

**IN THE UNITED STATES DISTRICT  
FOR THE NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

UNITED STATES OF AMERICA,	§	
<i>ex rel.</i> MISTY WALL, Relator,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	No. 3:07-cv-00604-M
	§	
VISTA HOSPICE CARE, INC. d/b/a	§	
VISTACARE, and VISTACARE, INC.,	§	
	§	
Defendants.	§	

**MEMORANDUM OPINION AND ORDER**

Before the Court are Defendants’ Motion for Summary Judgment [Docket Entry #235], Motion to Strike the Testimony of Dr. Kriegler [Docket Entry #229], and Motion to Strike the Testimony of Dr. Karl Steinberg [Docket Entry #232], as well as Relator’s Motion to Strike the Opinion of Dr. Michael Salve [Docket Entry #246], Motion to Strike the Opinions of Drs. Bull and Hughes [Docket Entry #249], and Motion to Exclude Witnesses Pursuant to Rule 37(c)(1) [Docket Entry #254]. The Court held a hearing on the Motions on May 6, 2016. For the reasons stated on the record and in this Opinion, the Defendants’ Motions to Strike the Testimony of Drs. Kriegler and Steinberg are **GRANTED** in part, the Defendants’ Motion for Summary Judgment is **GRANTED** in part and **DENIED** in part, and Relator’s Motions are **DENIED** as moot.<sup>1</sup> Defendants also filed objections to Relator’s summary judgment evidence [Docket Entry #336]. To the extent the objections are not addressed below, they are **DENIED** as moot.

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<sup>1</sup> At the hearing, the Court also **DENIED** Defendants’ Motion to Strike Sur-Rebuttal Expert Testimony [Docket Entry #233], and Motion to Strike Testimony of Elizabeth Lattanzi and Barbara Huffstetler [Docket Entry #332] and will not address those Motions here.

## I. BACKGROUND

Relator Misty Wall brings this *qui tam* action on behalf of the United States for alleged violations of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (“FCA”), in connection with claims for the Medicare Hospice Benefit (“MHB”), between 2003 and 2012.

Defendants Vista Hospice Care, Inc. and VistaCare, Inc. (“the VistaCare entities” or “Defendants”)<sup>2</sup> provided hospice services in fourteen states during the relevant period, as to all of which Relator makes claims.<sup>3</sup> Approximately 93% of Defendants’ patients are Medicare beneficiaries.

Relator, a social worker employed at Defendants’ Denton, Texas office from April 2003 until April 2005, claims Defendants violated the FCA by: (1) causing patients who were not eligible for the MHB to be certified as eligible, and then submitting claims for ineligible patients; (2) certifying compliance with the Anti-Kickback Statute (“AKS”), while engaging in schemes to pay kickbacks to promote hospice enrollment; and (3) retaliating against Relator for lawful acts taken in furtherance of the Relator’s FCA claims. Relator claims such retaliation also violated the Texas Medicaid Fraud Prevention Act.

## II. PROCEDURAL HISTORY

Relator filed suit on April 6, 2007 [Docket Entry #1]. The Court dismissed a number of Relator’s claims, and Relator filed a Second Amended Complaint, asserting claims the Court had dismissed without prejudice [Docket Entry #58]. In light of new Fifth Circuit case law, the Court later granted Relator leave to reassert a claim previously dismissed with prejudice, and

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<sup>2</sup> Defendants have been acquired multiple times during this suit. Odyssey Healthcare, Inc. acquired the VistaCare entities in 2008. Gentiva Health Services acquired Odyssey in 2010, and Kindred Healthcare merged with Gentiva in early 2015. Only the VistaCare entities are named as defendants.

<sup>3</sup> The states are Alabama, Arizona, Colorado, Georgia, Indiana, Massachusetts, New Mexico, Nevada, Ohio, Oklahoma, Pennsylvania, South Carolina, Texas, and Utah.

Relator filed a Third Amended Complaint [Docket Entry #81]. On July 23, 2012, the Court dismissed more of Relator's claims [Docket Entry #91].

On August 30, 2013, Relator and Defendants jointly moved for leave for Relator to file a Fourth Amended Complaint. Other relators—Elizabeth Lattanzi and Barbara Huffstetler (nurses who had been employed by Defendants' Montgomery, Alabama location)—had filed another suit against the VistaCare entities, for alleged FCA violations that occurred after Relator's employment by the Defendants ended. The parties signed an agreement, dated August 30, 2013, by which Lattanzi and Huffstetler agreed to dismiss their case, and Defendants agreed to allow Relator to file her Fourth Amended Complaint, extending the relevant period in this case to 2012, and not to challenge Wall's status as Relator for the extended time period [Docket Entry #260, at A20]. Lattanzi and Huffstetler are not parties to this case, but they have signed an agreement with Relator that entitles them, collectively, to 35% of any recovery in this case.

### **III. THE MEDICARE HOSPICE BENEFIT**

The MHB is a benefit under Medicare Part A, a 100% federally subsidized health insurance program. The MHB is administered by the Centers for Medicare and Medicaid Services ("CMS") on behalf of the Department of Health and Human Services ("HHS"). The MHB pays a predetermined fee, based on the type of care provided by the hospice provider, for each day an eligible patient receives hospice care.<sup>4</sup>

The government conditions reimbursement to providers of hospice services on certification of hospice eligibility.<sup>5</sup> The MHB provides two 90-day benefit periods for eligible

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<sup>4</sup> That per diem payment is limited by two caps: the first limits the total amount a hospice provider can receive annually from Medicare for a particular patient, and the second limits the total amount a hospice provider can receive annually for all of its Medicare patients.

<sup>5</sup> 42 U.S.C. § 1395f.

patients, followed by an unlimited number of 60-day benefit periods.<sup>6</sup> At the end of each period, the patient can be recertified for hospice care if the patient still meets the requirements for eligibility.<sup>7</sup> During the first 90 days, a hospice provider must obtain a written certification that the patient is “terminally ill” from (1) the hospice medical director or a physician in the hospice interdisciplinary group (“IDG”),<sup>8</sup> and (2) the individual’s attending physician (if any).<sup>9</sup> For subsequent periods, certification of terminal illness may be from either the hospice medical director or a physician in the hospice IDG.<sup>10</sup> The hospice provider is to obtain the written certification “at the beginning of the period,”<sup>11</sup> and “must obtain the written certification before it submits a claim for payment.”<sup>12</sup> The regulations provide that “[i]f the hospice cannot obtain the written certification within 2 calendar days, after a period begins, it must obtain an oral certification within 2 calendar days and the written certification before it submits a claim for payment.”<sup>13</sup>

A patient is terminally ill when “the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.”<sup>14</sup> The attending physician and medical director must certify that the patient is terminally ill based on their clinical judgment of normal course of the patient’s illness.<sup>15</sup> “Clinical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical

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<sup>6</sup> 42 U.S.C. § 1395d(a)(4).

<sup>7</sup> *Id.* § 1395f(a)(7).

<sup>8</sup> The IDG must include at least one physician, one registered professional nurse, one social worker employed by the agency or organization, and at least one pastoral or other counselor. 42 C.F.R. § 418.56.

<sup>9</sup> 42 U.S.C. § 1395f(a)(7)(A)(i). The attending physician is a physician, who may or may not be employed by the hospice, “whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.” 42 U.S.C. § 1395x(dd)(3)(B).

<sup>10</sup> 42 U.S.C. § 1395f(a)(7)(A)(ii).

<sup>11</sup> 42 U.S.C. § 1395f(a)(7)(A).

<sup>12</sup> 42 C.F.R. § 418.22.

<sup>13</sup> 42 C.F.R. § 418.22.

<sup>14</sup> 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3.

<sup>15</sup> 42 U.S.C. § 1395f(a)(7).

record . . . . Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment."<sup>16</sup> The certification also must include a narrative description of the patient, and the certifying physician must "confirm[ ] that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient."<sup>17</sup>

"[E]ligibility for hospice services under the [MHB] has always been based on the prognosis of the individual, not [the] diagnosis . . . ."<sup>18</sup> The prognosis takes into account the diagnoses and all other things that relate to a patient's life expectancy.<sup>19</sup> Thus, "the medical director must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness."<sup>20</sup>

CMS recognizes that prognostication is "uncertain" and not "an exact science." In a Program Memorandum to Intermediaries/Carriers, CMS has stated:

Recognizing that prognoses can be uncertain and may change, Medicare's benefit is not limited in terms of time. Hospice care is available as long as the patient's prognosis meets the law's six month test. This test is a general one. As the governing statute says: "The certification of terminal illness of an individual who elects hospice shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." CMS recognizes that making medical prognostication of life expectancy is not always an exact science. Thus, physicians need not be concerned. There is no risk to a physician about certifying an individual for hospice care that he or she believes to be terminally ill.<sup>21</sup>

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<sup>16</sup> 42 C.F.R. § 418.22.

<sup>17</sup> 418.22(b)(3)(iii).

<sup>18</sup> 78 Fed. Reg. 48234, 48245 (Aug. 7, 2013).

