed practice of refilling a prescription "after 75% of the previous supply is used," or at the very least constituted a reasonable interpretation of the law.

Here, the Court finds that Defendant's interpretation of the law is reasonable. Though no proof of specific intent to defraud the Government is required, "innocent mistakes and negligence are not offenses under the Act." *Quirk*, 278 F.3d at 767 (*quoting Oliver*, 195 F.3d at 464–65) (internal quotation marks omitted); *Raynor*, 690 F.3d at 957 (*quoting Hixson*, 613 F.3d at 1191) ("As we have said, to prevail here the relators must show that there is no reasonable interpretation of the law that would make the allegedly false statement true."). Defendant's alleged practice of refilling OCPs every 63 days does not rise above a negligent interpretation of the law. The 75% rule is not without ambiguity, both in its use of the phrase "previous supply" and its mandate that refills are measured based on the time at which the previous supply is "used." *See, e.g., Ketroser,*

729 F.3d at 830–32 (defendant's interpretation of code requirement of "report" not to require, for each use of code, a "written report" found to be reasonable when other codes specified a written report requirement and relators submitted no specific evidence that Medicare or pay agents responsible for approving claims expect a written report or that Medicare considered a written report a material condition of payment); *Minnesota Ass'n of Nurse Anesthetists v. Alina Health Sys. Corp.*, 276 F.3d 1032, 1052–53 (8th Cir. 2002) (interpreting requirement that anesthesiologist be "continuously involved" in a case, finding, on review of a motion for summary judgment, no reasonable ambiguity as to that term); *Hixson*, 613 F.3d at 1190–91 (finding reasonable interpretation of unanswered legal question regarding whether provider must seek reimbursement from third party in medical malpractice cases involving Medicaid-eligible clients insufficient to support an FCA claim when Defendant's interpretation "perhaps even the most reasonable" interpretation of existing law); *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288–89 (D.C. Cir. 2015) (legal questions of term's ambiguity and reasonableness of defendant's interpretation answered in the affirmative with respect to term "regular commissions," when that term is susceptible to multiple meanings and defendant's interpretation not "objectively unreasonable" even if term is best understood another way, but addressing factual issue of whether defendant had been warned off of their chosen interpretation).

An interpretation of the 75% rule's "use" requirement to mean anticipated use assuming appropriate compliance with the drug's use instructions—rather than requiring the prescriber to actually verify the number of pills used—is certainly reasonable. Furthermore, the Court cannot say that utilization of the automatic refill procedure alleged (sending a new pack of OCPs every 63 days) rises to the level of "deliberate ignorance" or "reckless disregard" of the law's requirements. 31 U.S.C. § 3729(b). The regulation falls short of a "clear requirement" regarding the timeline of OCP disbursements. "[T]he absence of a clear requirement," paired with Defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." *Ketroser*, 729 F.3d at 831–32. This is particularly true in light of the fact that the law intentionally allows for a surplus. Lawmakers have demonstrated their understanding of their ability and willingness to reduce the allowable surplus by later modifying the rule to allow for prescription refills only when "85% of the prior supply" is used. *See* Prescribed Drugs Manual, Ch. III, P. 7 (July 28, 2008) (changing general refill requirement to 85% or previous supply used for certain medications). Mere existence

of a surplus does not render a prescription "medically unnecessary." If that were the case, the prohibition on payment for "medically unnecessary" services could prohibit all claims for drugs in excess of a certain amount—even those amounts within the allowable range of surplus—from being reimbursed. This is not the contemplated effect of the law. Though Defendant was arguably negligent in its application of the 75% rule, negligence does not give rise to an FCA claim. *Quirk*, 278 F.3d at 767 (citation omitted); *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996) ("The statutory phrase 'known to be false' does not mean 'scientifically untrue;' it means 'a lie.' Likewise, the statutory phrase 'known to be false' does not mean incorrect as a matter of proper accounting methods, it means a lie.").

Because the terms "previous supply" and "used" are both somewhat ambiguous, and Defendant's interpretation of those terms was not unreasonable, the Court finds that Defendant therefore could not have acted with the requisite scienter with respect to this regulation. This conduct therefore does not form the basis for an actionable FCA claim.

