No. 20-

IN THE

Supreme Court of the United States

ROLLINSNELSON LTC CORP., VICKI ROLLINS, AND WILLIAM NELSON,

Petitioners,

v.

UNITED STATES OF AMERICA EX REL. JANE WINTER, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This case turns on whether a Medicare reimbursement claim for inpatient hospital care can be alleged "false" under the False Claims Act ("FCA") based solely on a *post hoc* review of medical records that disagrees with the admitting physician's medical opinion. At issue here are the clinical judgments of several physicians, each expressing the view that inpatient hospital care was reasonable and necessary for a particular Medicare beneficiary. Medicare's regulations directed those physicians to apply indeterminate and purposefully vague standards governing whether care was reimbursable. Indeterminate standards give providers the flexibility they need to supply covered healthcare to beneficiaries who present with an infinite array of ailments. By their nature, though, indeterminate standards are also subject to differing opinions and medical judgments, which are impossible in most circumstances to prove *objectively* false.

Unfortunately, the lower courts have become irreconcilably split as to whether the FCA's falsity element requires an objective falsehood, and therefore whether a difference of opinion over medical judgments is actionable. The decision below wrongly rejected the objective falsehood requirement, deepening and worsening the split. Healthcare professionals and Medicare providers deserve a unified national standard for falsity under the FCA.

Thus, the question presented is: Whether the False Claims Act requires pleading and proof of an objectively false statement.

PARTIES TO THE PROCEEDING

The following list identifies all parties appearing here and in the United States Court of Appeals for the Ninth Circuit. *See* Supreme Court Rule 14.1(b). The petitioners here, and appellees below, are defendants RollinsNelson LTC Corp., Vicki Rollins, and William Nelson. The respondent here, and appellant below, is the United States of America *ex rel.* Jane Winter, a *qui tam* relator. The government has declined to intervene in this False Claims Act case under 31 U.S.C. § 3730(b)(2).

The additional defendants named in the district court, but who are not party to this petition, are Gardens Regional Hospital and Medical Center, Inc., S&W Health Management Services, Inc., Beryl Weiner, Prode Pascual, Rafaelito Victoria, Arnold Ling, Cynthia Miller-Dobalian, Edgardo Binoya, Namiko Nerio, and Manuel Sacapano.

CORPORATE DISCLOSURE STATEMENT

Petitioner RollinsNelson LTC Corp. states under Supreme Court Rule 29.6 that it has no corporate parent and that no publicly held company owns ten percent or more of its stock.

RELATED PROCEEDINGS

- *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, No. CV 14-08850-JFW, U.S. District Court for the Central District of California. Judgement date Dec. 29, 2017.

- *Winter v. Gardens Reg'l Hosp. & Med. Ctr.*, No. 18-55020, U.S. Court of Appeals for the Ninth Circuit. Judgment entered Mar. 23, 2020.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners RollinsNelson LTC Corp., Vicki Rollins, and William Nelson respectfully petition this Court for a writ of certiorari to review the decision of the United States Court of Appeal for the Ninth Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals is published as *Winter v. Gardens Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1113 (9th Cir. 2020), and is reprinted at Pet. App. 1a. The order of the court of appeals denying rehearing and rehearing *en banc* is reprinted at Pet. App. 52a. The district court's unpublished opinion dismissing respondent's complaint is available on Westlaw at *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, No. CV 14-08850-JFW (Ex), 2017 WL 8793222, at *1 (C.D. Cal. Dec. 29, 2017), and is reprinted at Pet. App. 28a.

JURISDICTIONAL STATEMENT

The United States Court of Appeals for the Ninth Circuit entered its opinion and judgment on March 23, 2020. Petitioner filed a petition for rehearing and for rehearing *en banc* on April 6, 2020, which the court of appeals denied on July 15, 2020. On March 19, 2020, this Court ordered that "the deadline to file any petition for a writ of certiorari due on or after the date of this order is extended to 150 days from the date of the lower court judgment, order denying discretionary review, or order denying a timely petition for rehearing." (Order of Mar. 19, 2020.) This Court has jurisdiction under 28 U.S.C. § 1254(1).

RELEVANT STATUTES AND REGULATIONS

The relevant provisions of 31 U.S.C. § 3729(a)(1), 42 U.S.C. § 1395y, and 42 C.F.R. § 412.3(d) are reprinted at Pet. App. 54a-55a, 60a-127a, and 128a-130a respectively.

STATEMENT OF THE CASE

A. The Parties

Petitioners owned fifty percent of the hospital management company that oversaw operations at Gardens Regional Hospital and Medical Center, Inc., otherwise known as Tri-City Regional Medical Center ("Tri-City"). Pet. App. 9a. Tri-City, now bankrupt, is a non-profit, acute care hospital with inpatient and outpatient services. Pet. App. 30a. The other defendants named in the district court, who are not petitioners here, are the other owners of the hospital management company and several attending physicians with admitting privileges at Tri-City. *Id.*

Respondent Jane Winter is a registered nurse who began working in the Tri-City emergency room on August 11, 2014. Her employment was terminated on November 6, 2014. Respondent filed her False Claims Act lawsuit under seal on November 14, 2014 in the United States District Court for the Central District of California, invoking the statute's *qui tam* provisions, 31 U.S.C. § 3730(b), which allow private plaintiffs to sue on behalf of the government under certain circumstances and to keep a share of the proceeds if successful. Pet. App. 36a. After conducting a "thorough investigation" of the allegations in the sealed complaint, the government declined to intervene on March 16, 2017. Pet. App. 37a.

B. Respondent's False Claims Act Theory

The FCA's remedies, which include treble damages and per-violation civil penalties, are "essentially punitive in nature." *Universal Health Servs.*, 136 S. Ct. at 1996 (citation omitted). Those steep remedies attach to any person who knowingly presents or causes to be presented a false claim for payment or anyone who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false claim. 31 U.S.C. §§ 3729(a)(1)(A)-(B). The FCA also provides for conspiracy liability. 31 U.S.C. § 3729(a)(1)(C). Respondent alleged all of those theories here.

Respondent's allegations are about Medicare's reimbursement requirement for inpatient hospital treatment. Medicare generally reimburses inpatient care at higher amounts than outpatient care. The operative pleading (Respondent's Second Amended Complaint) alleges that Petitioners submitted false claims, or caused them to be submitted, by certifying the medical necessity of inpatient hospital admissions at Tri-City. Respondent identified approximately 65 such claims. Pet. App. 10a. There is no allegation that Petitioners or Tri-City failed to actually deliver inpatient care. Respondent argues only that the treatment was not reimbursable. *Id.*

The applicable statutory scheme requires that inpatient admissions be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A). Regulations further provide that inpatient treatment "is generally appropriate for payment under Medicare Part A when the *admitting*

physician expects the patient to require hospital care that crosses two midnights," or if other circumstances requiring inpatient care are "supported by the medical record." 42 C.F.R. § 412.3(d)(1), (3) (emphasis added); Pet. App. 60a and 128a-130a.

This regulatory requirement is sometimes called the "two-midnight rule." *See* Pet. App. 35a. To guide the admitting physician in developing his or her "expectation" in relation to the two-midnight rule, the regulation provides this, and only this:

> The expectation of the physician should be based on such *complex medical factors* as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

42 C.F.R. § 412.3(d)(1)(i) (emphasis added). Importantly, these regulations do *not* require the physician to amass a medical record that *proves* the patient will require care spanning two midnights. It is enough for the physician to develop an expectation based on complex medical factors documented in the patient's record. Put simply, the framework asks for an informed clinical opinion, not a certification of objective fact.

Respondent alleged that Tri-City physicians certified the necessity of all the relevant inpatient admissions, whereas her own after-the-fact review of patient records yielded a different conclusion. (Pet. App. 31a.)

Respondent's review allegedly concluded that each admission was medically unnecessary, resulting in false claims to Medicare under an "implied false certification" theory. Pet. App. 40a. But she made that determination *not* by independently applying her understanding of "complex medical factors" or the two-midnight rule. *Id.*

Instead, Respondent "observed that Defendants . . . admitted or caused to be admitted a significant number of patients from skilled nursing facilities owned by [Respondents] that did not meet inpatient hospital admission criteria, as objectively determined with the applicable InterQual criteria—criteria that CMS uses when auditing or inspecting hospitals." (Respondent's Second Amended Complaint ¶ 56 (emphasis added).)[1] The "InterQual Criteria" are published by a third party, McKesson Health Solutions, LLC, and are not promulgated or formally adopted by any Medicare authority. Pet. App. 31a. Nevertheless, Respondent asserts that claims for payment are false if the underlying hospital admission diverges from the InterQual criteria, as she applied them during her review of the cold files. Pet. App. 32a.

C. The District Court's Dismissal

Petitioners and other defendants moved to dismiss on the grounds that (a) Respondent had not alleged an objectively false claim for payment and (b) the allegedly false certifications were not material to the government's payment decision as a matter of law. Pet. App. 41a. The district court granted the motions in their entirety. *Id.*

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1. CMS refers to the Centers for Medicare and Medicaid Services, the subdivision of the Department of Health and Human Services that administers Medicare. Pet. App. 6a.

First, as the district court accurately acknowledged, Respondent's "contention that the medical provider's certifications were false is based on her own after-the-fact review of Tri-City's admission records." *Id.* The district court applied the Ninth Circuit's holding in *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1477-78 (9th Cir. 1996), to this contention and found Respondent's allegations insufficient. Like many courts before it, the district court read *Hagood* to require a plaintiff to allege "that a defendant knowingly made an *objectively false* representation to the Government that caused the Government to remit payment." Pet. App. 42a.[2] Respondent's allegations, however, identified at most a "difference of opinion." *Id.* The mere "fact that [Respondent] reached a different conclusion on the issue of medical necessity does not render the provider's certification false." *Id.* Instead, the district court concluded that Respondent's allegations were "based on

2. District courts in the Ninth Circuit, and even the Ninth Circuit itself, had routinely interpreted *Hagood* as requiring an objectively false statement for FCA liability to attach. *See, e.g.*, *United States ex rel. Berg v. Honeywell Int'l, Inc.*, 740 F. App'x 535, 537 (9th Cir. 2018), *cert. denied* 139 S. Ct. 1456 (2019). (affirming summary judgment in defendant's favor because "[t]he scope of Honeywell's statements and the qualifications upon them were sufficiently clear, so that the statements—so qualified—were *not objectively false* or fraudulent.") (emphasis added); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1032-33 (D. Nev. 2006) ("[P]laintiff must demonstrate that an objective gap exists between what the Defendant represented and what the Defendant would have stated had the Defendant told the truth"); *United States ex rel. Englund v. Los Angeles County*, No. CIV. S-04-282 LKKJFM, 2006 WL 3097941, at *10 (E.D. Cal. Oct. 31, 2006) ("It is well established in this Circuit and elsewhere that imprecise statements or differences in interpretation growing out of a disputed legal question are not false under the FCA.").

subjective medical opinions that cannot be proven to be objectively false." *Id.*

Respondent's reliance on the InterQual criteria could not satisfy the objective falsehood requirement either. The district court explained that the private InterQual criteria are not Medicare's interpretation of the ultimate payment standard. Rather, they purport to be a "collection of data" that "represent a consensus of medical opinions." *Id.* Respondent's reliance on such a collection of third-party medical opinions, even if they proved to disagree with Tri-City's admission decisions, could "not demonstrate that the providers' certifications that the admissions and relevant services were medically necessary were objectively false." *Id.* Put differently, InterQual's compendium of opinions, even if in Respondent's favor, still established only a difference of opinion, not any objectively false statement.

Second, the district court applied this Court's holding in *Universal Health Services., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016), and found the allegedly false certifications immaterial as a matter of law.

The district court therefore dismissed Respondent's FCA allegations, including her claim that Respondents conspired to violate the FCA, without leave to amend. Pet. App. 44a. Although Respondent's claim for retaliation under 31 U.S.C. § 3730(h) survived the motion, Respondent voluntarily dismissed that claim to enable her appeal to the Ninth Circuit. Pet. App. 12a n.6.

D. The Ninth Circuit's Reversal

The court of appeals held that the FCA does not require a plaintiff to plead an objective falsehood and that

implied certifications of medical necessity are material because they are a condition of payment. Pet. App. 19a.

First, the court of appeals held that "the FCA imposes liability for all 'false or fraudulent claims'—it does not distinguish between 'objective' and 'subjective' falsity or carve out an exception for clinical judgments and opinions." Pet. App. 15a. Remarkably, the court of appeals failed even to mention its *Hagood* decision, which the district court correctly cited as requiring an objective falsehood.[3] *Hagood* had since 1996 directed the many lower courts of the Ninth Circuit that reasonable disputes about the application of indeterminate legal standards are not "false" in the sense intended by the FCA, even if the defendant's application is later seen as reaching the wrong result. *Hagood*, 81 F.3d at 1477; *Berg*, 740 F. App'x at 537. The court of appeals departed from that established rule without a direct explanation.

The court of appeals also acknowledged the obvious concerns about rampant liability for honestly held medical judgments, and struggled to meet those concerns by pivoting to other elements. Any concerns about open-ended liability attaching to the difficult application of indeterminate hospital admission standards should be addressed using the materiality and scienter elements under *Universal Health Services*, 136 S. Ct. at 2001, not by distinguishing between objectively false certifications and mere differences in medical judgments, the court of appeals held. Pet. App. 15a.

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3. Petitioners raised this irregularity in their petition for rehearing *en banc*, but the court of appeals declined to amend its opinion. Pet. App. 53a.

In other words, an alleged disagreement with a doctor's clinical judgment to admit a Medicare beneficiary for inpatient care satisfies the FCA's falsity element, and leaves the parties to litigate scienter and materiality. Thus, Respondent had stated an FCA claim by her allegation that Tri-City's admissions failed to satisfy the admission criteria *as applied by Respondent*, an ER nurse, despite the physicians' judgments to the contrary. Pet. App. 21a.

The court of appeals also expressly joined the Third and Tenth Circuits in "rejecting the 'bright-line rule that a doctor's clinical judgment cannot be 'false'" in the sense intended by the FCA. Pet. App. 17a (citing *United States ex rel. Druding v. Care Alternatives*, 952 F.3d at 89, 100 (3d Cir. 2020) and *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730, 742 (10th Cir. 2018)). In doing so, the court of appeals questioned the Eleventh Circuit's holding that "'a claim that certifies that a patient is terminally ill . . . cannot be "false"—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood,'" but suggested that the Eleventh Circuit rule may not ultimately be inconsistent with its holding. Pet. App. 17a (quoting *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1296-97 (11th Cir. 2019).[4]

Second, although not relevant to this Petition, the court of appeals also held that "a false certification of medical necessity can be material." Pet. App. 24a. Petitioner sought rehearing and rehearing *en banc*, which the court of appeals denied. Pet. App. 53a.

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4. As explained in further detail below, the court of appeals' attempt to harmonize its reversal with the Eleventh Circuit's *AseraCare* holding is not persuasive.