<sup>19</sup> 78 Fed. Reg. 48234, 48245-46.

<sup>20</sup> 73 Fed. Reg. 32088, 32138 (June 5, 2008); 42 C.F.R. § 418.25(b) ("In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information: (1) Diagnosis of the terminal condition of the patient; (2) Other health conditions, whether related or unrelated to the terminal condition; (3) Current clinically relevant information supporting all diagnoses.").

<sup>21</sup> *Program Memorandum Intermediaries/Carriers, Subject: Provider Education Article*, CMS-Pub. 60AB (Mar. 28, 2003) (quoting 42 U.S.C. § 1395f(a)(7)) (A1275-81).

CMS has not created clinical benchmarks that must be satisfied to certify a patient as terminally ill. In 2008, CMS announced a rule specifying what a hospice medical director “must consider” in making an initial certification.<sup>22</sup> CMS initially proposed a rule labeling considerations as “criteria,” but removed that word, explaining:

In the proposed rule, we called [areas to consider] “criteria,” and we believe that this term may have been the source of commenter concern. Our intent was to ensure that medical directors carefully examine all relevant information that is gathered about the patient before making this determination . . . . We have removed the term “criteria” in order to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness.<sup>23</sup>

CMS guidance also states that a patient who stabilizes or improves may nevertheless remain eligible for hospice care.

[B]eneficiaries in the terminal stage of their illness that originally qualify for the [MHB] but stabilize or improve while receiving hospice care, yet have a reasonable expectation of continued decline for a life expectancy of less than 6 months, remain eligible for hospice care. The [hospice medical director] must assess and evaluate *the full clinical picture* of the Medicare hospice beneficiary to make the determination whether the beneficiary still has a medical prognosis of 6 months or less, regardless of whether the beneficiary has stabilized or improved.<sup>24</sup>

*See also* 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010) (“A patient’s condition may temporarily improve with hospice care.”); 74 Fed. Reg. 39384, 39399 (Aug. 6, 2009) (“We also acknowledge that at recertification, not all patients may show measurable decline.”).

CMS administers Medicare through Medicare Administrative Contractors (“MACs”), private companies that process and pay Medicare claims. MACs issue Local Coverage

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<sup>22</sup> 42 C.F.R. § 418.102(b) (“The physician must consider the following when making this determination: (1) The primary terminal condition; (2) Related diagnosis(es), if any; (3) Current subjective and objective medical findings; (4) Current medication and treatment orders; and (5) Information about the medical management of any of the patient’s conditions unrelated to the terminal illness.”).

<sup>23</sup> 73 Fed. Reg. 32088, 32138 (June 5, 2008).

<sup>24</sup> 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014) (emphasis added).

Determinations (“LCDs”), which are “administrative and educational tools to assist providers in submitting correct claims,” and they also give “guidance to the public and medical community.”<sup>25</sup> Each LCD covers only a specific geographical area,<sup>26</sup> and LCDs specify different clinical criteria depending on the primary terminal diagnosis of the patient. Meeting the clinical criteria in LCDs for the patient’s primary diagnosis is *one path* to eligibility under the MHB, but hospices may “otherwise demonstrate to the [MAC] that the patient has a terminal prognosis.”<sup>27</sup> Thus, although a patient may not meet an LCD’s criteria for a primary diagnosis, evidence of terminal decline or other comorbidities, like additional diagnoses, could justify a prognosis of less than six months.<sup>28</sup>

Hospice providers use various clinical tools to document eligibility, specifically the Functional Assessment Staging Scale (“FAST”), the Palliative Performance Scale (“PPS”), and Mid-Arm Circumference (“MAC”). The FAST scoring, generally used for Alzheimer’s and dementia patients, ranges from one to seven, with one indicating fully functional, and seven representing complete loss of function.<sup>29</sup> The PPS also measures functionality, with 100% representing fully functional, and 0% death.<sup>30</sup> MAC is used to measure a decline in weight. CMS does not require particular FAST or PPS scores or a change in MAC for eligibility, and the

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<sup>25</sup> Medicare Program Integrity Manual, Ch. 13.1.3, *available at* <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf>.

<sup>26</sup> The MACs at issue here are Palmetto GBA and National Government Services (“NGS”). *See* Kriegler Report, Def. Appx. at 524.

<sup>27</sup> Steinberg Report, Rel. Appx. at 8. The parties agree that, at least under the LCDs at issue, failure to meet criteria in an LCD does not mean a patient is ineligible. *See* Resp. to Mot. for Summary J. [Docket Entry #302-1] at 3 (referring to LCDs as “guidance” and “a key tool.”); Steinberg Rebuttal Report, Rel. Appx. at 497–98 (“If the patient met the LCDs, in general I found them to be per se eligible. . . . I concluded in some cases that patients could be eligible even when they clearly did not meet the LCDs after looking at the patient’s decline, comorbidities, and other clinical factors.”); Steinberg Depo, Docket Entry #239-2, at A 973 (stating that LCDs are “guidelines,” are “not requirements,” and patients “definitely can” be eligible for the MHB if they do not satisfy all the criteria in an LCD).

<sup>28</sup> Def. Appx. at 972–73.

<sup>29</sup> Steinberg Report, Rel. Appx. at 8–9.

<sup>30</sup> *Id.*

parties agree that, although some LCDs use such scores to determine automatic coverage, they are not necessary for eligibility. As Relator's expert acknowledged, determination of terminal illness is not based on any set of clinical benchmarks.<sup>31</sup>

In order to receive the MHB, an eligible patient must file an election statement acknowledging that the patient "has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness."<sup>32</sup> Palliative care is "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering" and "involves addressing physical, intellectual, emotional, social, and spiritual needs and . . . facilitat[ing] patient autonomy, access to information, and choice."<sup>33</sup> The election must also acknowledge that "certain Medicare services" are waived by the election, namely "Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition," except for services provided by the designated hospice or the individual's attending physician.<sup>34</sup> As long as a particular treatment does not extend a patient's life expectancy beyond six months, the regulations do not specify that the decision to receive any treatment renders a patient ineligible.

An election of hospice care continues through the initial election period and through subsequent election periods without a break in care as long as the individual: (1) remains in the care of a hospice; (2) does not revoke the election; and (3) is not discharged.<sup>35</sup> A patient is free to revoke the election of the MHB at any time and for any reason.<sup>36</sup>

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<sup>31</sup> Steinberg Depo., Docket Entry #239-2, at A 973-94.

<sup>32</sup> 42 C.F.R. § 418.24.

<sup>33</sup> 42 C.F.R. § 418.3.

<sup>34</sup> 42 C.F.R. § 418.24; *see also* 42 U.S.C. § 1395y(a)(1)(c) ("[N]o payment may be made . . . for any expenses incurred for items or services . . . in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness.").

<sup>35</sup> 42 C.F.R. § 418.24.

<sup>36</sup> 42 C.F.R. § 418.28.



#### **IV. RELATOR'S EVIDENCE**

Relator's evidence consists of: (1) documents and testimony alleged to establish "a culture of admitting and maintaining patients who were ineligible for hospice," including depositions of Wall, Lattanzi, Huffstetler, and some of Defendants' other employees, who describe pressure allegedly imposed on them and others to falsify information in patient charts, which allegedly resulted in such information being falsified, and physicians certifying patients without reviewing patient files;<sup>37</sup> (2) a report by Relator's expert, Dr. Steinberg, a hospice physician, summarizing his review of 291 patient files and conclusion that a large percentage of those patients were not eligible for the MHB for at least some days they were on the MHB, because they did not have a prognosis of six months or less; and (3) a report by Dr. Kriegler, Relator's expert statistician, in which he extrapolates from Dr. Steinberg's report to draw conclusions about the number of false claims submitted for approximately 12,000 patients.

##### **A. DEFENDANTS' BUSINESS PRACTICES AND CULTURE**

###### ***1. "Open Access" Policy***

Relator points to Defendants' "Open Access" philosophy, arguing "VistaCare educated its employees to admit patients 'early' in their illness, thereby extending the period of time during which a patient could receive the benefits of hospice care."<sup>38</sup> Relator notes that hospice providers with open access philosophies are the most profitable providers, and that Defendants adopted the philosophy in part to increase profits. Defendants admit they hoped to have a profitable business, but claim they did not admit patients before they reached eligibility, instead attempting to enroll patients as soon as they were eligible. Indeed, Defendants advertised the

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<sup>37</sup> Relator also points to evidence which does not appear relevant to any false claim, specifically, evidence that Defendants withdrew expensive services from patients after enrollment and encouraged patients to revoke hospice care if they wanted to pursue expensive treatments.

<sup>38</sup> Resp. at 5.