D. Billing for Medications Never Delivered

Plaintiff next argues that Defendant requested Medicaid reimbursement for medications that were never delivered to their original recipients. Plaintiff alleges that Defendant thereafter failed to reduce its Medicaid reimbursement requests when delivered medication was returned unused, in violation of 31 U.S.C. § 3729(a)(1)(G). TAC ¶ 92. To establish a reverse FCA claim under § 3729(a)(1)(G), a plaintiff must show that the Government "was owed a specific, legal obligation at the time that the alleged false record or statement was made." *Q Int'l Courier, Inc.*, 131 F.3d at 772–73; *see also Vigil*, 639 F.3d at 801–02. An "obligation" is defined by the act as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3).

The TAC alleges that Defendant "instructed its staff to return OCPs that had been returned to Defendant [PPH] in the mail to its inventory of OCPs and to reship such returned OCPs to future clients, thereby effectively billing Iowa Medicaid Enterprise and/or Iowa family Planning Network at least twice for the same OCPs." TAC ¶ 75. Defendant argues that this claim fails for two reasons. First, Defendant argues that the return and reuse of drugs is specifically allowed under Iowa law. Second, Defendant argues that Plaintiff has failed to cite any law or regulation requiring Defendant to reduce its Medicaid claims when it recycles OCPs. The Court notes, as a preliminary matter,

that the TAC cites no specific regulation in support of its assertion that Defendant was obligated to credit Medicaid for returned and recycled OCPs. However, Plaintiff's resistance cites the Prescribed Drugs Manual for the proposition that any previous charges for intact unit-dose packages of distributed drugs must be credited to Medicaid when those intact units are returned. Pl. Resistance P. 18 [Dkt. 78] (*citing* Prescribed Drugs Manual P. 41). Again, upon further examination of the context of this Manual regulation, it is inapplicable to the case at hand.

The language Plaintiff cites exists within a list of items under the heading "Basis of Payment for Drugs and Supplies." Prescribed Drugs Manual, Chapter III, P. 38 (January 1, 2006). Item number four in that list is labeled "Reimbursement for Unit-Dose Packaging." *Id.* at 41. That section explains that "[a]dditional reimbursement of one cent per dose, added to the ingredient cost, is available for dispensing oral solids to nursing home patients in unit-dose packages prepared by the pharmacist." *Id.* After providing some instructions on how to claim this additional reimbursement, the Prescriber Manual goes on to state:

> **Note:** Payment may be made only for unit-dose packaged drugs that are consumed by the patient. Any previous charges for intact unit-dose packages returned to the pharmacy must be credited to the Medicaid program. Such credits may be shown on future billings. If no additional billings are to be made, direct a refund in the drug cost component.

Id. Though the parties do not discuss this development, further language was added to this section effective July 1, 2007. At that time, the manual was edited to add the following:

> In accordance with state and federal law, proper crediting to Iowa Medicaid is required for the return of unused medications upon therapy discontinuation or a member's discharge, transfer, or death.
>
> Both the long-term-care pharmacy and the nursing facility are subject to financial review by the state to ensure that medications are being returned to the pharmacy when permitted by state and federal law and proper credits are applied to the Iowa Medicaid program.

Id. at 47–48 (July 1, 2007 and after).

Once again, the language Plaintiff relies on to create a general obligation operates in a specific context: additional one-cent reimbursements of unit-dose packages of oral solids dispensed to nursing home patients. That context is clearly inapplicable here. Plaintiff's liberal reading of this note does not establish a "specific, legal obligation at the time that the alleged false record or statement was made" that is more than . . . "merely [] a potential liability," or that PPH "had a present duty to pay money or property that was created by a statute, regulation, contract,

judgment, or acknowledgment of indebtedness." *Q Int'l Courier, Inc.*, 131 F.3d at 772–73; *see also Vigil*, 639 F.3d at 801–02. Plaintiff cites no regulation explaining if and how Defendant is obligated to credit Medicaid for recycled OCPs.