REASONS FOR GRANTING THE PETITION

The decision below joined the wrong side of a deepening circuit split. The Eleventh Circuit recently affirmed that the FCA's falsity element requires an objectively false statement, following the Fourth and Seventh Circuits. Shortly after the Eleventh Circuit ruled, the Third Circuit rejected the objective falsehood requirement on facts indistinguishable from that Eleventh Circuit case, expressly acknowledging that it was creating a split of authority. The Tenth Circuit appears to agree with the Third Circuit, but the Fifth and Sixth Circuits have articulated holdings so unclear that they are cited by both sides of the split.

The decision below exacerbates this confusion by joining the Third Circuit in rejecting the objective falsehood requirement—despite Ninth Circuit precedent that has been cited for decades as *supporting* the objective falsehood requirement. Still more confusing, the court of appeals tried unconvincingly to harmonize its holding with the Eleventh Circuit's affirmation of the objective falsehood requirement, muddying the waters by suggesting there is no circuit split after all. Only this Court's intervention can reconcile this morass of conflicting standards.

This dispute also presents the right vessel for resolving the split. Respondent's FCA theory depends on an alleged difference of opinion: Tri-City's physicians versus Respondent and her *post hoc* application of the medical opinions memorialized in the InterQual criteria. The resolution of the split is therefore key to correct resolution of this case, and a reversal of the decision below

would dispose of Respondent's FCA allegations entirely. More broadly, the question presented is exceptionally important, and it merits immediate review, without awaiting yet another circuit court to further destabilize the law without any hope of resolving the irreconcilable positions of the courts of appeals already on record. Medicare payment rules, even the purposefully vague ones, apply nationally, and the FCA's punitive remedies weigh heavily on practitioners and providers. A uniform, national answer to whether the FCA penalizes differences in medical judgment is sorely needed.

The question presented here is also closely related to the pending Petition for a Writ of Certiorari filed in *Care Alternatives v. United States ex rel. Druding*, No. 20-371. The Third Circuit's holding in *Care Alternatives* is at the core of the circuit split identified in this Petition, and the *Care Alternatives* petition cites the Ninth Circuit's decision below as evidence that "the courts of appeal are in open disarray over when opinions, such as a physician's clinical judgment about life expectancy or the necessity of treatment, can be deemed 'false' under the FCA." *Care Alternatives* Pet. at 21. Accordingly, Petitioners respectfully submit that, to the extent the *Care Alternatives* petition is granted, this Petition be granted along with it to resolve the related questions together.

I. The Decision Below Deepens and Worsens a Recent Circuit Split.

A. The lower courts have become irreconcilably split as to whether the FCA's falsity element requires an objective falsehood, and therefore whether a difference of opinion over medical judgments is actionable. On the

correct side of the split is the Eleventh Circuit's *AseraCare* decision. 938 F.3d 1278 (11th Cir. 2019). In *AseraCare*, the government challenged a hospice facility's claims for Medicare reimbursement for end-of-life hospice care. The facility's medical professionals had determined in their judgment that particular patients were "terminally ill," which is the prerequisite for triggering Medicare coverage in that context. *Id.* at 1289. The government alleged that these certifications were false because they were made "on the basis of *erroneous clinical judgments* that those patients were terminally ill." *Id.* at 1281 (emphasis added). A battle of the experts ensued, in which the government's medical expert testified after reviewing the cold patient records that "in his opinion, the patients were not terminally ill." *Id.* at 1287.

Importantly, the Eleventh Circuit acknowledged that a physician's terminal illness diagnosis is, at root, a statement of his or her medical opinion, not an assertion of fact. *Id.* at 1296-97. Such a medical opinion "cannot be 'false'—and thus cannot trigger FCA liability—*if the underlying clinical judgment does not reflect an objective falsehood*." *Id.* (emphasis added). As a result, "a reasonable difference of opinion among physicians reviewing medical documentation *ex post* is not sufficient on its own to suggest that those judgments—or any claims based on them—are false under the FCA." *Id.* at 1297.

The Eleventh Circuit agrees with the Fourth and Seventh Circuits. The Fourth Circuit has long held the FCA's falsity element to require objective falsehood. *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008) ("To satisfy this first element of an FCA claim, the statement or conduct alleged

must represent an objective falsehood."). The Seventh Circuit also requires an objective falsehood and therefore rejects allegations that turn only on differences between the judgment of the *qui tam* relator and the defendant. *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011) ("A statement may be deemed 'false' for purposes of the False Claims Act only if the statement represents 'an objective falsehood.'") (citation omitted); *United States ex rel. Presser v. Acacia Mental Health Clinic*, LLC, 836 F.3d 770, 780 (7th Cir. 2016) ("Many potential relators could claim that 'in my experience, this is not the way things are done.' . . . Ms. Presser's *subjective evaluation*, standing alone, is not a sufficient basis for a fraud claim.") (emphasis added).

On the other side of the split is the Third Circuit's *Care Alternatives* holding, for which a petition for certiorari is pending. The *Care Alternatives* case presented the same facts as the Eleventh Circuit's *AseraCare* case, *i.e.*, a hospice facility whose doctors had diagnosed terminal illnesses and a battle of the experts as to whether those certifications were in error. 952 F.3d at 94. But the Third Circuit expressly rejected any requirement for "objective falsity." *Id.* at 96. Notably, the Third Circuit did *not* hold that a physician's terminal illness diagnosis constituted a statement of fact. Instead, it held that "medical opinions may be 'false' and an expert's testimony challenging a physician's medical opinion can be appropriate evidence for the jury to consider on the question of falsity." *Id.* at 98. Parting with the Eleventh Circuit (and with the Fourth and Seventh, albeit silently) the Third Circuit concluded that a "difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity." *Id.* at 100.

The Third Circuit cited the Tenth Circuit's holding in *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018), with approval. That case, like the decision below, addressed a medical opinion that services were "reasonable and necessary." The Tenth Circuit held that "a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." *Id.* at 743. Both the third Circuit and the decision below cited *Polukoff* as authority for rejecting the objective falsehood requirement.

The Fifth and Sixth Circuits have not taken clear positions on the objective falsehood requirement, adding to the confusion in the lower courts. For instance, although both the decision below and the Third Circuit cited *United States v. Paulus*, 894 F.3d 267, 275-76 (6th Cir. 2018)), as rejecting the objective falsehood requirement, the Sixth Circuit actually held that "certain good-faith medical diagnoses by a doctor cannot be false," citing the district court's order from the *AseraCare* case. *See Paulus*, 894 F.3d at 275 (citing *United States v. AseraCare, Inc.*, 176 F. Supp. 3d 1282 (N.D. Ala. 2016)). And in a published order affirmed by the Sixth Circuit, a district court ruled that, "[a]t a minimum, the FCA requires proof of an objective falsehood. Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." *United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) (emphasis added) (citing *Hagood*, 81 F.3d at 1477-78), *aff'd*, 302 F.3d 637 (6th Cir. 2002).

Similarly, the Fifth Circuit's most relevant precedent appears to straddle the divide between the *AseraCare* and

Care Alternatives holdings. In *United States ex rel. Riley v. St. Luke's Episcopal Hospital*, 355 F.3d 370, 376 (5th Cir. 2004), the Fifth Circuit "agree[d] in principle" that "expressions of opinion or scientific judgments about which reasonable minds may differ cannot be 'false,'" under the FCA. *Id.* But, the Fifth Circuit went on to hold that certifications of "medical necessity" *can be false* if they are "a lie," but not if they are "an error," a holding that would appear to conflate falsity with scienter. The Fifth Circuit's position is so unclear that the decision below in this case cited *Riley* as supporting the Third Circuit's side of the split, Pet. App. 17a, whereas the Third Circuit itself actually chastised its district court for relying on *Riley*, *see Care Alternatives*, 952 F.3d at 94 (characterizing the Fifth Circuit standard as "not previously embraced or established by this Court").

This confusion pervades the Ninth Circuit's precedent, too. Right up until it issued the decision below, the Ninth Circuit also required allegations of objective falsity. In *Hagood*, a contracting case, the plaintiff's evidence proved that a cost allocation submitted to the government was neither current nor accurate, but given the "fairly wide discretion" granted under the relevant statute, it was not "*false* within the meaning of the False Claims Act." *Hagood*, 81 F.3d at 1477 (emphasis in original). Several courts correctly understood that holding as requiring an objectively false statement because subjective disagreements about the application of imprecise legal standards did not carry the day in *Hagood*. *See Berg*, 740 F. App'x at 537; *supra* n.2. In fact, the Fourth Circuit's articulation of the objective falsehood requirement cites *Hagood* for the proposition that "differences in interpretation growing out of a disputed legal question are . . . not false under the FCA." *Wilson*, 525 F.3d at 377 (citations omitted).

There is broad agreement among the lower courts that the falsity element is the "*sine qua non*" of the FCA. *See, e.g.*, *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). There is, however, complete disarray among the lower courts as to what the element requires.

B. The court of appeals' decision below made this circuit split worse, not better. In the first place, by joining the Third Circuit without expressly overruling its *Hagood* decision, the Ninth Circuit switched sides. This rendered uncertain the 24 years of cases decided under *Hagood* in the largest of the courts of appeals, a particularly destabilizing move given that the Ninth Circuit's *Hagood* holding also formed part of the basis of the objective falsehood requirement in at least the Fourth Circuit, as noted above.

Worse yet, the decision below held—despite its rejection of the objective falsehood requirement—that the "Eleventh Circuit's recent decision in [*AseraCare*] is *not directly to the contrary*." Pet. App. 17a (emphasis added). In stark contrast, the Third Circuit acknowledged that it was "departing from [its] sister circuit," by "disagree[ing]" with *AseraCare*. *Care Alternatives*, 952 F.3d at 99, 100. To put it somewhat differently, the decision below seemingly creates a circuit split about whether there even is a circuit split. If this circumstance is allowed to persist, the district courts will be justifiably adrift in any effort to apply the ruling below.

In any event, the court of appeals' attempts to harmonize its holding with *AseraCare* do not hold up

to scrutiny. First, the court of appeals observed that, because the Eleventh Circuit listed some ways a clinical judgment could be false—*i.e.*, if the doctor does not actually hold the opinion or relies on facts known to be incorrect—*AseraCare* must not actually demand an objective falsehood in every case. This, as the decision below acknowledged, is not consistent with the Eleventh Circuit's "language about 'objective falsehoods.'" Pet. App. 18a.

Second, the Eleventh Circuit identified the ultimate certification of medical necessity—*i.e.*, the ultimate payment standard that Respondent alleges in this case—as a backstop against impunity for false certifications to Medicare. *AseraCare* might therefore be read to agree that the "'objective falsehood' requirement did not necessarily apply to a physician's certification of medical necessity." *Id.* (citation omitted). On closer examination, this, too, is difficult to square with the rest of *AseraCare*.

For instance, the Eleventh Circuit parsed the Medicare regulations as follows: "The relevant regulation requires only that 'clinical information and other documentation that support the medical prognosis . . . accompany the certification' and 'be filed in the medical record.'" 938 F.3d at 1294 (emphasis in opinion) (quoting 42 C.F.R. § 418.22(b)(2)). The Eleventh Circuit further explained, by way of rejecting the government's argument that the documentation requirement supplied an objective test for hospice care eligibility:

> had Congress or CMS intended the patient's medical records to objectively demonstrate terminal illness, it could have said so. Yet,

> Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review. And CMS's own choice of the word "support"—instead of, for example, "demonstrate" or "prove"—does not imply the level of certitude the Government wishes to attribute to it.

AseraCare, 938 F.3d at 1294.

This analysis applies perforce to the inpatient admission criteria at issue here. Just as in *AseraCare*, the regulation here requires only that inpatient admission be "supported by the medical record," even for admissions that fall short of the two-midnight rule, showing the absence of an objective criterion. *See* 42 C.F.R. § 412.3(d)(1), (3). Focusing on the more specific CMS regulation instead of the ultimate "reasonable and necessary" requirement drives a further wedge between the decision below and *AseraCare*.

In the end, the existence of this circuit split cannot be reasonably denied. The Eleventh Circuit "affirmed . . . the 'objective' falsity test" that the decision below and the Third Circuit expressly rejected. *Care Alternatives*, 952 F.3d at 99. The court of appeals' attempt to reconcile these divergent cases only fuels the confusion in the lower courts by suggesting that two irreconcilable lines of cases (to say nothing of the less clear decisions from the Fifth and Sixth Circuits) can be somehow harmonized on grounds that do not hold up to scrutiny. This stark conflict and deep confusion among the lower courts warrants this Court's review.

II. This Dispute Is An Opportune Case For Resolving This Exceptionally Important Question.

This case presents a timely opportunity to resolve the otherwise intractable circuit split over the objective falsehood requirement. Indeed, resolution of the split is both vitally important to ensuring the correct result in this case and to guiding countless medical professionals in their hospital admission decisions.

A. Resolving the circuit split correctly would completely dispose of this case. Respondent's falsity allegations depend on whether the physicians who worked at Tri-City "falsely" determined that inpatient care was reasonable and necessary for treating each Medicare beneficiary. But rather than specifically define which medical conditions warrant inpatient care, CMS elected to empower physicians, in the first instance, to make hospital admission decisions. Physicians are advised by regulation to develop an "expectation" as to whether the patient's care will span two midnights under the two-midnight rule. Doctors are further entrusted to base their expectation on "such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event." 42 C.F.R. § 412.3(d)(1)(i).

Accordingly, Respondent's falsity allegations are not testable by reference to any objective standard. Tri-City physicians expressed an opinion that patients would require inpatient care based on their understanding of complex medical factors; Respondent holds another conclusion based on her after-the-fact review of paperwork. Pet. App. 42a. That difference of opinion forms the basis

of her allegation that Tri-City's inpatient care was not reasonable and necessary and therefore that Petitioners submitted false claims for reimbursement of that care. Pet. App. 42a-43a.

This difference of opinion led the district court to find no objective basis for determining whether the physicians' judgments were "false." Pet. App. 43a. The court of appeals did not hold that Respondent would have satisfied objective falsity; instead, it excused Respondent from her burden to even plead an objectively false claim and expressly credited Respondent's reliance on other "medical professionals' *opinions*" in the form of the InterQual criteria. Pet. App. 21a (emphasis added). Thus, if this case had arisen in the Fourth, Seventh, or Eleventh Circuits, the district court's dismissal would have been affirmed. The court of appeals' decision to depart from the objective falsehood requirement is what saved Respondent's case.

This dispute therefore cleanly tees up the split: If the Eleventh Circuit (and the district court below) is correct, then Respondent states no claim because the differences of opinion she identified cannot be objectively false under the FCA. If, however, the Third Circuit (and the court of appeals below) is correct, then Respondent's case will move forward with the law accurately framed for summary judgment. And if the Fifth or the Sixth Circuits have the better position by straddling the two extremes, correcting the law now may prevent further appeals in this case and many others.

The disagreement among the circuits here is stark, and it is not going to improve without this Court's

intervention. Despite the court of appeals' attempt to harmonize the cases, the lower courts simply diverge on whether an objective falsehood is required by the FCA.

B. The question presented here is also exceptionally important. Medicare regulations are rules of national application that directly affect how beneficiaries receive care and healthcare workers make a living. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) ("One way or another, Medicare touches the lives of nearly all Americans."). Their enforcement through the FCA also affects livelihoods and liberties. *See Universal Health Servs.*, 136 S. Ct. at 1996 ("Congress also has increased the Act's civil penalties so that liability is 'essentially punitive in nature.' Defendants are subjected to treble damages plus civil penalties of up to $10,000 per false claim.") (citation omitted).