Open Access philosophy as a “philosophy of care . . . that accepts all *eligible* patients, regardless of medical complexity, hope for recovery, environment of care, or financial restrictions.”<sup>39</sup>

Defendants claim that, because CMS pays a per diem regardless of the cost of services, some providers would not admit patients with expensive care needs, while Defendants would admit such patients.<sup>40</sup>

## ***2. Admitting Patients Before Determining Eligibility***

Relator alleges Defendants had a policy of admitting patients prior to determining their eligibility, with the intention of discharging ineligible patients before the first benefit period expired. Wall testified, “I was often told to admit people, and we will determine eligibility later,”<sup>41</sup> and Dr. Priscu, a contract doctor at the Indianapolis location, stated that he believed “it came from corporate that [nurses] were supposed to admit the patient and then we would determine eligibility very soon thereafter,”<sup>42</sup> and that, as a result, he “was recommending discharge on an awful lot of patients that had been admitted whenever, a day before, three days before.”<sup>43</sup> Lattanzi testified that, during her training, she watched “a computer module on eligibility that said it’s okay to admit people who are not eligible because we can watch them.”<sup>44</sup> She claimed bills were submitted for such patients, but later admitted she “[was]n’t involved in billing” and “did not know the specifics of billing” and that she believed bills were submitted for those patients because it “just makes sense.”<sup>45</sup> Lattanzi’s conclusion regarding the submission of bills is inadmissible as speculative, and not based on personal knowledge, and thus will not be considered on the pending motions.

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<sup>39</sup> Resp. at 5–6 (emphasis added).

<sup>40</sup> *Id.*

<sup>41</sup> Rel. Appx. at 1673.

<sup>42</sup> *Id.* at 2109.

<sup>43</sup> *Id.* at 2111.

<sup>44</sup> *Id.* at 1934–40.

<sup>45</sup> *Id.* at 1941–42.

Charlene Ross, a former VistaCare compliance officer, stated the company “would say [to] admit a patient . . . if you found the patient, based on the referral, based on the verbal certification of the physician, prognosis was six months or less,” but if after additional observation employees concluded “that the patient wasn’t eligible,” to discharge the patient.<sup>46</sup> Relator claims that, because of this policy, Defendants were submitting claims for ineligible patients, pointing to a 2006 email in which one of Defendants’ employees advised Ross, “[t]he sites have been instructed that when in doubt they can admit the patient and then if after two months the patient is not eligible, do a [Discharge Medically Ineligible (“DMI”).]” Ross responded:

We should always err on the side of a patient when admitting to hospice. VistaCare has a standard of 7 days to help as a guideline to determine on best judgment if the patient is eligible or not on admission. It is to give us time to gather the necessary supporting information for eligibility. If we feel at that time that the patient does not meet eligibility, then we discharge and do not bill Medicare. However, our assessment for eligibility should be ongoing, not to wait for 2 months and then decide. . . . In general, the supporting documentation does not have to be present prior to admission. However, you do have to obtain documentation which goes back to our standard of 7 days to finalize our determination of admission eligibility.<sup>47</sup>

Ross explained Defendants’ policy in her deposition, saying:

[T]here’s shades of gray related to eligibility. And our philosophy was to err on the side of the patient. If the physician believed the patient had [a] prognosis of six months or less, they would admit them because the physicians gave us our certification. And then we would gather the information to help support it.<sup>48</sup>

In a 2004 email, VistaCare CEO Richard Slager explained VistaCare’s policy to Chief Medical Officer Dr. Bruce Chamberlain:

If a patient is eligible, we should take them in. If the eligibility is gray, we want to error [*sic*] on the side of the patient (in all sites). Morally, ethically

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<sup>46</sup> Rel. Appx. at 1305.

<sup>47</sup> Rel. Appx. at 1479–80.

<sup>48</sup> Rel. Appx. at 1309.

and philosophically I believe that this is the right thing to do. I would rather find myself on the side of the patient th[a]n on the side of refusing a patient who is in the vast gray zone of hospice eligibility. . . . When someone is brought to our door that is in the gray zone, our question should be how is this person eligible, help me legitimately build a case for eligibility, not the reverse. . . . I would never advocate taking on an ineligible patient, but I'd hate even more denying eligibility to someone who if we just dug a little deeper, asked the right questions, physically visited with the patient or listened more attentively to the attending physician or our gut, we would find to be eligible.<sup>49</sup>

### ***3. Policy for Discharging Patients***

Relator claims that Defendants knowingly kept ineligible patients on hospice by making it difficult to discharge them. Hospice providers may discharge patients based on (1) a patient's choice to move to another hospice or to revoke the MHB, (2) because the patient is dangerous or disruptive, or (3) because the patient is not eligible for the MHB.<sup>50</sup>

Relator points to a 2004 email, from Dr. Chamberlain to Defendants' Chief Compliance Officer, Roseanne Berry, stating, "[w]e have an excellent live discharge process in place that gives the patient two and often three or four reviews before the live discharge takes place."<sup>51</sup>

From his review of corporate documents, Relator's expert, Dr. Steinberg, concluded that several weeks before it was time to recertify a patient for eligibility, a nurse employed by Defendants would review the patient's condition, and, if the nurse was not sure whether the patient was eligible, the nurse would discuss the patient's condition with the attending physician "to determine if there [wa]s additional support for eligibility."<sup>52</sup> Then, if the patient appeared ineligible, his or her records would be sent to the Medical Review Team, which could "direct [nurses] to assess the patient's eligibility under other diagnos[e]s, suggest a diagnostic or

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<sup>49</sup> Rel. Appx. at 2601.

<sup>50</sup> 42 C.F.R. § 418.26.

<sup>51</sup> Rel. Appx. 2602.

<sup>52</sup> Rel. Appx at 29–30

laboratory test, or recommend a visit from [a] Medical Director for further evaluation. . . . to ensure that all eligible patients receive[d] the hospice benefit they deserve[d].”<sup>53</sup> A patient’s medical records would then be reviewed by the Defendants’ Area or Regional Medical Director and, in some cases, by Area Vice Presidents and Executive Directors.<sup>54</sup> An email sent by a Medical Clinical Review Advisor to Ross stated that review by an Area Medical Director significantly increased percentages of patients found eligible.<sup>55</sup>

#### ***4. Training on Charting and Prognoses***

Relator claims Defendants trained their staff to use charting practices to make ineligible patients appear eligible for the MHB. VistaCare’s Care Process Guideline stated that “documentation should justify that the patient is terminally ill with a prognosis of 6 months or less. . . . Compile forms in the patient’s medical record that will assist in supporting eligibility,” and that, “on each visit, [Defendants’ employees were to] document information related to the patient’s terminal diagnosis.”<sup>56</sup> The form instructed employees not to use vague or general terms, using as examples terms that would undermine eligibility—e.g., “stable,” “having a great day,” and “offers no complaints.”<sup>57</sup> VistaCare’s Admission Eligibility Worksheet stated that users should paint a picture of the person and factors contributing to a limited prognosis.<sup>58</sup> Lattanzi testified that “they teach you . . . in orientation how that note needs to be written. They tell you to ‘paint a picture of eligibility.’”<sup>59</sup> She claimed that, when filling out patient evaluations, “[y]ou couldn’t make statements like [‘stable,’ or ‘no change’ or ‘doing well’].”<sup>60</sup>

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<sup>53</sup> *Id.* (quoting Phyllis Rust, RN, former head of the Medical Review Team).

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* at 30.

<sup>56</sup> *Id.* at 932–33.

<sup>57</sup> *Id.* at 582–85, 932.

<sup>58</sup> *Id.* at 38–40, 1318.

<sup>59</sup> *Id.* at 1806–07.

<sup>60</sup> *Id.* 1861–62.

Relator also cites a presentation given by VistaCare’s Chief Medical Director, Dr. John Manfredonia, at VistaCare’s Western Regional Medical Directors Symposium, on January 20, 2017, which included a slide stating “>90% of prognoses are over-estimated; Greater than half the time, life expectancy is *over*-estimated by more than twice the observed life span; Based on this, if a clinician feels an individual’s life expectancy is: 6 months, it is likely considerably shorter; 12 months, true life expectancy likely meets the HMB definition.”<sup>61</sup>

### ***5. Employee Testimony Regarding Falsifying Medical Records***

As a social worker, Wall was a member of the IDG, and claims she “weighed in on admissions and a patient’s eligibility.”<sup>62</sup> She claims physicians at the Denton location knowingly “allowed ineligible patients to be admitted to hospice and maintained on hospice”<sup>63</sup> and says that in IDG meetings, employees “routinely” discussed withdrawing services from ineligible patients to see if they “bec[a]me eligible once they deteriorated.”<sup>64</sup> She alleges that IDG meetings sometimes took place, and patients would be certified, with no medical director present, although she did not personally witness this conduct, and could not associate it with any claim or patient.<sup>65</sup> She claims an admissions coordinator forged a physician’s signature on a certification for one identified patient, but did not witness this conduct, and testified that she had no knowledge of whether the certification was subsequently approved by a physician or whether a claim was submitted for the patient.<sup>66</sup>

Regarding specific patients, Wall alleges a patient, J.M., was admitted with a primary diagnosis of breast cancer, but Defendants did not simultaneously obtain records supporting the

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<sup>61</sup> *Id.* at 1100.

<sup>62</sup> *Id.* at 1676–77.