Plaintiff's complaint fails to state a reverse FCA claim for Defendant's failure to credit Medicaid or return money to Medicaid for recycled OCPs. This practice is not prohibited by law. *See* IOWA ADMIN. CODE § 657-6.15 ("For the protection of the public health and safety, prescription drugs and devices, controlled substances, and items of personal contact nature may be returned to the pharmacy for reuse or resale only as herein provided . . . .") (same language throughout relevant timeframe). Plaintiff attempts to draw a distinction based on the fact that these pills were "never delivered" rather than "recycled." Pl. Resistance P. 18 n.26 [Dkt. 78]. The Court fails to see how that distinction is meaningful here, given the TAC's allegation that medications not delivered to clients by reason of the client's change in address were "returned by the U.S. Postal Service" to Defendant, and Defendant "instructed its staff to return OCPs that had been returned . . . to its inventory of OCPs and to reship such returned OCPs to future clients, thereby effectively billing" Medicaid twice. TAC ¶¶ 73, 75. Though Plaintiff does not call this practice "recycling," that is what the TAC describes. Furthermore, Plaintiff cites no Medicaid provisions or regulations imposing this obligation on Defendant. *See U.S. ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 437–38 (3rd Cir. 2004) (discussing whether regulations require adjustment for returned medications and noting that "if there is no requirement to adjust the claim, there is no liability for a failure to do so."). This conduct therefore cannot form the basis of Count I.

E. Failure to Provide a Comprehensive Examination Prior to Prescribing OCPs

Finally, Plaintiff argues that Defendant failed to adhere to the All Provider Manual's requirement that conduct meet existing standards of professional practice. The TAC focuses on an early 2006 change in policy from requiring a "comprehensive" examination to a "Hormonal Option Without Pelvic Exam" or "HOPE" examination, during which "the client, without the involvement of a physician or other qualified practitioner, and with the assistance of a non-medical employee of Defendant [PPH], completed a simple form and had her blood pressure checked. TAC ¶¶ 50, 51. Plaintiff's challenge is not to any claim for reimbursement for the examination performed. Plaintiff does not allege that claims for HOPE examinations should not be reimbursed, or that claims for HOPE examinations were claims for services "so worthless" as to essentially constitute a factually false claim. *See Chesbrough*, 655 F.3d at 468 (*citing Straus*, 274 F.3d at 702–03) ("A

test known to be of 'no medical value,' that is billed to the government would constitute a claim for 'worthless services,' because the test is 'so deficient that for all practical purposes it is the equivalent of no performance at all.'"); *U.S. ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1221 (E.D. Cali. 2002). Plaintiff also fails to cite any regulation requiring a "comprehensive" examination, and instead relies solely on the argument that the failure to perform one was a failure to adhere to professional standards as required by the All Provider Manual.

The parties dispute whether the FCA is an appropriate vehicle to challenge the quality of care provided to patients whose services are reimbursed by Medicaid. The All Provider Manual states that Medicaid will not pay for services that "fail to meet existing standards of professional practice [or] are currently professionally unacceptable." All Provider Manual, Chapter I, PP. 20–21 (March 1, 2008). The question is whether the FCA is an appropriate vehicle to enforce quality of care standards.

> The FCA was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment—and to construe the impliedly false certification theory in an expansive fashion would improperly burden the Act's reach. Moreover, a limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the Federal Government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that the regulation of health and safety matters is primarily, and historically, a matter of local concern.

Straus, 274 F.3d at 699–700; *See also Universal Health Servs., Inc.*, 2016 WL 3317565, at *12 (June 16, 2016) ("We emphasize, however, that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations."). Furthermore, "permitting qui tam plaintiffs to assert that [a] defendant['s] quality of care failed to meet medical standards would promote federalization of medical malpractice, as the Federal Government or the qui tam realtor would replace the aggrieved patient as plaintiff." *Straus*, 274 F.3d at 700 (internal citations omitted). "[C]ourts are not the best forum to resolve medical issues concerning levels of care. State, local, or private medical agencies, boards, and societies are better suited to monitor quality of care issues." *Id.*

The Court declines to extend the implied certification theory so far as to allow an FCA *qui tam* Plaintiff to challenge a medical practice as subjective, personal, and individualized as the type of examination a woman should undergo before obtaining contraception. Though the All Provider