Meanwhile, this is a time of unprecedented stress on our healthcare system. Inpatient hospital admission decisions are today as fraught as they perhaps ever will be, and hospital staff are being pushed to their limits. The court of appeals' holding will further burden medical professionals who need to make real-time decisions without worrying about crippling financial liability brought about by a disgruntled colleague who disagrees with their medical judgments *post hoc*. Stripping away the objective falsehood requirement and depleting the FCA's falsity bar to the level of disagreements over indeterminate legal standards—contrary to at least three other circuits—was a weighty imposition on the healthcare industry working within the Ninth Circuit. It deserves the attention of this Court if for no other reason than to ensure a nationally applicable rule is applied uniformly.

CONCLUSION

In Long Beach, an alleged difference of medical opinion alone suffices to show a claim is "false" under the False Claims Act; in Miami Beach, the same difference of opinion, without more, establishes no false claim. Visitors to these two port cities might reliably identify their many differences, but their application of the False Claims Act ought not to be among them. The Court should grant the petition.

Respectfully submitted,

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December 3, 2020

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT, FILED MARCH 23, 2020

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 18-55020

JANE WINTER, EX REL.
UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

GARDENS REGIONAL HOSPITAL AND MEDICAL CENTER, INC., DBA TRI- CITY REGIONAL MEDICAL CENTER, A CALIFORNIA CORPORATION, ROLLINSNELSON LTC CORP., A CALIFORNIA CORPORATION, VICKI ROLLINS, BILL NELSON, S&W HEALTH MANAGEMENT SERVICES, INC., A CALIFORNIA CORPORATION, BERYL WEINER, PRODE PASCUAL, M.D., RAFAELITO VICTORIA, M.D., ARNOLD LING, M.D., CYNTHIA MILLER-DOBALIAN, M.D., EDGARDO BINOYA, M.D., NAMIKO NERIO, M.D., MANUEL SACAPANO, M.D.,

Defendants-Appellees.

Appendix A

Appeal from the United States District Court
for the Central District of California
John F. Walter, District Judge, Presiding

Argued and Submitted
September 13, 2019 Pasadena, California

Filed March 23, 2020

Before: Johnnie B. Rawlinson, John B. Owens,
and Mark J. Bennett, Circuit Judges.

Opinion by Judge Bennett.

SUMMARY[*]

False Claims Act

The panel reversed the district court's dismissal for failure to state a claim and remanded in an action under the False Claims Act, alleging that defendants submitted, or caused to be submitted, Medicare claims falsely certifying that patients' inpatient hospitalizations were medically necessary.

Plaintiff alleged that the admissions were not medically necessary and were contraindicated by the patients' medical records and the hospital's own admissions criteria. The district court held that "to prevail

[*] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

on an FCA claim, a plaintiff must show that a defendant knowingly made an objectively false representation," and so a statement that implicates a doctor's clinical judgment can never state a claim under the FCA because "subjective medical opinions . . . cannot be proven to be objectively false."

The panel held that a plaintiff need not allege falsity beyond the requirements adopted by Congress in the FCA, which primarily punishes those who submit, conspire to submit, or aid in the submission of false or fraudulent claims. The panel stated that Congress imposed no requirement of objective falsity, and the panel had no authority to rewrite the statute to add such a requirement. The panel held that a doctor's clinical opinion must be judged under the same standard as any other representation. A doctor, like anyone else, can express an opinion that he knows to be false, or that he makes in reckless disregard of its truth or falsity. Agreeing with other circuits, the panel therefore held that a false certification of medical necessity can give rise to FCA liability. The panel also held that a false certification of medical necessity can be material because medical necessity is a statutory prerequisite to Medicare reimbursement.

OPINION

BENNETT, Circuit Judge:

Appellant-Relator Jane Winter ("Winter"), the former Director of Care Management at Gardens Regional

Hospital ("Gardens Regional"), brought this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33. Winter alleges Defendants[1] submitted, or caused to be submitted, Medicare claims falsely certifying that patients' inpatient hospitalizations were medically necessary. Winter alleges that the admissions were not medically necessary and were contraindicated by the patients' medical records and the hospital's own admissions criteria. The district court dismissed Winter's second amended complaint ("the complaint") for failure to state a claim. The district court held that "to prevail on an FCA claim, a plaintiff must show that a defendant knowingly made an objectively false representation," so a statement that implicates a doctor's clinical judgment can never state a claim under the FCA because "subjective medical opinions . . . cannot be proven to be objectively false."

We have jurisdiction under 28 U.S.C. § 1291. We hold that a plaintiff need not allege falsity beyond the requirements adopted by Congress in the FCA, which primarily punishes those who submit, conspire to submit, or aid in the submission of false or fraudulent claims. Congress imposed no requirement of proving "objective falsity," and we have no authority to rewrite the statute to add such a requirement. A doctor's clinical opinion must be judged under the same standard as any other representation. A doctor, like anyone else, can express

1. The Defendants include Gardens Regional Hospital, the hospital management company (S&W Health Management Services) and its owners (RollinsNelson, Rollins, Nelson, and Weiner), and individual physicians who diagnosed and admitted patients.

an opinion that he knows to be false, or that he makes in reckless disregard of its truth or falsity. *See* 31 U.S.C. § 3729(b)(1). We therefore hold that a false certification of medical necessity can give rise to FCA liability.[2] We also hold that a false certification of medical necessity can be material because medical necessity is a statutory prerequisite to Medicare reimbursement. Accordingly, we reverse and remand.

BACKGROUND

A. The "Medical Necessity" Requirement

The Medicare program provides basic health insurance for individuals who are 65 or older, disabled, or have endstage renal disease. 42 U.S.C. § 1395c. "[N]o payment may be made . . . for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A). Medicare reimburses providers for inpatient hospitalization only if "a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose[.]" 42 U.S.C. § 1395f(a)(3).

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2. The FCA covers claims that are "false or fraudulent." 31 U.S.C. § 3729(a)(1). For convenience, we will generally use "false" to mean "false or fraudulent."

Appendix A

The Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS"), administers the Medicare program and issues guidance governing reimbursement. CMS defines a "reasonable and necessary" service as one that "meets, but does not exceed, the patient's medical need," and is furnished "in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition . . . in a setting appropriate to the patient's medical needs and condition[.]" CMS, Medicare Program Integrity Manual § 13.5.4 (2019). The Medicare program tells patients that "medically necessary" means health care services that are "needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." CMS, Medicare & You 2020: The Official U.S. Government Medicare Handbook 114 (2019).

Admitting a patient to the hospital for inpatient—as opposed to outpatient—treatment requires a formal admission order from a doctor "who is knowledgeable about the patient's hospital course, medical plan of care, and current condition." 42 C.F.R. § 412.3(b). Inpatient admission "is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights," but inpatient admission can also be appropriate under other circumstances if "supported by the medical record." *Id.* § 412.3(d)(1), (3).

The Medicare program trusts doctors to use their clinical judgment based on "complex medical factors," but does not give them unfettered discretion to decide

whether inpatient admission is medically necessary: "The factors that lead to a particular clinical expectation *must be documented in the medical record* in order to be granted consideration." *Id.* § 412.3(d)(1)(i) (emphasis added). And the regulations consider medical necessity a question of fact: "No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification . . . in determining the medical necessity of inpatient hospital services . . . . A physician's order or certification will be evaluated in the context of the evidence in the medical record." *Id.* § 412.46(b).

B. The False Claims Act

The FCA imposes significant civil liability on any person who, *inter alia*, (A) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," (B) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or (C) "conspires to commit a violation of subparagraph (A), [or] (B)[.]" 31 U.S.C. § 3729(a)(1). The Act allows private plaintiffs to enforce its provisions by bringing a *qui tam* suit on behalf of the United States. *Id.* § 3730(b).

A plaintiff must allege: "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing, (4) the government to pay out money or forfeit moneys due." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017). Winter's allegations fall under a "false certification"

theory of FCA liability.[3] *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001, 195 L. Ed. 2d 348 (2016). Because medical necessity is a condition of payment, every Medicare claim includes an express or implied certification that treatment was medically necessary. Claims for unnecessary treatment are false claims. Defendants act with the required scienter if they know the treatment was not medically necessary, or act in deliberate ignorance or reckless disregard of whether the treatment was medically necessary. *See* 31 U.S.C. § 3729(b)(1).

C. The Allegations in Winter's Complaint[4]

Winter, a registered nurse, became the Director of Care Management and Emergency Room at Gardens Regional in August 2014, and came to the job with thirteen years of experience as a director of case management at hospitals in Southern California and Utah.

Winter reviewed hospital admissions using the admissions criteria adopted by Gardens Regional—the InterQual Level of Care Criteria 2014 ("the InterQual criteria"). The InterQual criteria, promulgated by

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3. The complaint alleges both express and implied false certification.

4. All facts are taken from Winter's second amended complaint. "We accept all factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Outdoor Media Grp., Inc. v. City of Beaumont*, 506 F.3d 895, 900 (9th Cir. 2007).

McKesson Health Solutions LLC and updated annually, "are reviewed and validated by a national panel of clinicians and medical experts," and represent "a synthesis of evidence-based standards of care, current practices, and consensus from licensed specialists and/or primary care physicians." Medicare uses the criteria to evaluate claims for payment. And, as the criteria require a secondary review of all care decisions, Winter's job included reviewing Garden Regional patients' medical records and applying the criteria to evaluate the medical necessity of hospital admissions.

In mid-July 2014, Defendant RollinsNelson—which owned and operated nursing facilities in the Los Angeles area—acquired a 50% ownership interest in Defendant S&W, the management company that oversaw operations at Gardens Regional. RollinsNelson then began jointly managing the hospital with S&W. When Winter started work, she noticed that the emergency room saw an unusually high number of patients transported from RollinsNelson nursing homes, including from a facility sixty miles away. The RollinsNelson patients were not just treated on an outpatient basis or held overnight for observation—most were admitted for inpatient hospitalization. In August 2014, 83.5% of the patients transported from RollinsNelson nursing homes were admitted to Gardens Regional for inpatient treatment—an unusually high admissions rate based on Winter's experience and judgment.

Winter was concerned about this pattern and scrutinized Gardens Regional's admissions statistics,

comparing July and August 2014 to prior months. She realized that the spike in admissions from RollinsNelson nursing homes corresponded with RollinsNelson's acquisition of S&W. Not only did the number of admissions increase, the number of Medicare beneficiaries admitted rose as well. The number of Medicare beneficiaries admitted in August 2014, for example, surpassed that of any month before RollinsNelson began managing the hospital. Winter alleges that RollinsNelson and S&W—including the individual owners of both entities—"exerted direct pressure on physicians to admit patients to [Gardens Regional] and cause false claims to be submitted based on false certifications of medical necessity."

Winter's complaint details sixty-five separate patient admissions—identified by the admitting physician, patient's initials, chief complaint, diagnosis, length of admission, the Medicare billing code, and the amount billed to Medicare— that Winter alleges did not meet Gardens Regional's admissions criteria and were unsupported by the patients' medical records. She alleges that none of the admissions were medically necessary. Winter observed several trends: i) admitting patients for urinary tract infections ("UTIs") ordinarily treated on an outpatient basis with oral antibiotics; ii) admitting patients for septicemia with no evidence of sepsis in their records; and iii) admitting patients for pneumonia or bronchitis with no evidence of such diseases in their medical records. Winter estimates that in less than two months—between July 14 and September 9, 2014—Gardens Regional submitted $1,287,701.62 in false claims to the Medicare program.

Winter repeatedly tried to bring her concerns to the attention of hospital management, with no success. In her first week, she reported the high number of unnecessary admissions to the hospital's Chief Operating Officer. After receiving no response, she reached out to the hospital's Chief Executive Officer. When she still received no response, she tried confronting Dr. Sacapano directly. He told her: "You know who I'm getting pressure from." Winter understood Dr. Sacapano to mean the hospital management.

At the beginning of September 2014, Defendants Rollins, Nelson and Weiner—the owners of S&W and RollinsNelson—"called an urgent impromptu meeting," and "instructed case management not to question the admissions to [Gardens Regional.]" When Winter tried to speak up, Rollins cut her off, using profanity. Shortly after the meeting, Rollins instructed one of the hospital's case managers to "coach" physicians, explaining in an email that "[t]hese Mds will most likely increase their admits because their documentation will be 'assisted.'"

In November 2014, Gardens Regional fired Winter and replaced her with an employee who had never questioned any inpatient admissions. Winter filed her complaint a week later.

D. Procedural History

In November 2017, after the Government had declined to intervene and Winter had filed the second amended complaint, Defendants RollinsNelson, Rollins, Nelson,

S&W, Weiner and Dr. Pascual filed motions to dismiss the complaint for failure to state a claim.[5] The district court granted the motions, dismissing Winter's three FCA claims against all Defendants for the same reasons: (1) because a determination of "medical necessity" is a "subjective medical opinion[] that cannot be proven to be objectively false," and (2) because the alleged false statements, which the district court characterized as the "failure to meet InterQual criteria," were not material.[6]

STANDARD OF REVIEW

We review the grant of a motion to dismiss de novo. *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1030 (9th Cir. 2008). "In reviewing the dismissal of a complaint, we inquire whether the complaint's factual allegations, together with all reasonable inferences, state a plausible claim for relief." *Cafasso, United States ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054 (9th Cir. 2011). As with all fraud allegations, a plaintiff must plead FCA claims "with particularity" under Federal Rule of Civil Procedure 9(b). *Id.*

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5. At oral argument, Winter's counsel acknowledged that Dr. Sacapano and Dr. Nerio had not yet been served with the second amended complaint when the district court, in granting the moving Defendants' motions to dismiss, sua sponte dismissed the complaint against them as well. Oral Argument at 10:58, *Winter v. Gardens Regional Hosp., et al.*, No. 18-55020 (9th Cir. Sept. 13, 2019), https://www.ca9.uscourts.gov/media/view_video.php?pk_vid=0000016196.

6. The district court did not dismiss Winter's retaliation claim against Gardens Regional. Winter voluntarily dismissed that claim without prejudice to allow for an appeal.

Appendix A

DISCUSSION

A. Winter properly alleges false or fraudulent statements

We interpret the FCA broadly, in keeping with the Congress's intention "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232, 88 S. Ct. 959, 19 L. Ed. 2d 1061 (1968). For that reason, the Supreme Court "has consistently refused to accept a rigid, restrictive reading" of the FCA, *id.*, and has cautioned courts against "adopting a circumscribed view of what it means for a claim to be false or fraudulent," *Escobar*, 136 S. Ct. at 2002 (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270, 393 U.S. App. D.C. 223 (D.C. Cir. 2010)).