<sup>63</sup> *Id.* at 1630, 1636–37.

<sup>64</sup> *Id.* at 1695.

<sup>65</sup> *Id.* at 1702–06.

<sup>66</sup> *Id.* at 1710–17

diagnosis, and two years later received records showing J.M. did not have cancer.<sup>67</sup> Wall does not know who certified the patient as eligible, whether the patient had an attending physician, or where the referral came from.<sup>68</sup> She also claims another patient, P.G., was admitted for an unverified terminal cancer diagnosis, that patient C.B. was admitted to the MHB, but did not meet LCD criteria for chronic obstructive pulmonary disease, and that patient G.G. was admitted to the MHB, despite not meeting certain criteria for dementia.<sup>69</sup>

Lattanzi and Huffstetler testified that they falsified patient records when instructed to do so by Defendants' supervisors, and that doctors relied on those false records to certify patients as eligible for the MHB. As a result, they claim ineligible patients were regularly admitted and maintained on hospice. Specifically, they allege that the Montgomery, Alabama patient care manager, executive director, and quality assurance nurse routinely placed sticky notes on patients' paperwork, instructing them to change data in patient evaluations.<sup>70</sup> Huffstetler testified she was "forced to change information" and changed PPS and FAST scores "all the time" to make patients "look more eligible,"<sup>71</sup> and that she "couldn't begin to count the number[ ] of times that [her] paperwork was returned [for her to change it] both as a case manager and especially as the admissions nurse."<sup>72</sup> She recalled one instance where she "scored [a patient as an 80 on the PPS scale] from objective material, and [a supervisor] . . . said to change it to 50 percent. [The physician] said it will not go as a certification unless it is under 50

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<sup>67</sup> *Id.* at 1722–29.

<sup>68</sup> *Id.* at 1726.

<sup>69</sup> *Id.* at 1731–36, 40–44.

<sup>70</sup> Rel. Appx. 1561–63; 1509–10 ("I would get my admissions paperwork back with sticky notes, 'Change this. Change that.' I had IDG meetings where the physician would say, 'the PPS has got to be lower than this.' I would score it as an 80 or a 60, and [the supervisor] would make me drop it to a 50, and the doctor told me, 'they won't admit on a 50 PPS. It's got to be lower,' so, [the supervisor] . . . told me 'Change your paperwork. Make it work.'"); Rel. Appx. 1806–07.

<sup>71</sup> Rel. Appx. 1584, 1518.

<sup>72</sup> Rel. Appx. 1509.

percent. . . . So, [the supervisor] said, ‘Change your paperwork.’<sup>73</sup> Huffstetler claims she then reduced the PPS score, but cannot remember if she told the physician she did so. She alleged another patient was admitted even though the patient was “with it all the way around mentally, physically,” and she described an instance where a patient was discussed in an IDG meeting and recertified, although the nurse responsible for that patient was not present and had not completed an assessment of the patient.<sup>74</sup>

Lattanzi also claimed she was “told to change . . . objective data on a visit so it looks like someone’s eligible” and to “make these people look really bad so we get payment.”<sup>75</sup> She alleged “you’d say something about a patient, about them being ineligible, and [a supervisor] would kind of just say ‘make it work.’ And what ‘make it work’ meant was make that paperwork [meet LCD guidelines].”<sup>76</sup> As a result, she says the physicians got “bad information . . . . we fed it to [the physician] and he signed it.”<sup>77</sup> Lattanzi also claims one of the Montgomery physicians “would sign anything.”<sup>78</sup>

## **6. Focus on Census**

Relator claims Defendants placed pressure on employees to certify patients in order to meet admissions and census goals for the number of patients admitted or on hospice during a particular time. In support, she points to evidence that, during the relevant period, Defendants had a live discharge rate that was approximately twice the national average,<sup>79</sup> which, according

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<sup>73</sup> Rel. Appx. 1519.

<sup>74</sup> Rel. Appx. 1506–07.

<sup>75</sup> Rel. Appx. 1928.

<sup>76</sup> *Id.* at 1809.

<sup>77</sup> *Id.* at 1788, 1802.

<sup>78</sup> *Id.* at 1907, 1960, 1962–64.

<sup>79</sup> *Id.* at 27–28.



to an email from Defendants' regional medical director, was due to "the pressure on the sites to convert high percentages of referrals to admissions."<sup>80</sup>

### **7. *Employee Bonuses for Referrals***

Relator presents evidence that Defendants offered financial incentives to all classes of its employees to generate admissions and retain patients, by paying bonuses to employees for meeting admission and census goals. These programs most frequently rewarded salespeople, but sometimes rewarded all staff. For example, the 2004 "Growth Incentive Plan" provided cash incentives to all site employees if the site reached a "target goal" for new admissions.<sup>81</sup> Site executive directors received \$1000 for hitting the admissions quota, and \$75 for each additional admission, and admission coordinators would receive \$500 for reaching the quota, and \$50 for each additional admission.<sup>82</sup> A "March Madness" plan awarded \$500 weekend getaways to the top executive directors, area vice presidents, and regional vice presidents in each region who exceeded admissions goals for the month, while a "Spring Madness" promotion awarded the same to patient care managers and admissions coordinators at sites in each area achieving the highest average compared to the plan for achieving admissions goals over three months.<sup>83</sup>

These policies were apparently instituted, despite the expressed discomfort of Defendants' compliance personnel with paying bonuses to clinical staff. With reference to Defendants' program called "Shooting for the Stars," in which employees could receive \$25 gift cards for referring eligible patients, Chief Compliance Officer Roseanne Berry stated she "was not comfortable with providing a one for one gift to . . . employees [for] bringing in an

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<sup>80</sup> *Id.* at 1250.

<sup>81</sup> *Id.* at 2611.

<sup>82</sup> *Id.* Relator claims that some hospice medical directors were employees and would have also received bonuses, but does not produce competent evidence to that effect. *See* Rel. Br. [Docket Entry #302-1] at 18 n. 108 (stating that "Wall testified that she had been told on more than one occasion that VistaCare medical directors received a bonus based on maintenance of average daily census").

<sup>83</sup> Rel. Appx. 945-52; *see also* Rel. Br. [Docket Entry #302-1] at 18-22

admission. A pizza party for the team, okay. Movie tickets for the team, okay. One for one, not so okay.”<sup>84</sup> Meeting notes from a 2006 meeting of Defendants’ Compliance Committee also confirm that Committee members were concerned that rewarding non-sales staff for individual referrals could be a “conflict of interest” that might “encourage inappropriate behaviors.”<sup>85</sup>

Relator claims these bonuses caused employees to falsify patient records to get ineligible patients certified.<sup>86</sup> However, Relator does not identify any ineligible patient who was enrolled so that an employee could get a bonus, nor does she provide testimony from an employee who falsified information to get a bonus.<sup>87</sup> Huffstetler and Lattanzi concluded, in testimony Relator tendered, that supervisors in the Montgomery office were rewarded with bonuses for admitting patients, but this testimony is based on hearsay and speculation from the spending habits of supervisors in the Montgomery office that they received bonuses.<sup>88</sup> That speculation is not admissible.

#### ***8. Gifts to Referral Sources***

Relator claims Defendants also rewarded their external referral sources. Wall testified she saw referral sources being given gift certificates, “swag,” and lunches,<sup>89</sup> and corporate documents state that referral sources could be given \$25 gift certificates, fresh cookies, and “golf kits.”<sup>90</sup> In one marketing initiative, referral sources who completed a survey were entered into a raffle to win a \$100 gift card.<sup>91</sup> Quarterly Sales Planners of Defendants budgeted for a happy hour, ladies tea, and quarterly luncheon for residents and staff at a nursing home.<sup>92</sup>

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<sup>84</sup> Rel. Appx. 1192 – 95; Rel. Appx. 940.

<sup>85</sup> *Id.* at 720–22.

<sup>86</sup> Wall Depo. at 173, Rel. Appx. 1674.

<sup>87</sup> *See* Rel. Appx. 1567.

<sup>88</sup> Rel. Appx. 1567–69, 1884–89.

<sup>89</sup> Rel. Appx. 1679.

<sup>90</sup> Rel. Appx. 1167–68.

<sup>91</sup> Rel. Appx. at 954.

<sup>92</sup> Rel. Appx. 2452.

## **B. EXPERT TESTIMONY**

### ***1. Dr. Kriegler***

Dr. Kriegler, a statistician, identified a patient population (“the Population”), defined as: (1) VistaCare patients who were discharged on or after January 1, 2004 and admitted on or before December 31, 2012; and (2) on hospice for a total of at least 365 days. Of the approximately 700,000 patients who received services from Defendants during the relevant time, approximately 12,000 met these parameters and were included in the Population.<sup>93</sup> Dr. Kriegler categorized patients in the Population into three strata based on their discharge dates: before Odyssey acquired Defendants (“the VistaCare period”), after the Odyssey acquisition (“the Odyssey period”), and after the Gentiva acquisition (“the Gentiva period”). Dr. Kriegler then selected a stratified sample of 291 patients for Dr. Steinberg to evaluate (“the Sample”).<sup>94</sup> Dr. Kriegler extrapolated from Dr. Steinberg’s analysis to form an opinion as to the total number of claims submitted by Defendants for the approximately 12,000 patients in the Population that were false.<sup>95</sup>

### ***2. Dr. Steinberg***

Dr. Steinberg, a practicing geriatrician, hospice and palliative care specialist and family physician, (1) provided an overview of the hospice industry; (2) reviewed Defendants’ policies and practices, including their “Open Access” policy, training on charting, and live discharge

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<sup>93</sup> Hr’g Tr. at 11.