Manual explains that payment will not be made for services that do not comply with professional standards, that language is not dispositive. *Universal Health Servs., Inc.*, 2016 WL 3317565, at *12 (June 16, 2016). Furthermore, even if it were, Plaintiff has alleged nothing more than the fact that some doctors disagreed about whether "appropriate standards of medical practice" required a comprehensive examination. *See* TAC ¶ 83. Demonstrating that some doctors disagreed with this chosen course of treatment does not establish that providing a "comprehensive examination"—whatever that may entail—was the standard practice in the field, the absence of which rendered the underlying service "professionally unacceptable." *See United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1153 (W.D. Mo. 2000) ("At the other end of the spectrum the Court would not find a cognizable claim under the FCA if the United States simply disagreed with a reasonable medical or care treatment administered by the Defendant. In that case, the Defendant would obviously be innocent of fraud in its billing practices, but rather it would simply be at odds with the entity that pays the treatment it provided.").

The Court finds the policy considerations articulated in *Straus* regarding the need to limit the reach of the implied certification theory persuasive. The FCA is not the appropriate avenue of redress when a plaintiff merely disagrees with the course of medical treatment administered by a defendant. *See Universal Health Servs., Inc.*, 2016 WL 3317565, at *12 (June 16, 2016) (noting that Plaintiff's claims "center[ed] on allegations of fraud, not medical malpractice."); *NHC Healthcare Corp.*, 115 F. Supp. 2d at 1153; *U.S. ex rel. Phillips v. Permian Residential Care Center*, 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005) (discussing *NHC Healthcare* and *Straus* and stating that the FCA "should not be used to call into question a health care provider's judgment regarding a specific course of treatment"). The purpose of the FCA is to combat fraud, not to impose quality of care standards in the medical field. Though "Congress intended to allow the government to choose among a variety of remedies, both statutory and administrative, to combat fraud," the FCA was not intended to be a mechanism for the Government or a third party to conduct a federal medical malpractice trial regarding qualitative healthcare standards. *Onnen*, 688 F.3d at 415. The TAC alleges, at best, some disagreement among medical professionals over the necessity of a physical examination prior to a woman's receipt of contraception. Use of the theory of implied

certification to impose treble damages on a healthcare provider for choosing a course of care that other doctors may not extends the FCA beyond its intended reach.[8]

With respect to Count I, Plaintiff has pleaded sufficient facts to support an FCA claim under 31 U.S.C. §§ 3729(a)(1)(A)-(C) and Iowa Code §§ 685.2(1)(a)-(c) concerning Plaintiff's allegation that Defendant distributed OCPs without prescription from an authorized practitioner. Plaintiff's Count I survives on this basis. To the extent that Plaintiff's Count I is based on failure to provide a certain quality of care, Defendant's reasonable interpretation of the 75% refill requirement, the absence of "valid patient-practitioner relationship," or Defendant's failure to credit Medicaid for recycled prescriptions, Count I is dismissed. Finally, any reverse FCA claim alleged in Count I pursuant to 31 U.S.C. §§ 3729(a)(1)(G) and/or Iowa Code §§ 685.2(1)(G) is dismissed.

2. Fraudulent or False Billing for Abortion Related Services

Plaintiff's Count II claims that Defendant participated in a fraudulent scheme with respect to billing for services performed in connection with abortions, in violation of 31 U.S.C. §§ 3729(a)(1)(A)-(C) and (G) and Iowa Code §§ 685.2(1)(a)-(c) and (g). Plaintiff alleges that, despite a prohibition on receipt of Medicaid funding for abortion-related services, Defendant sought reimbursement for "services and supplies rendered as part of the provision of abortions, including, without limitation, office visits, ultrasounds, Rh factor tests, lab work, general counseling, and abortion aftercare, all of which were, when provided, integral to and/or related to" a patient's abortion. TAC ¶ 98. Plaintiff claims Defendant improperly "unbundled" or "fragmented" abortion-related services, meaning Defendant failed to disclose a service's connection to an abortion on the service's claim form in order to receive payment for the services. TAC ¶¶ 102–03.