"[W]e start, as always, with the language of the statute." *Id.* at 1999 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 668, 128 S. Ct. 2123, 170 L. Ed. 2d 1030 (2008)). The plain language of the FCA imposes liability for presenting, or causing to be presented, a "false or fraudulent claim for payment or approval," making "a false record or statement material to a false or fraudulent claim," or conspiring to do either. 31 U.S.C. § 3729(a)(1)(A)-(C). Because Congress did not define "false or fraudulent," we presume it incorporated the common-law definitions, including the rule that a statement need not contain an "express falsehood" to be actionable. *Escobar*, 136 S. Ct. at 1999 ("[I]t is a settled principle of interpretation that, absent other indication,

Congress intends to incorporate the well-settled meaning of the common-law terms it uses." (quoting *Sekhar v. United States*, 570 U.S. 729, 732, 133 S. Ct. 2720, 186 L. Ed. 2d 794 (2013))). And, in at least one respect, Congress intended for the FCA to be broader than the common law: Under the FCA, "'knowingly' . . . require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B).

"[O]pinions are not, and have never been, completely insulated from scrutiny." *United States v. Paulus*, 894 F.3d 267, 275-76 (6th Cir. 2018) (upholding conviction for Medicare fraud where physician justified unnecessary procedures by exaggerating his interpretation of medical tests); *see also Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1049 (9th Cir. 2012) (holding that false estimates "can be a source of liability under the FCA"). Under the common law, a subjective opinion is fraudulent if it implies the existence of facts that do not exist, or if it is not honestly held. Restatement (Second) of Torts § 525; *id.* § 539. As the Supreme Court recognized, "the expression of an opinion may carry with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 191, 135 S. Ct. 1318, 191 L. Ed. 2d 253 (2015) (quoting W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 109, at 760 (5th ed. 1984)).

Defendants and amici curiae American Health Care Association, National Center for Assisted Living, and California Association of Health Facilities urge this court

to hold the FCA requires a plaintiff to plead an "objective falsehood." But "[n]othing in the text of the False Claims Act supports [Defendants'] proposed restriction." *Escobar*, 136 S. Ct. at 2001. Under the plain language of the statute, the FCA imposes liability for all "false or fraudulent claims"—it does not distinguish between "objective" and "subjective" falsity or carve out an exception for clinical judgments and opinions.

Defendants are correct that if clinical judgments can be fraudulent under the FCA, doctors will be exposed to liability they would not face under Defendants' view of the law. "But policy arguments cannot supersede the clear statutory text." *Id.* at 2002. Our role is "to apply, not amend, the work of the People's representatives." *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1726, 198 L. Ed. 2d 177 (2017). And the Supreme Court has already addressed Defendants' concern: "Instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." *Escobar*, 136 S. Ct. at 2002 (quotation marks, alterations, and citation omitted).

We have similarly explained that the FCA requires "the 'knowing presentation of what is known to be false'" and that "[t]he phrase 'known to be false'. . . does not mean 'scientifically untrue'; it means 'a lie.' The Act is concerned with ferreting out 'wrongdoing,' not scientific errors." *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) (citations omitted), *overruled on other grounds by United*

States ex rel. Hartpence v. Kinetic Concepts, Inc., 792 F.3d 1121 (9th Cir. 2015) (en banc). This does not mean, as the district court understood it, that only "objectively false" statements can give rise to FCA liability. It means that falsity is a necessary, but not sufficient, requirement for FCA liability—after alleging a false statement, a plaintiff must still establish scienter. *Id.* ("What is false as a matter of science is not, by that very fact, wrong as a matter of morals."). To be clear, a "scientifically untrue" statement is "false"—even if it may not be actionable because it was not made with the requisite intent. And an opinion with no basis in fact can be fraudulent if expressed with scienter.

We are not alone in concluding that a false certification of medical necessity can give rise to FCA liability. In *United States ex rel. Riley v. St. Luke's Episcopal Hospital*, the Fifth Circuit recognized that "claims for medically unnecessary treatment are actionable under the FCA." 355 F.3d 370, 376 (5th Cir. 2004). The plaintiff alleged the defendants filed false claims "for services that were . . . medically unnecessary," *id.* at 373, and the Fifth Circuit reversed the district court's dismissal for failure to state a claim, explaining that because the complaint alleged that the defendants ordered medical services "knowing they were unnecessary," the statements were lies, not simply errors. *Id.* at 376.

Likewise, in *United States ex rel. Polukoff v. St. Mark's Hospital*, the Tenth Circuit recognized "[i]t is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA[.]" 895 F.3d 730, 742 (10th Cir. 2018). The court looked to CMS's definition of

"medically necessary," and held, "a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase." *Id.* at 743. The Third Circuit reached a similar conclusion in *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 2020 U.S. App. LEXIS 6795, 2020 WL 1038083 (3d Cir. 2020), rejecting the "bright-line rule that a doctor's clinical judgment cannot be 'false.'" 2020 U.S. App. LEXIS 6795, [WL] at *7 (holding that, in the context of certifying terminal illness, "for purposes of FCA falsity, a claim may be 'false' under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements," and that "a physician's judgment may be scrutinized and considered 'false,'" 2020 U.S. App. LEXIS 6795, [WL] at *9).

The Eleventh Circuit's recent decision in *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), is not directly to the contrary. In *AseraCare*, the Eleventh Circuit held that "a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the False Claims Act, when there is *only* a reasonable disagreement between medical experts as to the accuracy of that conclusion, *with no other evidence* to prove the falsity of the assessment." *Id.* at 1281 (emphases added). We recognize that the court also said "a claim that certifies that a patient is terminally ill . . . cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood." *Id.* at 1296-97. But we conclude that our decision today does not conflict with *AseraCare* for two reasons.

First, the Eleventh Circuit was not asked whether a medical opinion could ever be false or fraudulent, but whether a reasonable disagreement between physicians, *without more*, was sufficient to prove falsity at summary judgment. *Id.* at 1297-98. Notwithstanding the Eleventh Circuit's language about "objective falsehoods," the court clearly did not consider all subjective statements—including medical opinions—to be incapable of falsity, and identified circumstances in which a medical opinion would be false.[7]

Second, the Eleventh Circuit recognized that its "objective falsehood" requirement did not necessarily apply to a physician's certification of medical necessity—explicitly distinguishing *Polukoff*. *Id.* at 1300 n.15. Rather, the court explained that the "hospice-benefit provision at issue" purposefully defers to "whether a physician has based a recommendation for hospice treatment on a genuinely-held clinical opinion" whether a patient was terminally ill.[8] *Id.; see also id.* at 1295. In

7. For example, "if the [doctor] does not actually hold that opinion" or simply "rubber-stamp[s] whatever file was put in front of him," if the opinion is "based on information that the physician knew, or had reason to know, was incorrect," or if "no reasonable physician" would agree with the doctor's opinion, "based on the evidence[.]" *AseraCare*, 938 F.3d at 1302.

8. A patient must have less than six months to live to be eligible for hospice care. *AseraCare*, 938 F.3d at 1282. But, as the Eleventh Circuit explained, CMS "repeatedly emphasized that '[p]redicting life expectancy is not an exact science,' [and that] 'certifying physicians have the best clinical experience, competence and judgment to make the determination that an individual is terminally ill.'" *Id.* at 1295

fact, after holding that physicians' hospice-eligibility determinations are entitled to deference, the Eleventh Circuit explained that the less-deferential medical necessity requirement remained an important safeguard: "The Government's argument that our reading of the eligibility framework would 'tie CMS's hands' and 'require improper reimbursements' is contrary to the plain design of the law" because "CMS is statutorily prohibited from reimbursing providers for services 'which are not reasonable and necessary[.]'" *Id.* at 1295 (alteration and citation omitted). Thus, for the same reason the Eleventh Circuit recognized *AseraCare* did not conflict with *Polukoff*, we believe our decision does not conflict with *AseraCare*. And to the extent that *AseraCare* can be read to graft any type of "objective falsity" requirement onto the FCA, we reject that proposition. *See Druding*, 2020 U.S. App. LEXIS 6795, 2020 WL 1038083, at *8.

In sum, we hold that the FCA does not require a plaintiff to plead an "objective falsehood." A physician's certification that inpatient hospitalization was "medically necessary" can be false or fraudulent for the same reasons any opinion can be false or fraudulent. These reasons include if the opinion is not honestly held, or if it implies the existence of facts—namely, that inpatient hospitalization is needed to diagnose or treat a medical condition, in accordance with accepted standards of medical practice—that do not exist. *See Polukoff*, 895 F.3d at 742-43.

(quoting 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010) and 78 Fed. Reg. 48234, 48247 (Aug. 7, 2013)). By contrast, a certification of medical necessity is not entitled to deference. 42 C.F.R. § 412.46(b).

We now turn to Winter's complaint. We accept all facts alleged as true and draw all inferences in Winter's favor, and conclude that her complaint plausibly alleges false certifications of medical necessity.

First, the complaint "alleges a 'scheme' connoting knowing misconduct." *Riley*, 355 F.3d at 376. RollinsNelson and S&W—and their individual owners Rollins, Nelson and Weiner—had a motive to falsify Medicare claims and pressure doctors to increase admissions. Gardens Regional relied on Medicare for a "significant portion" of its revenue, and the spike in admissions corresponded with an increased number of Medicare beneficiaries in its care. Moreover, the increased admissions of RollinsNelson patients began when RollinsNelson started managing Gardens Regional.

Second, not only does Winter identify suspect trends in inpatient admissions—for example, hospitalizing patients for UTIs—she also alleges statistics showing an overall increase in hospitalizations once RollinsNelson started managing the hospital. For example, the daily occupancy rate jumped by almost 10%, the number of Medicare beneficiaries became the highest it had ever been by a significant margin, and the admissions rate from RollinsNelson nursing homes was over 80%. Plus, the large number of admissions that did not meet the criteria, and the fact that the vast majority of admissions came from a single doctor—Dr. Pascual, who had contractually agreed to use the InterQual criteria—decreases the likelihood that any given admission was an outlier.

Third, Winter's detailed allegations as to each Medicare claim support an inference of falsity. This is not a complaint that "identifies a general sort of fraudulent conduct but specifies no particular circumstances of any discrete fraudulent statement[.]" *Cafasso*, 637 F.3d at 1057. The complaint identifies sixty-five allegedly false claims in great detail, listing the date of admission, the admitting physician, the patient's chief complaint and diagnosis, and the amount billed to Medicare. The complaint alleges that each admission failed to satisfy the hospital's own admissions criteria—the InterQual criteria that Gardens Regional and Dr. Pascual had contractually agreed to use and that Winter's job as Director of Care Management required her to apply. And, as the district court recognized, the InterQual criteria represent the "consensus of medical professionals' opinions," so a failure to satisfy the criteria also means that the admission went against the medical consensus.

Finally, we note that many of the allegations supporting an inference of scienter also support an inference of falsity. *Cf. AseraCare*, 938 F.3d at 1304-05 (remanding for district court to consider evidence related to scienter in determining falsity on summary judgment). For example, when confronted, Dr. Sacapano corroborated Winter's suspicions, telling her that hospital management pressured him into recommending patients for medically unnecessary inpatient admission. And following Winter's numerous attempts to bring her concerns to the attention of hospital management, Defendants Rollins, Nelson, and Weiner held a meeting where they instructed Winter and other staff not to question the admissions.

Defendants argue that "Winter has alleged nothing more than her competing opinion with the treating physicians who actually saw the patients at issue." The district court similarly dismissed the complaint because Winter's "contention that the medical provider's certifications were false is based on her own after-the-fact review of [Gardens Regional's] admission records." To begin with, an opinion can establish falsity. *See Paulus*, 894 F.3d at 270, 277 (affirming doctor's conviction for healthcare fraud by performing medically unnecessary procedures and holding that experts' "opinions, having been accepted into evidence, are sufficient to carry the government's burden of proof"); *cf. AseraCare*, 938 F.3d at 1300 (distinguishing *Paulus* because in *AseraCare* "the Government's expert witness declined to conclude that [the clinical judgments of] AseraCare's physicians . . . were unreasonable or wrong"). Winter alleges more than just a reasonable difference of opinion. In addition to the allegations discussed above, she alleges that a number of the hospital admissions were for diagnoses that had been disproven by laboratory tests, and that several admissions were for psychiatric treatment, even though Gardens Regional was not a psychiatric hospital— and one of those patients never even saw a psychiatrist. Even if we were to discount Winter's evaluation of the medical records, as the district court did, the other facts she alleges would be sufficient to make her allegations of fraud plausible.

But more importantly, assessing medical necessity based on an "after-the-fact review" of patients' medical records *was Winter's job*. At the motion to dismiss stage, her assessment is "entitled to the presumption of truth[.]"

Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011). "The standard at this stage of the litigation is not that plaintiff's explanation must be true or even probable. The factual allegations of the complaint need only 'plausibly suggest an entitlement to relief.'" *Id.* at 1216-17 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 681, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009)). Winter's complaint satisfies that standard.[9]

B. Winter properly alleges material false or fraudulent statements

The district court also held that Winter failed to allege any material false statements. We disagree.

"[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "Under any understanding of the concept, materiality 'looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 136 S. Ct. at 2002 (quoting 26 Samuel Williston &

9. FCA claims must also be pleaded with particularity under Federal Rule of Civil Procedure 9(b). *Cafasso*, 637 F.3d at 1054. While a plaintiff need not "allege 'all facts supporting each and every instance' of billing submitted," she must "provide enough detail 'to give [defendants] notice of the particular misconduct which is alleged to constitute the fraud charged so that [they] can defend against the charge and not just deny that [they have] done anything wrong.'" *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010) (quoting *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051-52 (9th Cir. 2001)). Winter's detailed allegations clearly suffice to put Defendants on notice of their alleged false statements.

Richard A. Lord, Williston on Contracts § 69:12 (4th ed. 2003)) (alteration omitted). No "single fact or occurrence" determines materiality—"the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* at 2001, 2003 (citation omitted). For a false statement to be material, a plaintiff must plausibly allege that the statutory violations are "so central" to the claims that the government "would not have paid these claims had it known of these violations." *Id.* at 2004; *see also id.* at 2003 ("[P]roof of materiality can include . . . evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.").

The district court analyzed whether failure to meet the InterQual criteria was material and concluded that it was not because "[t]here is no mention of the InterQual criteria in any of the relevant statutes or regulations." This misreads the complaint. Winter does not allege that failure to satisfy the InterQual criteria made Defendants' Medicare claims per se false—although, as discussed above, she claims that the InterQual criteria support her allegations because they reflect a medical consensus. Rather, she alleges that "[Defendants'] claims for payment . . . were false in that the services claimed for (inpatient hospital admissions) were not medically necessary and economical," and that Defendants submitted "false certifications of . . . medical necessity."

We conclude that a false certification of medical necessity can be material. The medical necessity

requirement is not an "insignificant regulatory or contractual violation[.]" *Escobar*, 136 S. Ct. at 2004. Congress *prohibited* payment for treatment "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]" 42 U.S.C. § 1395y(a)(1)(A). And Medicare pays for inpatient hospitalization "*only if* . . . such services are required to be given on an inpatient basis for such individual's medical treatment[.]" *Id.* § 1395f(a)(3) (emphasis added). In fact, Medicare regulations require all doctors to sign an acknowledgment that states,

> Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

42 C.F.R. § 412.46(a)(2). In addition to highlighting the above Medicare statutes and regulations, Winter's complaint alleges that the government "would not" have "paid" Defendants' false claims "if the true facts were known." In sum, Winter alleges that Defendants' false certification of the medical necessity requirement is "so central" to the Medicare program that the government "would not have paid these claims had it known" that the inpatient hospitalizations were, in fact, unnecessary.