<sup>94</sup> In selecting a stratified sample, a statistician divides a population into subpopulations and draws a sample from each subpopulation. Here, Dr. Kriegler initially randomly selected a small sample from each period, and requested that Defendants provide files for those patients. Defendants were not able to locate and produce some of the requested files. A greater number of missing files were from the VistaCare period than from the other two periods. As Dr. Kriegler explained, when a population contains such missing units, a non-stratified sample may include “over-representation from certain sub-groups and under-representation from others” which may lead to “biased inferences about the whole population.” Kriegler Rept. at 16-31, Def. Appx. 513–517. Thus, Dr. Kriegler chose to select a stratified sample. *Id.*

<sup>95</sup> 291 is approximately 2.4% of 12,000. Dr. Kriegler selected the sample size based on the resources available, but says it is “well beyond the minimum sample size criteria that statistics textbooks recommend.” Kriegler Rept. at 5–6, Def. Appx. 501–02.

policy; (3) offered the opinion that these policies likely affected eligibility determinations, leading to the submission of false claims; and (3) reviewed files for patients in the Sample and offered an opinion on whether the patients were eligible for the MHB, concluding that more than 90% of them were not eligible for at least some days they were receiving hospice care from Defendants.

Dr. Steinberg offered one opinion on eligibility, applying standards he claimed a neutral third-party reviewer, such as a reviewer from the Office of Medicare Hearings and Appeals, would use to review claims (which he also characterized as “how a reasonably prudent hospice” would review patients). Then, he offered a second “broader” and more “lenient” view of each patient’s chart, “giving VistaCare the benefit of the doubt, and making all assumptions in VistaCare’s favor,” which he characterized as an opinion on when no reasonable physician could determine a patient was eligible.<sup>96</sup> Relator alleges that all claims were false that were submitted for a patient during a time when no reasonable physician could have concluded the patient was eligible for hospice.

Dr. Steinberg stated that “other than the life expectancy of six months or less,” he is not aware of any clinical benchmarks that must be used to determine whether a patient is terminally ill.<sup>97</sup> To determine eligibility, he considered a variety of factors. He testified that, “focus[ing] on the clinical question of whether or not patients met eligibility requirements for hospice services on the basis of their medical conditions and their stated or apparent goals of care,”<sup>98</sup> he:

assessed each case objectively, keeping in mind not only the regulatory framework, standard practice and local coverage determinations for hospice

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<sup>96</sup> Steinberg Rep. at 40; Steinberg Depo. at 967 (“As a general statement . . . reasonable clinicians/physicians can disagree about things and not necessarily be wrong. . . I gave sort of what a reasonably prudent hospice would do, and then I kind of extended that to, like, you know, the absolute at which, you know, my more liberal eligibility periods were that which no reasonable clinician would—would think that person was hospice eligible.”).

<sup>97</sup> Steinberg Depo. at 972

<sup>98</sup> Steinberg Rept. at 42.

eligibility (LCDs . . . ) but also the practical, real-life issues involved in the day-to-day operations of a hospice[, and] . . . the evolution of hospice standards for eligibility and retention on service.<sup>99</sup>

## V. ANALYSIS

### A. MOTION TO STRIKE RELATOR'S STATISTICAL EXPERT

Relator claims Dr. Kriegler's sampling and extrapolation is sufficient to show both damages *and liability* for the Population, because Dr. Kriegler's proposed testimony is the only evidence regarding those patients and claims. The Court is not persuaded that Dr. Kriegler's extrapolation evidence is reliable and consequently will not rely on, or allow testimony about, conclusions Dr. Kriegler reached through such extrapolation. In this context, statistical sampling of the type done by Dr. Kriegler (and assisted by Dr. Steinberg's analysis), cannot establish liability for fraud in submitting claims for ineligible patients, as the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians. Even if extrapolation could support a False Claims Act claim for submitting MHB claims for patients with greater than six month prognoses, the facts do not justify such extrapolation here.

“[T]he essence of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole.” *United States v. Pena*, 532 F. App'x 517, 520 (5th Cir. 2013). As a general matter, “the applicability of the science of inferential statistics has long been recognized by the courts.” *Id.* (citing *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1017 (5th Cir. 1997)). However, extrapolation is not always appropriate. The permissibility of statistical sampling turns on “the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.” *Tyson Foods, Inc. v. Bouaphakeo*, 136

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<sup>99</sup> *Id.* at 40.

S. Ct. 1036, 1046 (2016); *see In re Chevron U.S.A., Inc.* 109 F.3d at 1017 (disapproving of a trial court’s plan in a mass tort action to hold a trial on thirty selected cases and extrapolate liability to 3,000 plaintiffs, because the trial court did not “explain how the verdicts in the thirty (30) selected cases are supposed to resolve liability for the remaining 2970 plaintiffs” and did not identify “variables . . . that will impact on both the property and personal injury claims in this litigation”). Where the nature of the claim requires an individualized determination, that determination cannot be replaced by “Trial by Formula.” *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 367 (2011) (rejecting plaintiffs’ attempt to establish liability by selecting a random sample of class members “as to whom liability for sex discrimination . . . would be determined” and applying the “percentage of claims determined to be valid . . . to the entire remaining class”).

No circuit has resolved whether statistical sampling and extrapolation can be used to establish liability in an FCA case where falsity depends on individual physicians’ judgment regarding individual patients.<sup>100</sup> A district court, however, recently rejected such extrapolation in a case similar to this one. In *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, claims were alleged to be false because patients were not eligible for the MHB, and the court held, on a discovery motion, that statistical sampling and extrapolation could not be used to establish liability. 2015 WL 3903675, at \*2 (D.S.C. June 25, 2015).<sup>101</sup> Because “each and every claim at

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<sup>100</sup> Extrapolation has been used to establish damages in FCA cases. *See U.S. v. Fadul*, 2013 WL 781614, at \*14 (D. Md. Feb. 28, 2013). It has also been used in administrative decisions regarding overpayments on Medicare claims and to establish liability in cases where the defendant has consented to its use. *See U.S. v. Krizek*, 859 F. Supp. 5, 7 (D.D.C. 1994); *United States ex. rel. Loughren v. UnumProvident Corp.*, 604 F.Supp.2d 259 (D. Mass. 2009). One court allowed extrapolation to prove liability at the default judgment stage. *United States v. Cabrera–Diaz*, 106 F. Supp. 2d 234, 234 (D.P.R. 2000). These cases are distinguishable. To show liability, unlike damages, a relator must meet each element of an FCA claim. *Life Care Centers of Am., Inc.*, 114 F. Supp. 3d at 563. Using statistical sampling to determine overpayment amounts in administrative cases is explicitly authorized by the overpayment statute, but not by the FCA. *Id.* at 562–63 (citing 42 U.S.C. § 1395ddd(f)(3)). In cases where defendants consented to extrapolation, there is no basis for assuming there was a court analysis, and thus, those cases are not instructive. Extrapolation from sampling may also be appropriate where the evidence establishes that a defendant’s objective approach was similar in all cases, making the sample a reasonable basis for extrapolation to the whole. That is not the case here.

<sup>101</sup> This decision is on appeal to the Fourth Circuit. *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 15-2145.

issue” was “fact-dependent and wholly unrelated to each and every other claim,” and determining eligibility for “each of the patients involved a highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient,” the court found the case was not “suited for statistical sampling.” *Id.* at \*2, \*8. *See also United States v. Medco Phys. Unlimited*, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at \*23 (N.D. Ill. Mar. 15, 2000) (on motion for summary judgment, rejecting extrapolation of expert’s findings from a sixteen-claim sample to support a conclusion that every claim defendant submitted to Medicare was fraudulent and noting lack of “case law or other authority to support such a request”).