[8] Furthermore, even if the FCA were an appropriate vehicle to enforce the requirement that Defendant perform a comprehensive examination, Plaintiff has failed to articulate any basis on which the Court could find that failure to disclose the absence of a comprehensive exam would constitute a "material" misrepresentation or that Defendant "knowingly" failed to meet professional standards as that term is described in the FCA. Plaintiff has failed to plead any facts—aside from the language of the handbook—that failure to perform a comprehensive examination would be material to the Government's decision to pay for prescriptions resulting from that visit. *Universal Health Servs., Inc.*, 2016 WL 3317565, at *12 (June 16, 2016). The closest Plaintiff comes to pleading knowledge is to say that "on several occasions, physicians in the Iowa area, upon becoming aware of Defendant [PPH's] practice of dispensing birth control without a comprehensive examination of the client, objected to Defendant [PPH] or to others about this practice and stated that this practice was below the medical standard of care." TAC ¶ 83. *See Urquilla-Diaz v. Kaplan University*, 780 F.3d 1039, 1059 (11th Cir. 2015) (realtor's warning defendant that policies might not comport with federal law insufficient to establish actual knowledge).

Abortions are only covered by Federal and State Medicaid programs in limited circumstances. *See* TAC ¶¶ 15, 97 (citing laws prohibiting use of federal funds for abortion procedures, including the "Hyde Amendment"). Plaintiff makes no claims related to any billing for abortion procedures themselves, and instead focus on procedures and services related to abortions. The Iowa Administrative Code explains that "[p]ayment for an abortion or related service is made" when certain forms are completed and attached to the claim for services. IOWA ADMIN. CODE § 441.78.1(17). The Iowa Department of Human Services Medicaid Handbook explains when certain abortion-related procedures are covered and when they are not. "Services that would have been performed on a pregnant woman regardless of whether she was seeking an abortion" are covered by Medicaid. Department of Human Services, Medicaid Provider Manual, Physician Services, P. 70 (language unchanged between 2001 and 2012). Services covered as those that would be performed on any pregnant woman include "pregnancy tests," "tests to identify sexually transmitted diseases," and "laboratory tests routinely performed on a pregnant patient, such as pap smear and urinalysis, hemoglobin, hematocrit, rubella titre, hepatitis B, and blood typing." *Id.*

In contrast, some "abortion related services are not allowed when the abortion is not covered by federal or state criteria." *Id.* at 71. Noncovered services include "physician and surgical charges for performing the abortion," including "the usual, uncomplicated pre- and post-operative care and visits related to performing the abortion;" "hospital or clinic charges associated with the abortion," including "supplies and drugs necessary to perform the abortion, and charges associated with routine, uncomplicated pre- and post-operative visits by the patient;" "physician charges for administering the anesthesia necessary" to perform an abortion; "drug charges for medication usually provided to or prescribed for the patient who undergoes an uncomplicated abortion," "charges for other laboratory tests" performed prior to the abortion "to determine the anesthetic or surgical risk of the patient (e.g., CBC, electrolytes, blood typing)," and "uterine ultrasounds performed immediately following an abortion." *Id.*

The TAC alleges that Defendant billed Medicaid for "office visits, ultrasounds, Rh factor tests, lab work, general counseling, and abortion aftercare, all of which were, when provided, integral to and/or related to" a patient's abortion, in violation of the above (and other) regulations. TAC ¶ 98. The TAC alleges that Defendant billed for these services while purposefully failing to disclose their relationship to abortion procedures in an attempt to procure reimbursement. TAC ¶¶

101, 103. In response, Defendant points out that several services are listed as both "covered" and "noncovered," including "blood typing." Because regulations are ambiguous with respect to certain services, Defendant argues that Plaintiff fails to sufficiently allege a violation of the pertinent regulations.