Escobar, 136 S. Ct. at 2004. Thus, Winter has "sufficiently ple[d] materiality at this stage of the case." *Campie*, 862 F.3d at 907.

C. Scienter

Defendants urge us to determine whether Winter adequately alleged scienter. The district court did not reach this issue but expressed doubt that Winter had. Although we may consider alternate grounds for upholding the district court's decision, *see Islamic Republic of Iran v. Boeing Co.*, 771 F.2d 1279, 1288 (9th Cir. 1985), we decline to do so here.

We remind the district court, however, that under Rule 9(b), scienter need not be pleaded with particularity, but may be alleged generally. Fed. R. Civ. P. 9(b). A complaint needs only to allege facts supporting a plausible inference of scienter. *United States ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 997 (9th Cir. 2011). And unlike in common law fraud claims, a plaintiff need not prove a "specific intent to defraud" under the FCA—the Act imposes liability on any person acting "knowingly," which includes acting with "actual knowledge," as well as acting "in deliberate ignorance," or "in reckless disregard of the truth or falsity of the information[.]" 31 U.S.C. § 3729(b)(1). As the Supreme Court noted in another Medicare case, "[p]rotection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law[.]" *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 63, 104 S. Ct. 2218, 81 L. Ed. 2d 42 (1984).

CONCLUSION

We hold that a plaintiff need not plead an "objective falsehood" to state a claim under the FCA, and that a false certification of medical necessity can be material. Accordingly, we reverse the district court's dismissal of Winter's complaint and remand for further proceedings consistent with this opinion.

APPENDIX B — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, FILED DECEMBER 29, 2017

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

Case No. CV 14-08850-JFW (Ex)

UNITED STATES OF AMERICA
EX REL. JANE WINTER

-v-

GARDENS REGIONAL HOSPITAL AND MEDICAL CENTER, INC. *et al.*

December 29, 2017, Decided
December 29, 2017, Filed

HONORABLE JOHN F. WALTER,
UNITED STATES DISTRICT JUDGE.

PROCEEDINGS (IN CHAMBERS): ORDER GRANTING DEFENDANTS VICKI ROLLINS, WILLIAM NELSON, AND ROLLINSNELSON LTC CORPORATION'S MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT [Docket No. 120; filed 11/6/17]

Appendix B

ORDER GRANTING DEFENDANTS S&W HEALTH MANAGEMENT SERVICES, INC. AND BERYL WEINER'S MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT [Docket No. 122; filed 11/6/17]

ORDER GRANTING DEFENDANT PRODE PASCUAL, M.D.'S MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED COMPLAINT [Docket No. 123; filed 11/6/17]

On November 6, 2017, Defendants S&W Health Management Services, Inc. ("S&W") and Beryl Weiner ("Mr. Weiner") (collectively, the "S&W Defendants"), Vicky Rollins, William Nelson, and RollinsNelson LTC Corporation (collectively, the "RollinsNelson Defendants") and Prode Pascual, M.D. ("Dr. Pascual") filed Motions to Dismiss Plaintiff *Qui Tam* Relator Jane Winter's ("Ms. Winter") Second Amended Complaint ("SAC") (Docket Nos. 120, 122, 123). Plaintiff filed Oppositions to the Motions on November 15, 2017. On November 22, 2017, Defendants filed their Replies. Pursuant to Rule 78 of the Federal Rules of Civil Procedure and Local Rule 7-15, the Court found the matters appropriate for submission on the papers without oral argument. The matters were, therefore, removed from the Court's December 11, 2017 hearing calendar, and the parties were given advance notice. After considering the moving, opposing, and reply papers, and the arguments therein, the Court rules as follows:

Appendix B

I. Background

A. The Parties

The RollinsNelson Defendants own and operate several skilled nursing facilities in the greater Los Angeles area. In addition, RollinsNelson and Mr. Beryl own S&W. At all times relevant to this action, S&W owned an entity known as Sycamore Healthcare ("Sycamore"), which had a contract to manage operations at Gardens Regional Hospital and Medical Center, Inc., doing business as Tri-City Regional Medical Center ("Tri-City"). Tri-City is a non-profit, acute care hospital with inpatient and outpatient services, which filed for Chapter 11 bankruptcy protection on June 6, 2016 (Docket No. 45).

Dr. Pascual and non-moving defendants Rafaelito Victoria, Arnold Ling, Cynthia Miller-Dobalian, Edgardo Binoya, and Namiko Nerio were attending physicians with admitting privileges at Tri-City. Non-moving defendant Manuel Sacapano was an emergency room physician. Although Dr. Sacapano made primary and secondary medical diagnoses incident to attending physicians' admissions of patients to Tri-City, he did not have admitting privileges at Tri-City.

Ms. Winter is a registered nurse who worked briefly as the Director of Care Management and Emergency Room at Tri-City from August 11, 2014 until she was terminated on November 6, 2014.

B. Alleged False Claims

During her employment with Tri-City, Ms. Winter was responsible for the operation of the emergency room and for case management, social services, and utilization review. During the first week of her employment at Tri-City, Ms. Winter alleges that she noticed that a disproportionate number of patients were being transported to the hospital via ambulance from nursing homes owned and operated by RollinsNelson. As a result, Ms. Winter began investigating inpatient hospital admissions of patients from facilities owned and operated by RollinsNelson ("RollinsNelson Patients").

Ms. Winter identified approximately 65 claims, totaling approximately $1,287,701.62, related to inpatient hospital admissions of RollinsNelson Patients between July 14, 2014 and September 9, 2014 that she believed were medically unnecessary and, therefore, false. According to Ms. Winter, part of her job was to review and evaluate the appropriateness of medical admissions using a hospital industry standard set of criteria called InterQual Level of Care Criteria 2014 ("InterQual"). Ms. Winter alleges that she determined that none of the RollinsNelson Patients met the inpatient criteria for admission to the hospital under InterQual and, therefore, could not be properly billed to Medicare.

InterQual is a nationally recognized evidence-based clinical content and decision support criteria system developed by McKesson Health Solutions LLC that provides health facilities with assistance in determining

the medical appropriateness of hospital admission, continued stay, and discharge. The InterQual criteria are reviewed and validated by a national panel of clinicians and medical experts, including those in community and academic practice settings, as well as those within the managed care industry throughout the United States. According to Ms. Winter, when a Medicare patient presents to the hospital for inpatient admission or observation, InterQual criteria are used to assess the severity of their illness and the intensity of the required service. Ms. Winter alleges that the hospital can only bill Medicare for inpatient services if the InterQual criteria for severity of illness and intensity of service are both satisfied.

During the course of her investigation, Ms. Winter advised Tri-City's Chief Operating Officer ("COO") that she had determined that the hospital was admitting patients from RollinsNelson facilities that did not meet the InterQual criteria for inpatient admission to the hospital and that Tri-City was therefore improperly billing these charges to Medicare. Ms. Winter also notified Tri-City's Chief Executive Officer of her findings. Ms. Winter alleges that the doctors named as defendants in this action (the "Defendant Doctors") admitted the RollinsNelson Patients even though they knew the RollinsNelson Patients did not require inpatient care. Despite Ms. Winter's findings, Ms. Winter alleges that the S&W Defendants and the RollinsNelson Defendants pressured the Defendant Doctors to continue to admit patients and to continue to submit claims based on false certifications of medical necessity. In addition, Ms. Winter alleges that Ms. Rollins

and Mr. Nelson specifically instructed case management personnel not to question the decision to admit these patients, despite Ms. Winter's objections. According to Ms. Winter, the message from Ms. Rollins and Mr. Nelson was clear: "anyone who questioned admissions to Tri-City would be fired."

Ms. Winter alleges that in September of 2014, Ms. Rollins, in an email to case manager Elida Agatep, explained how to coach physicians at Tri-City to prepare the required documentation in order to increase qualifying patient admissions to Tri-City. Ms. Winter also alleges that the clear implication of the email was that the RollinsNelson Defendants and the S&W Defendants were attempting to override physicians' medical judgment in order to increase admissions to Tri-City and to increase its billings to Medicare.

On November 6, 2014, Ms. Winter was terminated from her position at Tri-City. She alleges that her employment was terminated because of her numerous attempts to stop the "rampant and blatant violations" of the False Claims Act ("FCA"). After Ms. Winter was terminated, Ms. Agatep was named the new Director of Care Management and Emergency Room at Tri-City.

C. Medicare System and Payments for Inpatient Services

Medicare is a health insurance program administered by the Centers for Medicare and Medicaid Services ("CMS"), designed to provide access to health insurance

for Americans aged 65 or older, people under age 65 with certain disabilities, and people of all ages with End-Stage Rental Disease (permanent kidney failure requiring dialysis or a kidney transplant). *See* 42 U.S.C. § 1395c. Eligible Medicare beneficiaries are provided a choice of either signing up for traditional fee-for-service (“”FFS”) coverage under Medicare Part A (Hospital Insurance) and Part B (Medical Insurance), or selecting a private plan option under Part C, which is also known as “Medicare Advantage.” 42 U.S.C. § 1395w-21(a). Under the traditional FFS model, physicians and hospitals (known as “providers”) who care for beneficiaries are reimbursed directly by the federal government.

To receive payment from Medicare for inpatient hospital services provided to beneficiaries, a physician must certify that the services are medically necessary. 42 U.S.C. § 1395f(a)(3). Medicare also provides: “to the extent provided by regulations, the certification and re-certification requirements” described in the statute “shall be deemed satisfied where, at a later date, a physician, nurse practitioner, clinical nurse specialist, or physician assistant” provides “certification of the kind” described in relevant provisions of the statute, but only if the “certification is accompanied by such medical and other evidence as may be required by such regulations.” 42 U.S.C. § 1395f(a)(8).

For purposes of payment under Medicare Part A, an individual qualifies as an inpatient of a hospital if he is formally admitted pursuant to an order for inpatient admission by a physician or qualified practitioner

eligible to admit patients. 42 C.F.R. § 412.3(a). In order for a hospital to receive payment for inpatient services provided to a beneficiary under Medicare Part A, the physician's order must be included in the medical record and supported by the admitting physician's admission and progress notes. 42 C.F.R. § 412.3(a). The physician must also certify that the services are required and include: a documented reason for the hospitalization for either inpatient medical treatment or diagnostic study, or special or unusual services for cost outlier cases; and a statement that the inpatient services were provided in accordance with the physician's order. 42 C.F.R. § 412.3(a).

Inpatient admission will generally qualify for payment under Medicare Part A when the admitting physician concludes or is of the opinion that the patient will "require hospital care that crosses two midnights." 42 C.F.R. § 412.3(d)(1). The physician's decision to admit a patient typically is based on complex medical factors such as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. 42 C.F.R. § 412.3(d)(1)(i). The factors that are relied on for a particular clinical explanation must be documented in the medical record in order to qualify for payment. 42 C.F.R. § 412.3(d)(1)(i). If unforeseen circumstances arise that result in a shorter stay than the physician expected at the time of admission (i.e., a stay that spans less than 24 hours), the patient may still be treated on an inpatient basis and payment for an inpatient hospital stay may be made under Medicare Part A. 42 C.F.R. § 412.3(d)(1)(ii). In addition, where the admitting physician concludes that a patient should be admitted to

the hospital but will not be required to stay for 2 days, payment for the stay may be made under Medicare Part A, provided the physician's decision is based on complex medical factors and the medical record supports the physician's determination. 42 C.F.R. § 412.3(d)(3).

Medicare will not make payments under Medicare Part A or B for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of a beneficiary's illness or injury. 42 U.S.C. § 1395y(a)(1)(A).

D. Procedural History

Ms. Winter filed this *qui tam* action against Defendants on November 14, 2014. On October 16, 2017, she filed a Second Amended Complaint ("SAC") asserting four claims for violations of the FCA. Specifically, Ms. Winter alleges four causes of action: (1) Violation of 31 U.S.C. Section 3729(a)(1)(A) against Tri-City, RollinsNelson, S&W, Ms. Rollins, Mr. Nelson, Mr. Weiner, Dr. Pascual, and six other doctors for knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval; (2) Violation of 31 U.S.C. Section 3729(a)(1)(B) against Tri-City, RollinsNelson, S&W, Ms. Rollins, Mr. Nelson, Mr. Weiner, Dr. Pascual, and six other doctors for knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim; (3) Violation of 31 U.S.C. Section 3729(a)(1)(C) against Tri-City, RollinsNelson, S&W, Ms. Rollins, Mr. Nelson, Mr. Weiner, Dr. Pascual, and six other doctors for conspiracy to violate the FCA; and

(4) Violation of 31 U.S.C. Section 3730(h) against Tri-City, Ms. Rollins, Mr. Nelson, RollinsNelson, Mr. Weiner, and S&W for retaliation. Although the United States conducted a thorough investigation of Ms. Winter's allegations, on March 16, 2017, it declined to intervene in this action.

II. Legal Standard

A motion to dismiss brought pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the claims asserted in the complaint. "A Rule 12(b)(6) dismissal is proper only where there is either a 'lack of a cognizable legal theory' or 'the absence of sufficient facts alleged under a cognizable legal theory.'" *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 304 (C.D. Cal. 1996) (quoting *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1988)). However, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (internal citations and alterations omitted). "[F]actual allegations must be enough to raise a right to relief above the speculative level." *Id.*

In deciding a motion to dismiss, a court must accept as true the allegations of the complaint and must construe those allegations in the light most favorable to the nonmoving party. *See, e.g., Wyler Summit P'ship v.*

Turner Broad. Sys., Inc., 135 F.3d 658, 661 (9th Cir. 1998). "However, a court need not accept as true unreasonable inferences, unwarranted deductions of fact, or conclusory legal allegations cast in the form of factual allegations." *Summit Tech.*, 922 F. Supp. at 304 (citing *W. Mining Council v. Watt*, 643 F.2d 618, 624 (9th Cir. 1981) *cert. denied*, 454 U.S. 1031, 102 S. Ct. 567, 70 L. Ed. 2d 474 (1981)).

"Generally, a district court may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion." *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n. 19 (9th Cir. 1990) (citations omitted). However, a court may consider material which is properly submitted as part of the complaint and matters which may be judicially noticed pursuant to Federal Rule of Evidence 201 without converting the motion to dismiss into a motion for summary judgment. *See, e.g., id.*; *Branch v. Tunnel*, 14 F.3d 449, 454 (9th Cir. 1994).

III. Discussion

The FCA imposes penalties against any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"; (3) "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or

property to the Government"; or (4) conspires to commit any of these violations. 31 U.S.C. § 3729(a)(1)(A)-(C), (G). A "claim includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program." *United States ex. rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017). The FCA permits individuals to sue on behalf of the Government to enforce the statute. 31 U.S.C. § 3730(b).