Some district courts have allowed extrapolation in similar circumstances. *See United States v. Life Care Centers of Am., Inc.*, 114 F. Supp. 3d 549, 556 (E.D. Tenn. 2014); *United States v. Robinson*, 2015 WL 1479396, at \*5–6 (E.D. Ky. Mar. 31, 2015); *United States v. AseraCare Inc.*, 2015 WL 8486874 (N.D. Ala. Dec. 4, 2014).<sup>102</sup> Only *AseraCare* is a case involving hospice care. The question here is not whether Defendants provided services that were reasonable and necessary, but whether, “based on the physician’s or medical director’s *clinical judgment* regarding the normal course of the individual’s illness” a patient had a life expectancy of 6 months or less.<sup>103</sup> Although *Life Care* and *Robinson* involved the clinical picture of individual patients, they did not require examination of the *subjective clinical judgment* of a number of certifying physicians applying the “uncertain,” “change[able],” and “[in]exact

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<sup>102</sup> In *U.S. ex rel. Ruckh v. Genoa Healthcare, LLC*, a case involving upcoding at rehabilitation centers, the relator moved *in limine* to admit evidence of a statistical sample that had not yet been created. 11-cv-01303-SMD-TBM (M.D. Fla. Apr. 28, 2015). Citing *LifeCare* and *Robinson*, the court rejected the defendant’s position that a sample could never be used to demonstrate falsity in an FCA case. The opinion does not contain a detailed significant analysis, but relies on citations to the cases described above, and simply defers ruling on the admissibility of extrapolation in that case until the evidence can be considered.

<sup>103</sup> 42 U.S.C. § 1395f(a)(7).

science” involved in predicting an individual’s life expectancy.<sup>104</sup> *Robinson* is further distinguishable, because the defendant was a single optometrist, so extrapolation was not used to make determinations about numerous physicians at multiple locations.

To the extent these cases are not distinguishable from this case, this Court disagrees with their conclusions if they stand for the proposition that sampling and extrapolation are *always* reliable, regardless of the nature of the data and the nature of the claim. The Supreme Court and the Fifth Circuit have made clear that sampling and extrapolation cannot always be used to prove liability, and courts are required to engage in a particularized analysis of the whether extrapolation from a particular data set can reliably prove the elements of the specific claim. *See Dukes*, 564 U.S. at 367; *In re Chevron U.S.A., Inc.* 109 F.3d at 1017.

In *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016), the Supreme Court acknowledged that, “[i]n many cases, a representative sample is the only practicable means to collect and present relevant data establishing a defendant’s liability.” *Id.* at 1046. But *Tyson Foods* concluded that the permissibility of statistical sampling turns on “the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.” *Id.* Here, Relator’s statistical evidence is not reliable in proving that false claims were submitted.<sup>105</sup> Further, statistical evidence was not the only practicable means to present data establishing Defendants’ liability. Relator declined to evaluate the claims for the 12,000 patients in issue. If individual review of each chart were impractical, Relator was not required to pursue all potential false claims submitted in fourteen states over nearly a decade, of which she did not have personal

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<sup>104</sup> *Program Memorandum Intermediaries/Carriers, Subject: Provider Education Article*, CMS-Pub. 60AB (Mar. 28, 2003) (quoting 42 U.S.C. § 1395f(a)(7)) (A1275-81) (“There is *no risk* to a physician about certifying an individual for hospice care that he or she *believes to be terminally ill.*” (emphasis added)).

<sup>105</sup> Because the Court will not allow Dr. Kriegler to testify as to the results of extrapolation for the reasons addressed above, the Court does not reach Defendants’ argument that extrapolation to show liability would violate Defendants’ due process rights.



knowledge. These choices, made by Relator, do not reduce her burden to produce reliable evidence of liability.

As did the court in *Michaels*, this Court finds that when a relator alleges the falsity of MHB claims because various doctors improperly found patients were terminally ill, the relator cannot extrapolate based on an expert's after-the-fact examination of the medical charts of a sample of patients. As Dr. Steinberg recognized, "in the practice of hospice medicine, you have to look at the individual patient,"<sup>106</sup> and "certainly you can't extrapolate" from how one physician assessed a patient's eligibility to make conclusions about another physician.<sup>107</sup> Thus, proof regarding one claim does not meet Relator's burden of proof regarding other claims involving different patients, different medical conditions, different caregivers, different facilities, different time periods, and different physicians.

Even if extrapolation were sufficient to prove the kind of FCA violations alleged here, Dr. Kriegler's analysis is deficient, because his methodology was fundamentally flawed.<sup>108</sup> "[I]n order to fairly and reliably draw . . . an inference" from a sample, "the sample must be randomly selected and . . . representative of the whole." *Pena*, 532 F. App'x 517, 520–21. Dr. Kriegler's

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<sup>106</sup> Steinberg Depo. at 956.

<sup>107</sup> Steinberg Depo., Def. Appx. 978.

<sup>108</sup> Federal Rule of Evidence 702 provides that a "witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise." Fed. R. Evid. 702. The expert's testimony may be admissible under Rule 702 if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993) (scientific testimony or evidence must be relevant and reliable). To determine reliability of the evidence, the Court must make a threshold determination that the expert is testifying as to scientific knowledge and that such knowledge will assist the trier of fact. *U.S. ex rel. Martin v. Life Care Centers of Am., Inc.*, 2014 WL 4816006, at \*2 (E.D. Tenn. Sept. 29, 2014) (citing *Daubert*, 509 U.S. at 590). The burden is on the proponent of the expert testimony to establish its admissibility by a preponderance of the evidence. *Daubert*, 509 U.S. at 592.

sample was not randomly selected from the entire Population, and he did not control for variables even Dr. Steinberg identified as important.<sup>109</sup>

Dr. Kriegler recognized that, generally, if “a sample is not selected in a random fashion, then scientifically valid extrapolations and margin of error calculations are no longer valid” and stated that a correctly defined population and a random sample drawn from that population are “critical to one’s ability to make valid statistical inferences about the population.”<sup>110</sup> Yet he admittedly selected the sample from a Population that contained duplicates, and he randomly excluded patients from the Population.<sup>111</sup> He also misclassified approximately 1,100 patients when he stratified the Population, placing patients from the Odyssey period in the Gentiva period.<sup>112</sup> He testified he stratified the sample “so that each stratum [would be] represented in proportion with the [P]opulation,”<sup>113</sup> but, because his stratification was erroneous, misclassified patients had a zero probability of being selected in the Odyssey period (thus increasing the probability of selection for other patients in the Odyssey period), and instead had a positive probability of being selected in the Gentiva period (thus decreasing the probability of selection for patients actually discharged in the Gentiva period).

Dr. Kriegler’s errors in selecting the sample are fatal to his conclusions. Although he claims to have later corrected these errors, he does not sufficiently explain how he did so, and thus there is no way for opposing counsel or the Court to check his work. *See Elsholtz v. Taser*

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<sup>109</sup> The Court notes that on April 13, 2016, a California state court decertified a class in a class action after “entirely reject[ing]” a report authored by Dr. Kreigler as “clearly invalid and unreliable.” *Williams v. Allstate Ins.*, No. BC382577 (Cal. App. Dep’t Super. Ct. Apr. 13, 2016) (“Kriegler strains to reach results favorable to his client”).

<sup>110</sup> Kriegler Decl. ¶10, ¶23, Def. Appx. at 799, 805.

<sup>111</sup> Dr. Kriegler wrongly assumed a patient could only have one ID number, when in fact a patient could have multiple IDs, which led to duplicate patients in the Population, some of whom were selected in the Sample. Kriegler Depo. at 139–41, 164; Def. Appx. at 919, 921. Further, the Population excluded patients because Dr. Kriegler wrongly assumed patients with common names were duplicates, and then removed them. *Id.* at 215, 218.

<sup>112</sup> Kriegler Depo. at 42–43; Rel. Appx. at 905.

<sup>113</sup> Resp. Br. at 3 (citing to Kriegler Rep. ¶¶41-4).

*Intern., Inc.*, 2007 WL 2781664, at \*2–3 (N.D. Tex. Sept. 25, 2007) (a court cannot “determine whether an expert’s opinions are reliable when he fails to provide any details regarding the methodology he used to conduct the tests that give rise to those opinions.”); *United States v. Aegis Therapies, Inc.*, 2015 WL 1541491, at \*3 (S.D. Ga. Mar. 31, 2015) (“The expert’s assurances that he has utilized generally accepted scientific methodology are insufficient”).

Dr. Kriegler also failed to control for relevant variables: he did not differentiate geographically across the fourteen states where VistaCare operated, with different clinical staffs and doctors,<sup>114</sup> or by disease type. By ignoring these variables, Dr. Kriegler ignored the testimony of Relator’s hospice expert, who testified that the predictability of life expectancy varies based on types of terminal illness (for example, cancer outcomes are more predictable than Parkinson’s),<sup>115</sup> that different physicians and clinical staffs assess eligibility differently,<sup>116</sup> and that he was sure practices “vari[ed] among the different specific sites.”<sup>117</sup>

Dr. Kriegler could have controlled for these relevant variables. For example, in *Life Care Centers*, the relator’s statistical expert performed a series of pre-sampling design tasks to determine the “frequencies and distributions of certain variables” so as to identify variables that needed to be controlled, and performed hundreds of pre-sampling simulations to mitigate variability. 2014 WL 4816006, at \*5–6 (E.D. Tenn. 2014). Relator does not dispute that Dr. Kriegler could have controlled for these variables when designing the sample, but he did not.

Given the nature of the underlying data, the nature of liability under the FCA, and Dr. Kriegler’s failure to select a random sample or to account for relevant variables, his extrapolation

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<sup>114</sup> As a result, in the VistaCare period, five of the fourteen states VistaCare operated in are not represented in the sample; in the Odyssey period, four of the fourteen states are not represented; and in the Gentiva period, one state is not represented.