The Court must assume the TAC's factual allegations are true and draw all reasonable inferences in the light most favorable to the Complaint. *Raynor*, 690 F.3d at 955. Drawing all reasonable inferences in the light most favorable to the Complaint, the TAC alleges that Defendant knowingly submitted forms masking services' relationship to abortions, including claims for regular office visits, general counseling, and lab testing, all of which constitute noncovered services. Furthermore, the regulations repeatedly note the limited application of Medicaid funding to abortions and abortion-related procedures, such that the Court finds that a misrepresentation with regard to a service's relationship to an abortion would be material. The degree to which the alleged services were covered as services that would have been performed regardless of patient's ultimate decision to obtain an abortion is a question of fact not appropriate for resolution on a motion to dismiss. Taking the allegations of the complaint as true, Plaintiff has pleaded sufficient facts to establish a claim to relief that is plausible on its face under 31 U.S.C. §§ 3729(a)(1)(A), (B), and/or (C) and Iowa Code §§ 685.2(1)(a)-(b) and/or (c). *Twombly*, 550 U.S. at 570.

Plaintiff also alleges a reverse FCA claim based on this alleged conduct. To establish a reverse FCA claim, a plaintiff must show that the Defendant "had a present duty to pay money or property that was created by a statute, regulation, contract, judgment, or acknowledgment of indebtedness." *Q Int'l Courier, Inc.*, 131 F.3d at 772–73; *see also Vigil*, 639 F.3d at 801–02. An obligation to pay money may to the Government may arise "from the retention of any overpayment." 31 U.S.C. § 3729(b)(3). Plaintiff has pleaded a reverse FCA claim regarding Defendant's failure to repay money allegedly improperly paid by the Government. Because Plaintiff has stated a claim to relief that is plausible on its face, Defendant's motion to dismiss Plaintiff's Count II is denied.

3. Solicitation of Donations and Failure to Reduce Reimbursement Requests

Finally, Plaintiff's Count III alleges that Defendant "collected what it characterized as 'voluntary donations' for Title XIX-Medicaid services" and then failed to reduce the amount of reimbursement claimed to account for the amount of those donations. TAC ¶ 47(c). The TAC includes several specific factual allegations about how Defendant allegedly "insisted" that

Medicaid-eligible clients pay a percentage of the cost of their services. TAC ¶ 111. The Complaint also alleges that Defendant "should have" reported these payments, "either in full payment for such services or as offsets or reductions of the amount of the bill for such services as were rendered to such Title XIX-Medicaid eligible clients." TAC ¶ 114.

However, the Complaint is devoid of even a single reference to a statute or regulation related to receipt of money characterized as donations by clinics serving Medicaid-eligible clients, let alone any regulation mandating reduction of Medicaid reimbursement claims for money received from clients and used for "purposes unrelated to the provisions of Title XIX-Medicaid services." TAC ¶ 115. Plaintiff's Resistance cites 42 C.F.R. § 447.15 as support for the proposition that providers must accept Medicaid reimbursement as payment in full for a service provided. That requirement is not at odds with the allegations of the TAC, which asserts that money received from clients was used for "purposes unrelated to the provision" of the service being covered by Medicaid. Therefore, even had the Complaint cited 42 C.F.R § 447.15, this regulation establishes no legal violation as a result of Defendant's alleged conduct. A factual allegation of wrongdoing, unsupported by citation to any legal authority, is insufficient to state a claim. *Cox*, 29 F. Supp. 2d at 1026 (citation omitted) ("[C]onclusory statements that [a] defendant's claims were false, without any indications of the claims' falsity, are insufficient to entitle [a plaintiff's] section 3729 claims to survive a motion to dismiss.") (*citing In re Syntex*, 95 F.3d 922, 926 (9th Cir. 1996)); *Ketroser*, 729 F.3d at 831–32. Plaintiff has failed to articulate a basis for Count III. Count III is therefore dismissed.

III. CONCLUSION

Plaintiff's Count I states a FCA claim pursuant to Rule 12(b)(6) with respect to the allegations that Defendant issued prescriptions without or prior to authorization by a licensed practitioner. Plaintiff's Count II states a claim upon which relief may be granted under Rule 12(b)(6). Plaintiff's Count III fails to state a cognizable claim and is dismissed with prejudice.

Upon the foregoing,

IT IS ORDERED that Defendant's motion to dismiss is **GRANTED** in part and **DENIED** in part.

DATED this 21st day of June, 2016.

JOHN A. JARVEY, Chief Judge
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF IOWA