To prevail on a claim under the FCA, a plaintiff must demonstrate: "(1) a false statement or fraudulent course of conduct; (2) made with scienter; (3) that was material, causing (4) the [G]overnment to pay out or forfeit moneys due." *Campie*, 862 F.3d at 899 (internal citation and quotation marks omitted). "It is not enough to allege regulatory violations . . . rather, the false claim or statement must be the *sine qua non* of receipt of . . . funding." *Id.* (internal citation and quotation marks omitted). Courts broadly construe the FCA and have recognized a number of schemes "that attach potential [FCA] liability to claims for payment that are not explicitly and/or independently false." *Id.* (internal citation and quotation marks omitted).

The FCA recognizes two types of actionable false claims-factually false claims and legally false claims. A plaintiff who relies on a legally false claim theory must prove the defendant's claim is false because the defendant certified to a government agency that it complied with laws, rules, or regulations governing the reimbursement of claims or other provision of benefits when it did not.

United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996). A legally false claim can rest on a theory of express false certification or implied false certification. Ms. Winter does not allege that Defendants billed the Government for services that were never provided-i.e., a "factually false" claim-or that Defendants expressly certified that the claims submitted complied with a law, rule, or regulation as part of the claims process. Rather, Ms. Winter's FCA claims are based on an implied false certification theory. Opp'n at 19.

"Implied false certification occurs when a defendant has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). "[I]t is the false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." *Id.* (internal citation and quotation marks omitted). The Supreme Court recently held that two conditions must be satisfied to prevail on an implied false certification theory: (1) the claim must not merely request payment, but also must make specific representations about the goods or services provided; and (2) the defendant's failure to disclose non-compliance with a material statutory, regulatory, or contractual requirement must "make[ ] those representations misleading half-truths." *Universal Health Servs., Inc. v. United States ex. rel. Escobar*, 136 S. Ct. 1989, 2000-2002, 195 L. Ed. 2d 348 (2017); *see also Campie*, 862 F.3d at 901. "The violation need not be of

a contractual, statutory, or regulatory provision that the Government expressly designated as a condition of payment." *Campie*, 862 F.3d at 901. "However, the misrepresentation must be material to the Government's payment decision." *Id.* (internal citation and quotation marks omitted). Although the Supreme Court clarified "the conditions upon which an implied false certification claim can be made [the elements of an FCA claim] remain the same." *Id.*

Defendants move to dismiss Ms. Winter's FCA claims on the grounds that: (1) Ms. Winter cannot demonstrate that they submitted claims based on objectively false statements; and (2) Ms. Winter cannot show that the alleged false statements were material to the Government's decision to pay the claims.

A. FCA Claims as Alleged in the First and Second Causes of Action

1. Ms. Winter Cannot Establish Defendants Submitted Objectively False Claims

Defendants argue that Ms. Winter's FCA claims must be dismissed because her theory of liability fails as a matter of law given that she has not alleged an objectively false claim. The Court agrees. The FCA only imposes liability on those who make a false or fraudulent statement. Although the statute does not define these terms, the Ninth Circuit has cautioned that falsity under the FCA "does not mean scientifically untrue", rather, it means "a lie". *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir.

1992). Thus, at minimum, to prevail on an FCA claim, a plaintiff must show that a defendant knowingly made an objectively false representation to the Government that caused the Government to remit payment. *United States v. St. Mark's Hosp.*, 2017 U.S. Dist. LEXIS 8167, 2017 WL 237615, at *9 (D. Utah Jan. 19, 2017); *see also Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1477-78 (9th Cir. 1996).

In the SAC, Ms. Winter cites the Medicare statutes and regulations that set forth the criteria that a physician must consider when determining whether to admit a patient for inpatient hospital services. Specifically, Ms. Winter relies on the provisions of the statutes and regulations that require a healthcare provider to submit a certification with a request for payment for services stating that the services were medically necessary. Ms. Winter also relies on the Medicare statutes and regulations that provide that Medicare will not pay for expenses incurred for items or services that are not medically necessary for the diagnosis or treatment of a beneficiary's illness or injury. Accordingly, Ms. Winter's FCA claims are based on her contention that Defendants represented that the services provided to RollinsNelson Patients were medically necessary and that these representations were false.

Ms. Winter's contention that the medical provider's certifications were false is based on her own after-the-fact review of Tri-City's admission records. However, the fact that Ms. Winter reached a different conclusion on the issue of medical necessity does not render the provider's certification false. "[W]hen two or more medical experts

look at the same medical records and reach different conclusions about whether those medical records" support a physician's decision to certify a patient for admission, "all that exists is a difference of opinion." *United States v. AseraCare Inc.*, 176 F. Supp. 3d 1282, 1285 (N.D. Ala. 2016); *see also St. Mark's Hosp.*, 2017 U.S. Dist. LEXIS 8167, 2017 WL 237615, at *9. "This difference of opinion" among medical professionals regarding patients' eligibility for admission alone is not sufficient to demonstrate falsity. *AseraCare*, 176 F. Supp. 3d at 1285. Indeed, "expressions of opinions, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false" for purposes of an FCA claim. *United States ex rel. Roby v. The Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000).

Moreover, as several courts have held, liability for an FCA violation may not be premised on subjective interpretations of imprecise statutory language such as "medically reasonable and necessary." *St. Mark's Hosp.*, 2017 U.S. Dist. LEXIS 8167, 2017 WL 237615, at *9 (collecting cases). Ms. Winter alleges she believes that many of the admissions were medically unreasonable and unnecessary, for example, because the patients' conditions were not severe enough to support inpatient admission. However these allegations are based on subjective medical opinions that cannot be proven to be objectively false.

In addition, Ms. Winter relies heavily on the InterQual criteria and erroneously suggests that they are dispositive in determining when it is medically necessary to admit a patient for inpatient hospital services. In doing so, Ms.

Winter improperly equates the InterQual criteria with the medical necessity standard imposed by Medicare. Medicare does not require compliance with the InterQual criteria before a physician can certify an inpatient admission and related services as medically necessary. Thus, requesting payment for services rendered that do not satisfy the InterQual criteria cannot amount to a fraudulent scheme under the FCA. *See e.g., Universal Health Srvs.*, 136 S. Ct. at 1999-2001 ("[t]he term medical necessity does not impart a qualitative element mandating a particular standard of medical care and [the relator] does not point to any legal authority requiring [the court] to read such a mandate into the form."). Moreover, Ms. Winter admits that the InterQual criteria are merely a collection of data and represent a consensus of medical professionals' opinions. Thus, even assuming there is factual support for Ms. Winter's allegation that Defendants did not satisfy the relevant InterQual criteria when admitting the patients, this does not demonstrate that the providers' certifications that the admissions and relevant services were medically necessary were objectively false. Accordingly, the Court concludes that Ms. Winter's first two FCA claims fail as a matter of law and must be dismissed.

2. Ms. Winter Cannot Establish the Failure to Follow InterQual Criteria Is Material to the Government's Payment

Defendants also argue that Ms. Winter cannot demonstrate that the alleged false statements were material. Under the FCA, a false statement is material if it has "a natural tendency to influence, or be capable

of influencing, the payment or receipt of money or property." *Campie*, 862 F.3d at 904-05. As the Supreme Court recently confirmed, the "materiality standard is demanding." *Universal Health Servs.*, 136 S. Ct. at 2003. The key question is whether the government is likely to attach significance to the requirement in deciding whether to tender payment. *Id.*

In an effort to establish materiality, Ms. Winter alleges that the InterQual criteria can be relied on to perform a secondary review of the appropriateness of the current or proposed level of care, including whether inpatient admission is medically necessary. In addition, Ms. Winter alleges that CMS uses the InterQual criteria when auditing and inspecting hospitals. Based on these allegations, Ms. Winter argues the failure to meet the InterQual criteria must have an impact on the Government's actual or likely behavior-i.e., because CMS uses InterQual criteria when auditing or inspecting hospitals. Mot. 18. The Court disagrees. The plain language of the Medicare statutes and regulations relied on by Ms. Winter do not support her argument that failure to meet InterQual criteria is material to the Government's decision to pay the claims. There is no mention of the InterQual criteria in any of the relevant statutes or regulations, and Ms. Winter has not cited to any other law, statute, or regulation that suggests that admission is not medically necessary simply because it does not meet the InterQual criteria. Moreover, the fact that CMS uses InterQual criteria when auditing or inspecting hospitals does not assist Ms. Winter's position because as the Medicare Program Integrity Manual Guidance states:

> CMS contractors are not required to automatically deny a claim that does not meet the admission guidelines of a screening tool. In all cases, in addition to screening instruments, the reviewer shall apply his/her own clinical judgment to make a medical review determination based on the documentation in the medical record.

CMS, News Flash: Guidance on Hospital Inpatient Admission Decisions, MLN No. SE 1037 Revised (July 31, 2012). Therefore, the Court concludes that Ms. Winter cannot establish that the failure to satisfy InterQual criteria would influence the Government's decision to pay the claims.

Accordingly, the Court **GRANTS** Defendants' Motions to Dismiss Ms. Winter's First and Second causes of action without leave to amend.

B. Conspiracy Claim

To maintain a claim for conspiracy under 31 U.S.C. Section 3729(a)(1)(C), a plaintiff must show: "(1) that the defendant conspired with one or more persons to get a false or fraudulent claim paid by the United States; (2) that one or more of the conspirators performed any act to effect the object of the conspiracy; and (3) that the United States suffered damages as a result of the false or fraudulent claim." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (internal citation and quotation marks omitted).

Because the Court concludes that Ms. Winter cannot demonstrate that Defendants submitted false claims based on the certifications that the inpatient services provided were medically necessary, Ms. Winter's conspiracy claim fails as a matter of law. *See, e.g., U.S. ex rel. Woodruff v. Haw. Pac. Health*, 560 F. Supp. 2d 988, 1004 (D. Haw. 2008) (holding that absent evidence of a false claim as alleged, the defendants cannot have conspired to have a false claim paid by the Government); *United States ex rel. Fent v. L-3 Commc'ns Aero Tech. LLC*, 2007 U.S. Dist. LEXIS 81976, 2007 WL 3283689, at *5 (N.D. Okla. Nov. 2, 2007) (holding that there can be no conspiracy "to submit a false claim if no false claim has been shown to exist"). Accordingly, the Court **GRANTS** Defendants' Motions to Dismiss Ms. Winter's conspiracy claim without leave to amend.

C. Retaliation Claim

The S&W Defendants and the RollinsNelson Defendants argue that Ms. Winter's retaliation claim must be dismissed because they were not her employer and, therefore, they cannot be liable for retaliation under Section 3730(h). Since 1986, the FCA has protected "whistleblowers" from retaliation "*by their employers*." *Moore v. Cal. Inst. of Tech. Jet Propulsion Lab*, 275 F.3d 838, 845 (9th Cir. 2002) (emphasis added). Although Congress removed the term "employer" from Section 3730(h) of the FCA when it amended the statute in 2009, courts have subsequently determined that the amendment was intended to broaden the category of employees eligible for whistleblower protection (to include contractors and agents), not to broaden the class of persons subject to

liability under this Section. *U.S. ex rel. Lupo v. Quality Assurance Servs., Inc.*, 242 F. Supp. 3d 1020, 1029 (S.D. Cal. 2017); *see, e.g.*, *Wichansky v. Zownie*, 2014 U.S. Dist. LEXIS 9586, 2014 WL 289924, at *3-5 (D. Ariz. Jan. 24, 2014); *Lipka v. Advantage Health Grp., Inc.*, 2013 WL 5304013, 2013 WL 5304013, at *12 (D. Kan. Sept. 20, 2013). Accordingly, the Court agrees with numerous other courts that have found that liability under Section 3730(h) does not extend to individuals, such as co-workers, supervisors, or corporate officers who lack an employment relationship with a plaintiff. *Accord United States v. Kiewit Pac. Co.*, 41 F. Supp. 3d 796, 814 (N.D. Cal. 2014); *Wichansky*, 2014 U.S. Dist. LEXIS 9586, 2014 WL 289924, at *3-5.

Ms. Winter argues that even if the statute is limited to claims against employers, the S&W Defendants and RollinsNelson Defendants are liable under Section 3730(h) as employers because they exercised dominion and control over her. However, the vague and conclusory allegations she relies on demonstrate, at best, that the S&W Defendants and RollinsNelson Defendants may have participated in the decision to terminate her merely because of the individuals' corporate positions and the corporations' ownership of Sycamore, which oversaw operations at Tri-City. These allegations are not sufficient to show that Ms. Winter had the required employment relationship with these defendants.[1] Indeed, Ms. Winter candidly admits that Tri-City was her employer. SAC ¶ 170.

1. Ms. Winter alleges that there is an alter ego relationship between S&W, Weiner, and RollinsNelson and between Rollins, Nelson, and RollinsNelson. However, she does not allege that any of these defendants have an alter ego relationship with Tri-City.

Accordingly, the Court concludes that Ms. Winter cannot maintain a retaliation claim against the S&W Defendants or the RollinsNelson Defendants and, therefore, the Court **GRANTS** their Motions to Dismiss the retaliation claim without leave to amend.

D. Leave to Amend Would Be Futile

Where a motion to dismiss is granted, a district court must decide whether to grant leave to amend. Generally, the Ninth Circuit has a liberal policy favoring amendments and, thus, leave to amend should be freely granted. *See, e.g., DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992). However, a Court does not need to grant leave to amend in cases where the Court determines that permitting a plaintiff to amend would be an exercise in futility. *See, e.g., Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 738 (9th Cir. 1987) ("Denial of leave to amend is not an abuse of discretion where the pleadings before the court demonstrate that further amendment would be futile.").

In light of the foregoing, the Court concludes that Ms. Winter's claims "cannot be saved by any amendment." *Miller v. Yokohama Tire Corp.*, 358 F.3d 616, 622 (9th Cir. 2004). Ms. Winter has had multiple opportunities to amend her original complaint and has not suggested any facts that she could add that could save her claims, and the Court cannot conceive of any amendment. Because Ms. Winter's claims rest entirely on her legally faulty theory that admitting patients that do not satisfy InterQual criteria gives rise to a false claim, the Court concludes

that it would be futile to permit Ms. Winter to further amend her complaint. *See id.* ("[w]here the plaintiff has previously filed an amended complaint . . . [a] district court's discretion to deny leave to amend is particularly broad.") (internal citation and quotation marks omitted).

IV. Conclusion

For all the foregoing reasons, Defendants' Motions are **GRANTED**. All of Ms. Winter's claims against the S&W Defendants, the RollinsNelson Defendants and Dr. Pascual are **DISMISSED, without leave to amend**. In light of the Court's ruling on the merits of Ms. Winter's claims and because identical law and facts on the issue of objective falsity apply to all of the defendants, the Court also concludes that non-moving defendants Rafaelito Victoria, M.D., Arnold Ling, M.D., Cynthia Miller-Dobalian, M.D., Edgardo Binoya, M.D., Namiko Nerio, M.D., and Manuel Sacapano, M.D. are entitled to dismissal of all of Ms. Winter's claims against them and that non-moving defendant Tri-City is entitled to dismissal of all of Ms. Winter's claims against it except for the retaliation claim. Accordingly, the Court exercises its discretion and *sua sponte* **DISMISSES, without leave to amend**, all of Ms. Winter's claims against the non-moving defendants except Ms. Winter's retaliation claim against Tri-City. *See Omar v. Sea-Land Serv., Inc.*, 813 F.2d 986 (9th Cir. 1987) ("A trial court may dismiss a claim sua sponte under Fed[eral Rule of Civil Procedure] 12(b)(6). . . Such a dismissal may be made without notice where the claimant cannot possibly win relief."); *see also Bonny v. Society of Lloyd's*, 3 F.3d 156, 161 (7th Cir. 1993) ("A court may

grant a motion to dismiss even as to nonmoving defendants where the nonmoving defendants are in a position similar to that of moving defendants or where the claims against all defendants are integrally related."). Accordingly, all claims in this action are **DISMISSED, with prejudice**, except Ms. Winter's retaliation claim against Tri-City.[2] Ms. Winter's counsel shall advise the Court on or before January 3, 2018 whether Ms. Winter intends to pursue her retaliation claim in the bankruptcy court or in this Court.