<sup>115</sup> Def. Appx. 981.

<sup>116</sup> Def. Appx. 978.

<sup>117</sup> Def. Appx. 1039.

is unreliable, even if it is assumed to be generally allowable. *See U.S. ex rel Trim v. McKean*, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998) (“[I]n light of the admittedly subjective nature of coding, the relatively small sample size, and the variation in years covered, . . . the audits are not a reliable or accurate representation of *all* EPBS claims.”). Thus, the Court will not permit him to extrapolate beyond the 291 patients.<sup>118</sup>

## **B. MOTION TO STRIKE RELATOR’S MEDICAL EXPERT**

As discussed at the hearing, the Motion to Strike Dr. Steinberg is **GRANTED** in part. Insofar as Dr. Steinberg summarized documents and testimony regarding Defendants’ marketing and business practices and then opined on how those practices impacted Defendants’ employees and the physicians who certified patients for hospice, such testimony is based on improper speculation, which the Court would not allow at trial, and thus the Court will not consider it. “Before a district court may allow a witness to testify as an expert, it must be assured that the proffered witness is qualified to testify by virtue of his ‘knowledge, skill, experience, training, or education.’” *United States v. Cooks*, 589 F.3d 173, 179 (5th Cir. 2009). Dr. Steinberg has no specialized knowledge, training, or experience that supports his conclusions about Defendants’ business practices, and it would not be helpful to a jury for him to surmise how such practices may have impacted the conduct of Defendants’ employees and others. *Daubert*, 509 U.S. at 579 (“The adjective ‘scientific’ implies a grounding in the methods and procedures of science. Similarly, the word ‘knowledge’ connotes more than subjective belief or unsupported speculation.”). Thus, Dr. Steinberg would not be allowed to testify that, among other things,

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<sup>118</sup> Because the Court is granting summary judgment as to Relator’s FCA claims, the Court need not reach the question of whether Dr. Kriegler could give testimony about claims submitted for the 291 patients whose files Dr. Steinberg evaluated.

“pressure from corporate would have caused ineligible patients to be admitted.” Steinberg Rept. at 31.

Further, “characterizations of documentary evidence” are not proper subjects for expert testimony, “because the trier of fact is entirely capable of determining whether or not to draw such conclusions without any technical assistance from . . . experts.” *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998). A large section of Dr. Steinberg’s report summarizes and describes documents produced by Defendants in the course of this litigation. *See, e.g.*, Steinberg Rept. at 28 (“It is clear from VistaCare’s documents that they had a formal, company-wide policy to have their Medical Review Team review all potential live discharges due to medical ineligibility.”); *id.* at 31 (“Based on the documents and witness testimony I have reviewed, VistaCare appears to have put immense pressure on its employees to maintain census.”). These summaries and characterizations would not be helpful to jurors, who are able make their own determinations about what relevant documents show, and such testimony therefore would not be allowed, and will not be considered here.

The Motion is also **GRANTED** insofar as Dr. Steinberg opines on Defendants’ intent. Although Relator maintains Dr. Steinberg did not comment on Defendants’ subjective intent, in fact, he testified that he could “opin[e] on the intent” of VistaCare.<sup>119</sup> He then did so, stating that Defendants: “intentionally” overstated PPS scores; “intentionally” misrepresented patient information to make them look eligible; “intentionally” overstated FAST scores; and had marketing materials that were “intentionally” deceptive.<sup>120</sup> Dr. Steinberg’s opinions on intent are inadmissible. *See U.S. ex rel. Ruscher v. Omnicare, Inc.*, 2015 WL 5178074, at \*6, \*11 (S.D.

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<sup>119</sup> Steinberg Depo. Def. Appx., at A 1064.

<sup>120</sup> Steinberg Depo., Def. Appx., at A 1064–65.

Tex. Sept. 3, 2015) (an expert “will not be permitted to testify about . . . intent, motive, or state of mind, as that is typically held to be within the province of the jury”).

The Court also would not allow Dr. Steinberg to make statements regarding standards for hospice eligibility that are belied by the record. Thus, the Court would not permit him to say that a patient must show measurable decline in order to remain eligible for the MHB,<sup>121</sup> that LCDs reflect criteria that patients must meet to be eligible, as opposed to constituting guidance,<sup>122</sup> and that patients are ineligible if they have not adopted a “hospice philosophy” (a mental orientation toward hospice beyond electing the MHB).<sup>123</sup> The Court **DENIES** the remainder of the Motion to Strike Dr. Steinberg.

### C. SUMMARY JUDGMENT STANDARD

Summary judgment is warranted “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56. A dispute as to a material fact is genuine if the evidence is sufficient to permit a reasonable factfinder to return a verdict for the nonmoving party. *Crowe v. Henry*, 115 F.3d 294, 296 (5th Cir. 1997). A fact is material if its resolution could affect the outcome of the action. *Weeks Marine, Inc. v. Fireman’s Fund Ins. Co.*, 340 F.3d 233, 235 (5th Cir. 2003). The substantive law determines which facts are material. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). A party seeking summary judgment who does not have the burden of proof at trial, like Defendants here, need only point to the absence of admissible evidence supporting the nonmovant’s claim. *See Duffy v. Leading Edge Prods., Inc.*, 44 F.3d 308, 312 (5th Cir. 1995).

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<sup>121</sup> See 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014) (patients may stabilize or improve and remain hospice eligible).

<sup>122</sup> See Resp. at 3 (referring to LCDs as “guidance” and “a key tool”); Steinberg Depo, Def. Appx., at A 973 (stating that LCDs are “guidelines,” are “not requirements,” and patients “definitely can” be eligible for the MHB if they do not satisfy all the criteria in an LCD).

<sup>123</sup> 42 C.F.R. § 418.24 (not requiring patients to have a particular mental state or orientation).

Once the movant meets its initial burden, the burden shifts to the nonmoving party to produce evidence or designate specific facts in the record showing the existence of a genuine issue for trial. *See Forderoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006).

#### **D. THE FALSE CLAIMS ACT**

The FCA establishes liability for “[a]ny person who . . . knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval . . . [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1–2).

When a *qui tam* suit is brought by a private relator and the government declines to intervene, the relator is entitled to approximately 30% of the recovery, § 3730(d)(2), as well as attorneys’ fees. Not all fraudulent conduct affecting the government is actionable under the FCA. *U.S. ex rel. Bennett v. Boston Sci. Corp.*, 2011 WL 1231577, at \*1 (S.D. Tex. Mar. 31, 2011) (Rosenthal, J.). “Evidence of an actual false claim is the ‘sine qua non of a False Claims Act violation.’” *Id.* at 2 (quoting *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)).

Generally, in considering liability under the FCA, the Fifth Circuit focuses on “(1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim).” *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 475 (5th Cir. 2012).

Under a false certification theory, a defendant may be liable where a claimant “falsely certifies compliance with [a] statute or regulation.” *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009) (quoting *U. S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*,

125 F.3d 899, 902 (5th Cir. 1997)). To prevail on such a claim of “legal falsity,” a relator must demonstrate that the defendant has improperly certified compliance with a statute or regulation (whether explicitly or impliedly), and that improper certification is material to the government’s payment decision. *Bennett*, 2011 WL 1231577, at 13 (citing *Thompson*, 125 F.3d at 902); *see also Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. \_\_ (2016).<sup>124</sup>

#### **E. RELATOR’S CLAIM THAT DEFENDANTS VIOLATED THE FCA BY ADMITTING AND MAINTAINING INELIGIBLE PATIENTS ON HOSPICE**

Relator claims some of Defendants’ patients were not eligible for the MHB, because they were not “terminally ill,” or because documentation supporting a six-month prognosis was not filed in their medical records. Fourth Am. Compl. [Docket Entry #121] at ¶82–83. Relator claims that as a result, the necessary certifications of eligibility and the Medicare claims for these patients were false.<sup>125</sup>

Medicare conditions reimbursement to hospice providers on certification that a patient “is terminally ill . . . based on the physician’s or medical director’s clinical judgment regarding the normal course of the individual’s illness.”<sup>126</sup> To show the certifications and related claims were false, Relator points to: (1) Dr. Steinberg’s opinions on patient eligibility; and (2) evidence of a

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<sup>124</sup> Relator’s only remaining claims rely on legal falsity. Relator originally asserted claims of factual falsity—that Defendants submitted an inaccurate description of goods or services provided or a request for reimbursement for goods or services never provided—but all such claims have been dismissed with prejudice. Opinion, Docket Entry #91, at 3 n. 15.