IT IS SO ORDERED.

2. Although Defendants have raised several other persuasive arguments in support of their motions-including whether Ms. Winter alleged the required elements of her FCA claims, specifically scienter, with the required particularity and specificity required by Federal Rules of Civil Procedure 8 and 9(b)-the Court concludes it is not necessary to address these arguments in light of its ruling.

APPENDIX C — ORDER DENYING REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT, FILED JULY 6, 2020

UNITED STATES COURT OF
APPEALS FOR THE NINTH CIRCUIT

No. 18-55020

JANE WINTER, EX REL.
UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

GARDENS REGIONAL HOSPITAL AND
MEDICAL CENTER, INC., DBA TRI-CITY
REGIONAL MEDICAL CENTER, A CALIFORNIA
CORPORATION; *et al.,*

Defendants-Appellees.

July 6, 2020, Filed

D.C. No. 2:14-cv-08850-JFW-E
Central District of California, Los Angeles

Appendix C

ORDER

Before: RAWLINSON, OWENS, and BENNETT, Circuit Judges.

The panel has voted to deny the petitions for panel rehearing and petitions for rehearing en banc.

The full court has been advised of the petitions for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35(f).

The petitions for panel rehearing and petitions for rehearing en banc are **DENIED**. (Dkt. 99, 100, 101).

APPENDIX D — STATUTES AND REGULATIONS

31 USCS § 3729

3729. False Claims

(a) Liability for certain acts.

(1) In general. Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers

the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) Reduced damages. If the court finds that—

1. So in original. Probably should read "Public Law 101-410".

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions. For purposes of this section—

(1) the terms "knowing" and "knowingly"—

(A) mean that a person, with respect to information—

(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; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"—

(A) 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—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means 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; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(c) Exemption from disclosure. Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) Exclusion. This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986 [26 USCS §§ 1 et seq.].

Appendix D

42 USCA § 1395y

§ 1395y. Exclusions from coverage and medicare as secondary payer

Effective: October 24, 2018

(a) Items or services specifically excluded.

Notwithstanding any other provision of this title [42 USCS §§ 1395 et seq.], no payment may be made under part A or part B [42 USCS §§ 1395c et seq. or 1395j et seq.] for any expenses incurred for items or services—

(1) **(A)** which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1861(ddd)(1) [42 USCS § 1395x(ddd)(1)]), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1861(s)(10) [42 USCS § 1395x(s)(10)], which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6) [42 USCS § 1395ww(e)(6)],

(E) in the case of research conducted pursuant to section 1142 [42 USCS § 1320b-12], which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1834(c)(2) [42 USCS § 1395m(c)(2)] or which is not conducted by a facility described in section 1834(c)(1)(B) [42 USCS § 1395m(c)(1)(B)], in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1861(nn) [42 USCS § 1395x(nn)], and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1861(uu) [42 USCS § 1395x(uu)],

(G) in the case of prostate cancer screening tests (as defined in section 1861(oo) [42 USCS § 1395x(oo)]), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d) [42 USCS § 1395m(d)],

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) [42 USCS § 1395w-3a(c)(6)(C)] for which payment is made under part B [42 USCS §§ 1395j et seq.] that is furnished in a competitive area under section 1847B [42 USCS § 1395w-3b], that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B [42 USCS §§ 1395j et seq.],

(L) in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1) [42 USCS § 1395x(xx)(1)]), which are performed more frequently than is covered under section 1861(xx)(2) [42 USCS § 1395x(xx)(2)],

(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1) [42 USCS § 1395x(yy)

(1)]), which is performed more frequently than is covered under section 1861(yy)(3) [42 USCS § 1395x(yy)(3)],

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA) [42 USCS § 1395x(s)(2)(AA)],

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg) [42 USCS § 1395x(ggg)]), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1861(hhh)(1) [42 USCS § 1395x(hhh)(1)]), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this Act and other than under a health benefits or

insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1861(aa)(1) [42 USCS § 1395x(aa)(1)], in the case of Federally qualified health center services, as defined in section 1861(aa)(3) [42 USCS § 1395x(aa)(3)], in the case of services for which payment may be made under section 1880(e) [42 USCS § 1395qq(e)], and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1814(f) [42 USCS § 1395(f)] and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this title [42 USCS §§ 1395 et seq.], physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part [42 USCS §§ 1395c et seq. or 1395j et seq.];

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8) [42 USCS § 1395x(s)(8)]) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) [42 USCS § 1395x(s)(10)] and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1861(s)(12) [42 USCS § 1395x(s)(12)];

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A [42 USCS §§ 1395c et seq.] in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1861(s)(2)(K) [42 USCS § 1395x(s)(2)(K)], certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient

of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1861(w)(1) [42 USCS § 1395x(w)(1)]) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate quality improvement organization (under part B of title XI [42 USCS §§ 1320c et seq.]) or a carrier under section 1842 [42 USCS § 1395u] has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1848(i)(2)(B) [42 USCS § 1395w-4(i)(2)(B)] applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997;

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a) [42 USCS § 1395w-3(a)]) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) [42

USCS § 1395w-3(b)] for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1888(e)(2)(A)(i) [42 USCS § 1395yy(e)(2)(A)(i)] and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1861(s)(2)(D) [42 USCS § 1395x(s)(2)(D)], which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1861(w)(1) [42 USCS § 1395x(w)(1)]) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1802(b) [42 USCS § 1395a(b)];

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician's professional services (as described in section 1861(s)(2)(A) [42 USCS § 1395x(s)(2)(A)]), that do not meet the standards and conditions (other

than any licensing requirement specified by the Secretary) under the second sentence of section 1861(p) [42 USCS § 1395x(p)] (or under such sentence through the operation of subsection (g) or (ll)(2) of section 1861 [42 USCS § 1395x]) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1861(m)(5) [42 USCS § 1395x(m)(5)], but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h), for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) [42 USCS § 1395m(e)(1)(B)] for which payment is made under the fee schedule established under section 1848(b) [42 USCS § 1395w-4(b)] and that are furnished by a supplier (as defined in section 1861(d) [42 USCS § 1395x(d)]), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B) [42 USCS § 1395m(e)(2)(B)];

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) [42 USCS § 1395rr(b)(14)]) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1861(aa)(3)(B) [42 USCS § 1395x(aa)(3)(B)].

In making a national coverage determination (as defined in paragraph (1)(B) of section 1869(f) [42 USCS § 1395ff(f)]) the Secretary shall ensure consistent with subsection (l) that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments

received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) Medicare as secondary payer.

(1) Requirements of group health plans.

(A) Working aged under group health plans.

(i) In general.

A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this title under section 226(a) [42 USCS § 426(a)], and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) Exclusion of group health plan of a small employer.

Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) Exception for small employers in multiemployer or multiple employer group health plans.

Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) Exception for individuals with end stage renal disease.

Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226 [42 USCS § 426]) would upon application be, entitled to benefits under section 226A [42 USCS § 426-1].

(v) "Group health plan" defined.

In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986 [26 USCS § 5000(b)(1)], without regard to section 5000(d) of such Code [26 USCS § 5000(d)].

(B) Disabled individuals in large group health plans.

(i) In general.

A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue of the individual's

current employment status with an employer is entitled to benefits under this title [42 USCS §§ 1395 et seq.] under section 226(b) [42 USCS § 426(b)].

(ii) Exception for individuals with end stage renal disease.

Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 226 [42 USCS § 426]) would upon application be, entitled to benefits under section 226A [42 USCS § 426-1].

(iii) "Large group health plan defined."

In this subparagraph, the term "large group health plan" has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986 [26 USCS § 5000(b)(2)], without regard to section 5000(d) of such Code [26 USCS § 5000(d)].

(C) Individuals with end stage renal disease.

A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is entitled to or eligible for benefits under this title [42 USCS §§ 1395 et seq.] under section 226A [42 USCS § 426-1] during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A [42 USCS §§ 1395c et seq.] under the provisions of section 226A [42 USCS § 426-1], or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 226A [42 USCS § 426-1] if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title [42 USCS §§ 1395 et seq.] when an individual is entitled to or eligible for benefits under this title [42 USCS §§ 1395 et seq.] under section 226A [42 USCS § 426-1] after the end of

the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 [enacted Aug. 5, 1997[1]], (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18-month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997 [enacted Aug. 5, 1997] [,] (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears.

(D) Treatment of certain members of religious orders.

In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an

1. So in original. The comma probably should not appear.

election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986 [26 USCS § 3121(r)].

(E) General provisions.

For purposes of this subsection:

(i) Aggregation rules.

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 [26 USCS § 52(a) or (b)] shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code [26 USCS § 414(m)]) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code [26 USCS § 414(n)(2)]) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of such Code [26 USCS § 414(n)].

In applying sections of the Internal Revenue Code of 1986 [26 USCS §§ 1 et seq.] under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) "Current employment status" defined. An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) Treatment of self-employed persons as employers. The term "employer" includes a self-employed person.

(F) Limitation on beneficiary liability. An individual who is entitled to benefits under this title [42 USCS §§ 1395 et seq.] and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) Medicare secondary payer.

(A) In general.

Appendix D

Payment under this title [42 USCS §§ 1395 et seq.] may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made[2] or can reasonably be expected to be made[3] under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure

2. So in original. Probably should be "made,".

to obtain insurance, or otherwise) in whole or in part.

(B) Conditional payment.

(i) Authority to make conditional payment.

The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii)[3] [subpara. (A)] has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) Repayment required.

Subject to paragraph (9), a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title [42 USCS §§ 1395 et seq.] with respect to an item or service if it is

3. So in original. Probably should be "subparagraph (A)".

demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) Action by United States.

Appendix D

In order to recover payment made under this title [42 USCS §§ 1395 et seq.] for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan. An action may not

be brought by the United States under this clause with respect to payment owed unless the complaint is filed not later than 3 years after the date of the receipt of notice of a settlement, judgment, award, or other payment made pursuant to paragraph (8) relating to such payment owed.

(iv) Subrogation rights.

The United States shall be subrogated (to the extent of payment made under this title [42 USCS §§ 1395 et seq.] for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) Waiver of rights.

The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this title [42 USCS §§ 1395 et seq.].

(vi) Claims-filing period.

Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(vii) Use of website to determine final conditional reimbursement amount.

(I) Notice to Secretary of expected date of a settlement, judgment, etc.

In the case of a payment made by the Secretary pursuant to clause (i) for items and services provided to the claimant, the claimant or applicable plan (as defined in paragraph (8)(F)) may at any time beginning 120 days before the reasonably expected date of a settlement, judgment, award, or other payment, notify the Secretary that a payment is reasonably expected and the expected date of such payment.

(II) Secretarial[4] providing access to claims information through a website.

The Secretary shall maintain and make available to individuals to whom items and services are furnished under this title (and to authorized family or other representatives recognized under regulations and to an applicable plan which has obtained the consent of the individual) access to information on the claims for such items and services (including payment amounts for such claims), including those claims that relate to a potential settlement, judgment, award, or other payment. Such access shall be provided to an individual, representative, or plan through a website that requires a password to gain access to the information. The Secretary shall update the information on claims and payments on such website in as timely a manner as possible but not later than 15 days after the date that payment is made. Information related to claims and payments subject to the notice under subclause (I) shall be maintained and made available consistent with the following:

4. So in original.

(aa) The information shall be as complete as possible and shall include provider or supplier name, diagnosis codes (if any), dates of service, and conditional payment amounts.

(bb) The information accurately identifies those claims and payments that are related to a potential settlement, judgment, award, or other payment to which the provisions of this subsection apply.

(cc) The website provides a method for the receipt of secure electronic communications with the individual, representative, or plan involved.

(dd) The website provides that information is transmitted from the website in a form that includes an official time and date that the information is transmitted.

(ee) The website shall permit the individual, representative, or plan to download a statement of reimbursement amounts (in

this clause referred to as a "statement of reimbursement amount") on payments for claims under this title relating to a potential settlement, judgment, award, or other payment.

(III) Use of timely web download as basis for final conditional amount.

If an individual (or other claimant or applicable plan with the consent of the individual) obtains a statement of reimbursement amount from the website during the protected period as defined in subclause (V) and the related settlement, judgment, award or other payment is made during such period, then the last statement of reimbursement amount that is downloaded during such period and within 3 business days before the date of the settlement, judgment, award, or other payment shall constitute the final conditional amount subject to recovery under clause (ii) related to such settlement, judgment, award, or other payment.

(IV) Resolution of discrepancies.

If the individual (or authorized representative) believes there is a discrepancy with the statement of reimbursement amount, the Secretary shall provide a timely process to resolve the discrepancy. Under such process the individual (or representative) must provide documentation explaining the discrepancy and a proposal to resolve such discrepancy. Within 11 business days after the date of receipt of such documentation, the Secretary shall determine whether there is a reasonable basis to include or remove claims on the statement of reimbursement. If the Secretary does not make such determination within the 11 business-day period, then the proposal to resolve the discrepancy shall be accepted. If the Secretary determines within such period that there is not a reasonable basis to include or remove claims on the statement of reimbursement, the proposal shall be rejected. If the Secretary determines within such period that there is a reasonable basis to conclude there is a discrepancy, the Secretary must respond in a timely manner by agreeing to the proposal to resolve the discrepancy or by

providing documentation showing with good cause why the Secretary is not agreeing to such proposal and establishing an alternate discrepancy resolution. In no case shall the process under this subclause be treated as an appeals process or as establishing a right of appeal for a statement of reimbursement amount and there shall be no administrative or judicial review of the Secretary's determinations under this subclause.

(V) Protected period.

In subclause (III), the term "protected period" means, with respect to a settlement, judgment, award or other payment relating to an injury or incident, the portion (if any) of the period beginning on the date of notice under subclause (I) with respect to such settlement, judgment, award, or other payment that is after the end of a Secretarial response period beginning on the date of such notice to the Secretary. Such Secretarial response period shall be a period of 65 days, except that such period may be extended by the Secretary for a period of an additional 30 days if the Secretary determines that additional time

is required to address claims for which payment has been made. Such Secretarial response period shall be extended and shall not include any days for any part of which the Secretary determines (in accordance with regulations) that there was a failure in the claims and payment posting system and the failure was justified due to exceptional circumstances (as defined in such regulations). Such regulations shall define exceptional circumstances in a manner so that not more than 1 percent of the repayment obligations under this subclause would qualify as exceptional circumstances.

(VI) Effective date.

The Secretary shall promulgate final regulations to carry out this clause not later than 9 months after the date of the enactment of this clause [enacted Jan. 10, 2013].

(VII) Website including successor technology.

In this clause, the term "website" includes any successor technology.

(viii) Right of appeal for secondary payer determinations relating to liability insurance (including self-insurance), no fault insurance, and workers' compensation laws and plans.

The Secretary shall promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this title for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan (as defined in paragraph (8)(F)) that is a primary plan under subsection (A)(ii)[5] [subpara. (A)], under which the applicable plan involved, or an attorney, agent, or third party administrator on behalf of such plan, may appeal such determination. The individual furnished such an item or service shall be notified of the plan's intent to appeal such determination[.][6]

(C) Treatment of questionnaires. The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a

5. So in original. Probably should be "subparagraph (A)".

6. So in original. Probably should be followed by a period.

primary plan.

(3) Enforcement.

(A) Private cause of action.

There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) Reference to excise tax with respect to nonconforming group health plans.

For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of the Internal Revenue Code of 1986 [26 USCS § 5000].

(C) Prohibition of financial incentives not to enroll in a group health plan or a large group health plan.

It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this title [42 USCS §§ 1395 et seq.] not to enroll (or to terminate enrollment) under a group health plan or a large group health plan

which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1128A [42 USCS § 1320a-7a] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [42 USCS § 1320a-7a(a)].

(4) Coordination of benefits.

Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this title [42 USCS §§ 1395 et seq.] (without regard to deductibles and coinsurance under this title [42 USCS §§ 1395 et seq.]) for the remainder of such charge, but—

(A) payment under this title [42 USCS §§ 1395 et seq.] may not exceed an amount which would be payable under this title [42 USCS §§ 1395 et seq.] for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this title [42 USCS §§ 1395 et seq.], when combined with the amount

payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this title [42 USCS §§ 1395 et seq.] on the basis of reasonable cost (or other cost-related basis) or under section 1886 [42 USCS § 1395ww], the amount which would be payable under this title [42 USCS §§ 1395 et seq.] on such basis, and

(ii) in the case of an item or service for which payment is authorized under this title [42 USCS §§ 1395 et seq.] on another basis—

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this title [42 USCS §§ 1395 et seq.] (without regard to deductibles and coinsurance under this title [42 USCS §§ 1395 et seq.]),

whichever is greater.

(5) Identification of secondary payer situations.

(A) Requesting matching information.

(i) Commissioner of Social Security.

The Commissioner of Social Security shall, not less often than annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(1)(12) of the Internal Revenue Code of 1986 [26 USCS § 6103(l)(12)]) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) Administrator.

The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of section 6103(l)(12) of the Internal Revenue Code of 1986 [26 USCS § 6103(l)(12)(B)].

(B) Disclosure to fiscal intermediaries and carriers. In addition to any other information provided under this title [42 USCS §§ 1395 et seq.] to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers

(or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) Contacting employers.

(i) In general.

With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 [26 USCS § 6051] by a qualified employer (as defined in section 6103(l)(12)(E)(iii) of such Code [26 USCS § 6103(l)(12)(E)(iii)]), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) Employer response.

Within 30 days of the date of receipt of

the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provisions of section 1128A [42 USCS § 1320a-7a] (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [42 USCS § 1320a-7a(a)].

(D) Obtaining information from beneficiaries.

Before an individual applies for benefits under part A [42 USCS §§ 1395c et seq.] or enrolls under part B [42 USCS §§ 1395j et seq.], the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(E) End date.

The provisions of this paragraph shall not apply to information required to be provided on or after July 1, 2016.

(6) Screening requirements for providers and suppliers.

(A) In general.

Notwithstanding any other provision of this title [42 USCS §§ 1395 et seq.], no payment may be made for any item or service furnished under part B [42 USCS §§ 1395j et seq.] unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) Penalties. An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1128A [42 USCS § 1320a-7a] (other than subsections (a) and (b)) shall apply to a civil money penalty under

the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [42 USCS § 1320a-7a(a)].

(7) Required submission of information by group health plans.

(A) Requirement.

On and after the first day of the first calendar quarter beginning after the date that is 1 year after the date of the enactment of this paragraph [enacted Dec. 29, 2007], an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall—

(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been—

(I) a primary plan to the program under this title; or

(II) for calendar quarters beginning on or after January 1, 2020, a primary

payer with respect to benefits relating to prescription drug coverage under part D; and

(ii) submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Enforcement.

(i) In general.

An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1128A [42 USCS § 1320a-7a] shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [42 USCS § 1320a-7a(a)]. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under

this title with respect to an individual.

(ii) Deposit of amounts collected.

Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund under section 1817 [42 USCS § 1395i].

(C) Sharing of information.

Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary—

(i) shall share information on entitlement under Part A [42 USCS §§ 1395c et seq.] and enrollment under Part B under this title [42 USCS §§ 1395j et seq.] with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii) may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii) may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(D) Implementation. Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(8) **Required submission of information by or on behalf of liability insurance (including self-insurance), no fault insurance, and workers' compensation laws and plans.**

(A) Requirement.

On and after the first day of the first calendar quarter beginning after the date that is 18 months after the date of the enactment of this paragraph [enacted Dec. 29, 2007], an applicable plan shall—

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this title [42 USCS §§ 1395 et seq.] on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Required information.

The information described in this subparagraph is—

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

Not later than 18 months after the date of enactment of this sentence [enacted Jan. 10, 2013], the Secretary shall modify the reporting requirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary

payer program under this subsection. Any such deadline extension notice shall include information on the progress being made in implementing such modification and the anticipated implementation date for such modification.

(C) Timing.

Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) Claimant. For purposes of subparagraph (A), the term "claimant" includes—

(i) an individual filing a claim directly against the applicable plan; and

(ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) Enforcement.

(i) In general.

An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant may be subject to a civil money penalty of up to $1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1128A [42 USCS § 1320a-7a] shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [42 USCS § 1320a-7a(a)]. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this title [42 USCS §§ 1395 et seq.] with respect to an individual.

(ii) Deposit of amounts collected.

Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) Applicable plan.

In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) Sharing of information.

The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(H) Implementation.

Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(I) Regulations.

Not later than 60 days after the date of the enactment of this subparagraph [enacted Jan. 10, 2013], the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for the specification of practices for which sanctions will and will not be imposed under subparagraph (E), including not imposing sanctions for good faith efforts to identify a beneficiary

pursuant to this paragraph under an applicable entity responsible for reporting information. After considering the proposals so submitted, the Secretary, in consultation with the Attorney General, shall publish in the Federal Register, including a 60-day period for comment, proposed specified practices for which such sanctions will and will not be imposed. After considering any public comments received during such period, the Secretary shall issue final rules specifying such practices.

(9) Exception.

(A) In general.

Clause (ii) of paragraph (2)(B) and any reporting required by paragraph (8) shall not apply with respect to any settlement, judgment, award, or other payment by an applicable plan arising from liability insurance (including self-insurance) and from alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) constituting a total payment obligation to a claimant of not more than the single threshold amount calculated by the Secretary under subparagraph (B) for the year involved.

(B) Annual computation of threshold.

(i) In general.

Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single threshold amount for 2014 shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for a year, the Secretary shall inform, and seek review of, the Comptroller

General of the United States with regard to such amount.

(ii) Publication. The Secretary shall include, as part of such publication for a year—

(I) the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents; and

(II) a summary of the methodology and data used by the Secretary in computing such threshold amount and such cost of collection.

(C) Exclusion of ongoing expenses.

For purposes of this paragraph and with respect to a settlement, judgment, award, or other payment not otherwise addressed in clause (ii) of paragraph (2)(B) that includes ongoing responsibility for medical payments (excluding settlements, judgments, awards, or other payments made by a workers' compensation law or plan or no fault insurance), the amount utilized for calculation of the threshold described in subparagraph (A) shall include only the cumulative value of

the medical payments made under this title [42 USCS §§ 1395 et seq.].

(D) Report to Congress.

Not later than November 15 before each year, the Secretary shall submit to the Congress a report on the single threshold amount for settlements, judgments, awards, or other payments for conditional payment obligations arising from liability insurance (including self-insurance) and alleged incidents described in subparagraph (A) for that year and on the establishment and application of similar thresholds for such payments for conditional payment obligations arising from worker compensation cases and from no fault insurance cases subject to this section for the year. For each such report, the Secretary shall—

(i) calculate the threshold amount by using the methodology applicable to certain liability claims described in subparagraph (B); and

(ii) include a summary of the methodology and data used in calculating each threshold amount and the amount of estimated savings under this title achieved by the Secretary implementing each such threshold.

(c) Drug products.

No payment may be made under part B [42 USCS §§ 1395j et seq.] for any expenses incurred for—

(1) a drug product—

(A) which is described in section 107(c)(3) of the Drug Amendments of 1962 [21 USCS § 321 note],

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and

(D) for which the Secretary has not determined there is a compelling justification for its medical need; and

(2) any other drug product—

(A) which is identical, related, or similar (as determined in accordance with section 310.6 of title 21 of the Code of Federal Regulations) to a drug product described in paragraph (1), and

(B) for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) Items or services provided for emergency medical conditions.

For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 [42 USCS § 1395dd] to an individual who is entitled to benefits under this title [42 USCS §§ 1395 et seq.], determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e) Item or service by excluded individual or entity or at direction of excluded physician; limitation of liability of beneficiaries with respect to services furnished by excluded individuals and entities.

(1) No payment may be made under this title [42 USCS §§ 1395 et seq.] with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) [42 USCS § 1320a-7, 1320a-7a, 1320c-5, or 1395u(j)(2)] from participation in the program under this title [42 USCS §§ 1395 et seq.]; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1128, 1128A, 1156 or 1842(j)(2) [42 USCS § 1320a-7, 1320a-7a, 1320c-5, or 1395u(j)(2)] from participation in the program under this title [42 USCS §§ 1395 et seq.] and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person).

(2) Where an individual eligible for benefits under this title [42 USCS §§ 1395 et seq.] submits a claim

for payment for items or services furnished by an individual or entity excluded from participation in the programs under this title [42 USCS §§ 1395 et seq.], pursuant to section 1128, 1128A, 1156, 1160 [42 USCS § 1320a-7, 1320a-7a, 1320c-5, 1320c-9] (as in effect on September 2, 1982), 1842(j)(2), 1862(d) [42 USCS § 1395u(j)(2), 1395y(d)] (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987 [enacted Aug. 18, 1987]), or 1866 [42 USCS § 1395cc], and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this title [42 USCS §§ 1395 et seq.], and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) Utilization guidelines for provision of home health services.

The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection

(a), under part A or part B [42 USCS §§ 1395c et seq. or 1395j et seq.] for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g) Contracts with quality improvement organizations.

The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title [42 USCS §§ 1395 et seq.], enter into contracts with quality improvement organizations pursuant to part B of title XI of this Act [42 USCS §§ 1320c et seq.].

(h) Waiver of electronic submission of claims.

(1) The Secretary—

(A) shall waive the application of subsection (a) (22) in cases in which—

(i) there is no method available for the submission of claims in an electronic form; or

(ii) the entity submitting the claim is a small provider of services or supplier; and

(B) may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term "small provider of services or supplier" means—

(A) a provider of services with fewer than 25 full-time equivalent employees; or

(B) a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) Awards and contracts for original research and experimentation of new and existing medical procedures; conditions.

In order to supplement the activities of the Medicare Payment Advisory Commission under section 1886(e) [42 USCS § 1395ww(e)] in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the type described in clause (ii) of section 1886(e)(6)(E) [42 USCS § 1395ww(e)(6)(E)(ii)] with respect to such a procedure if the Secretary finds that—

(1) such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2) research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3) such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

(j) Nonvoting members and experts.

(1) Any advisory committee appointed to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k) Dental benefits under group health plans.

(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)[7] [(b)(1)(A)(v)]) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.

(l) National and local coverage determination process.

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7. So in original. Probably should be "(b)(1)(A)(v)".

(1) Factors and evidence used in making national coverage determinations.

The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

(2) Timeframe for decisions on requests for national coverage determinations.

In the case of a request for a national coverage determination that—

(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) Process for public comment in national coverage determinations.

(A) Period for proposed decision.

Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

(B) 30-day period for public comment.

Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-day period for final decision.

Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

(i) make a final decision on the request;

(ii) include in such final decision summaries of the public comments received and responses to such comments;

(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) Consultation with outside experts in certain national coverage determinations.

With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

(5) Local coverage determination process.

(A) Plan to promote consistency of coverage determinations.

The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) Consultation.

The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) Dissemination of information.

The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

(D) Local coverage determinations.

The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

(i) Such determination in its entirety.

(ii) Where and when the proposed determination was first made public.

(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

(v) An explanation of the rationale that supports such determination.

(6) National and local coverage determination defined.

For purposes of this subsection—

(A) National coverage determination.

The term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

(B) Local coverage determination.

The term "local coverage determination" has the meaning given that in section 1869(f)(2)(B) [42 USCS § 1395ff(f)(2)(B)].

(m) Coverage of routine costs associated with certain clinical trials of category A devices.

(1) In general.

In the case of an individual entitled to benefits under part A [42 USCS §§ 1395c et seq.], or enrolled under part B [42 USCS §§ 1395j et seq.], or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) Category A clinical trial.

For purposes of paragraph (1), a "category A clinical trial" means a trial of a medical device if—

(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to

appropriate scientific and ethical standards; and

(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

(n) Requirement of a surety bond for certain providers of services and suppliers.

(1) In general.

The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

(2) Provider of services or supplier described.

A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the

level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1834(a)(16)(B) and 1861(o)(7)(C) [42 USCS §§ 1395m(a)(16)(B) and 1395x(o)(7)(C)].

(o) Suspension of payments pending investigation of credible allegations of fraud.

(1) In general.

The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

(2) Consultation.

The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier.

(3) Promulgation of regulations.

The Secretary shall promulgate regulations to carry out this subsection, section 1860D-12(b)(7) [42 USCS § 1395w-112(b)(7)] (including as applied pursuant to section 1857(f)(3)(D) [42 USCS

§ 1395w-27(f)(3)(D)]), and section 1903(i)(2)(C) [42 USCS § 1396b(i)(2)(C)].

(4) Credible allegation of fraud.

In carrying out this subsection, section 1860D-12(b)(7) [42 USCS § 1395w-112(b)(7)] (including as applied pursuant to section 1857(f)(3)(D) [42 USCS § 1395w-27(f)(3)(D)]), and section 1903(i)(2)(C) [42 USCS § 1396b(i)(2)(C)], a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

Appendix D

42 CFR 412.3

§ 412.3 Admissions.

(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. In addition, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622.

(b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is knowledgeable about the patient's hospital course, medical plan of care, and current condition. The practitioner may not delegate the decision (order) to another individual who is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.

(c) The physician order must be furnished at or before the time of the inpatient admission.

(d)(1) Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when

the admitting physician expects the patient to require hospital care that crosses two midnights.

(i) The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

(ii) If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A.

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A, regardless of the expected duration of care.

(3) Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the

admitting physician and medical record support for that determination. The physician's decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the medical record in order to be granted consideration.

(e) [Redesignated as subsection (d) by 79 FR 67030]