<sup>125</sup> The Supreme Court recently approved an implied false certification theory, under which FCA liability may attach when a defendant submits a claim for payment that “makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant’s noncompliance with a statutory, regulatory, or contractual requirement,” when such an “omission renders those representations misleading.” *Universal Health Servs., Inc.*, 579 U.S. \_\_. Relator’s Fourth Amended Complaint asserts that claims submitted for payment were “also false because [they] concealed the material fact that the individual for whom VistaCare was billing Medicare was not in fact eligible for hospice care or was certified for hospice care with deliberate indifference or a reckless disregard for whether that person was actually eligible for such care.” Compl. ¶ 84. The implied certification theory was not directly addressed by the parties in the briefing on the Motion for Summary Judgment, but, as Relator did not show Defendants admitted patients who were not properly certified to be terminally ill, the Court finds Relator cannot prevail under the implied certification theory set forth in her Complaint.

<sup>126</sup> 42 U.S.C. § 1395f (a)(7).



corporate “scheme” to admit and maintain patients, including a practice of admitting patients earlier than competitors, before determining their eligibility, requiring layers of review before discharging patients, and instructing staff to document evidence supporting eligibility, along with anecdotal evidence from a few of Defendants’ employees that some information in patient charts was falsified.

Because a physician must use his or her clinical judgment to determine hospice eligibility, an FCA claim about the exercise of that judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis.<sup>127</sup> “Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false.” *U.S. ex rel. Morton v. A Plus Benefits, Inc.*, 139 Fed. App’x 980, 982–83 (10th Cir. 2005); *U.S. ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004). For example, a relator could present evidence that a certifying physician was not, in fact, exercising the physician’s clinical judgment when certifying a patient, because the physician never reviewed the patient’s medical condition nor saw the patient, or that the physician did not actually believe that if the patient’s disease ran its normal course, the patient had a prognosis of six months or less. *See Geschrey*, 922 F. Supp. 2d at 703; *U.S. ex rel. Landis v. Hospice Care of Kansas, LLC*, 2010 WL 5067614, at \*4 (D. Kan. Dec. 7, 2010) (finding a relator adequately pled that claims were false by alleging “physicians could not legitimately exercise their medical judgment because defendants provided false information on which the physicians relied”).

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<sup>127</sup> Opinion [Docket Entry #52] at 10; Opinion [Docket Entry #91] at 7 (“To state an FCA claim properly, a plaintiff contending that patients were falsely certified for hospice care must rely on objectively verifiable facts inconsistent with the exercise of a physician’s clinical judgment, not on a subjective clinical analysis as to which prudent doctors might disagree.”).

A testifying physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity. See *United States v. AseraCare Inc.*, 2016 WL 1270521, at \*1 (N.D. Ala. Mar. 31, 2016); see also *U.S. ex rel. Fowler v. Evercare Hospice, Inc.*, 2015 WL 5568614, at \*9 (D. Colo. Sept. 21, 2015) (“[I]f the complaint was based entirely on disagreements with . . . certifying physicians in specific cases, . . . references to these six patients would be insufficient to state a claim.”). In *AseraCare*, the government relied on the testimony of an expert physician who reviewed patient files and opined that certain patients were ineligible for hospice. 2016 WL 1270521. Finding that the “case boil[ed] down to conflicting views of physicians about whether the medical records support . . . certifications that the patients at issue were eligible for hospice care,” the court entered judgment for the defendant, concluding “the opinion of one medical expert *alone* cannot prove falsity without further evidence of an objective falsehood.” *Id.*

Here, Dr. Steinberg's opinions are based on his subjective clinical analysis. Although he recognized that a certification for hospice is based on a “physician's own clinical judgment,” and that, as a general matter “reasonable clinicians/physicians can disagree about things and not necessarily be wrong,”<sup>128</sup> he found patients ineligible based on his own evaluation of their life expectancies, opining that patients who were admittedly “clearly not paragons of good health” and were suffering from “serious, progressive conditions” were not sick enough to be eligible.<sup>129</sup> Relator characterizes this as an “objective finding about eligibility.”<sup>130</sup> Yet the subjective nature of Dr. Steinberg's conclusions is obvious; he recognized that, in many cases, “there was not a single, clear date on which hospice services were appropriate or inappropriate,” and offered two

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<sup>128</sup> Steinberg Depo. at 965, 967.

<sup>129</sup> Rel. Appx. at 43.

<sup>130</sup> Hr'g Tr. at 9.

different opinions on eligibility for nearly every patient whose file he reviewed, yet he claimed physicians whose eligibility determinations fell outside the range he selected were objectively incorrect.<sup>131</sup> In fact, Medicare regulations *require* physicians making eligibility determinations to consider “*subjective . . . medical findings,*” and do not provide objective standards or criteria to cabin such determinations.<sup>132</sup> Dr. Steinberg’s subjective opinion is insufficient to prove certifying physicians erred in evaluating life expectancies, and says nothing about whether physicians certified patients without exercising their own clinical judgment or without finding patients to be terminally ill.<sup>133</sup>

As Relator conceded, Dr. Steinberg “did not make a decision about falsity.” Hr’g Tr. at 9. As the court held in *AseraCare*, “[a]llowing a mere difference of opinion among physicians alone to prove falsity would totally eradicate the clinical judgment required of the certifying physicians.” *AseraCare, Inc.*, 2:12-cv-00245 at \*3. If all that was necessary to prove falsity was to put up a medical expert to review medical records and provide an opinion at odds with that of the certifying physician, hospice providers would be subject to potential FCA liability “any time [a relator] could find a medical expert who disagreed with the certifying physician’s clinical judgment.” *Id.* at 3–4. That situation would be directly at odds with the assurances given by CMS that doctors need not fear the exercise of their medical judgment as to the future course of a terminal patient. Dr. Steinberg’s opinion that certain of Defendants’ patients were ineligible for hospice is insufficient to create a fact issue as to whether physician certifications and resulting claims were false.<sup>134</sup>

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<sup>131</sup> See Rel. Appx. at 41.

<sup>132</sup> 73 Fed. Reg. 32088 (June 5, 2008) (emphasis added).

<sup>133</sup> Steinberg Rept., Appx. 43.

<sup>134</sup> Further, Dr. Steinberg’s methodology is rife with errors, as discussed on the record at the hearing, and would be excluded for that reason. Hr’g Tr. 23–37. For example, as he admitted in his deposition, his report contained these errors and overstatements: his opinion that “patients who might still want treatment” were ineligible for the MHB was incorrect, Def. Appx. A 1052, his opinion that patients “must agree to give up life prolonging and/or curative

Relator argues that, when viewed together with evidence regarding Defendants' corporate culture, including anecdotal evidence from Wall, Lattanzi, and Huffstetler of a few false entries, a jury could infer that claims submitted for the 291 patients Dr. Steinberg reviewed were false. Hr'g Tr. at 10–12. Although Relator has produced some evidence of the Defendants' pressure on their employees to admit large numbers of hospice patients, and that a few employees falsified data on a few specified patient charts, a practice that could jeopardize the proper exercise of physician judgment, she has not tied that evidence to the patients whose charts Dr. Steinberg evaluated, nor to the submission of a single false claim. Relator concedes that she cannot do so. *See* Hr'g Tr. at 13, 64, 79 (conceding “there is not a nexus between Lattanzi and Huffstetler and Wall and the patients in the 291 sample”). Without *any* evidence about the nurses and doctors involved in treating or certifying the sampled patients for hospice, for Relator to prevail at trial, jurors would have to take an impermissible inferential leap to conclude that those patients' certifications were not based on the proper clinical judgment of physicians.

*AseraCare* reached the same conclusion as this Court does. There, after hearing evidence at a jury trial, the Court granted judgment, limiting the government to the evidence at trial and finding it insufficient, as a matter of law, to prove falsity. At trial, in addition to the physician's testimony, the government presented evidence of objectively verifiable facts inconsistent with the exercise of physician judgment, including evidence that a doctor “wasn't participating” during IDG meetings, and instead “was doing his drawings” with crayons and colored pencils, and that nurses would present him papers with “little stickies” to sign if he was present, or would

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treatment” to be eligible was “stated too strongly,” *id.* at A 962, his opinion that attending physicians “did not use any medical judgment when signing the certificate of terminal illness” was “stated too strongly” as “there's certainly some judgment involved,” *id.* at A 970, and his opinion that “LCDs specify what specific clinical criteria patients must meet” was “bad language” and incorrect, *id.* at 1025–26. Further, his report claimed to apply the standard a “third-party reviewer” would apply, but he later admitted he “[didn't] know [the] specific protocols” of various third-party reviewers whose standards he claimed to be applying. *Id.* at A 1000–01.

use a pre-signed form if he was not at the IDG meeting.<sup>135</sup> The government relied on this evidence to show the existence of a scheme, not tied to specific patients or claims. As the court held, had the government linked this evidence to its expert physician’s testimony, that evidence may have supported the jury’s verdict. The government did not do so, and the physician’s opinion, considered together with the scheme evidence, without the “necessary connection” between the two, did not create a fact issue as to falsity. *United States v. AseraCare Inc.*, 2015 WL 8486874, at \*2, 8–9 (N.D. Ala. Nov. 3, 2015).

Relator seemingly suggests she is only required to prove Defendants operated with reckless disregard as to falsity, and not that the certifications or claims were actually false or fraudulent. This view reflects a misunderstanding of the FCA’s falsity element, confusing the FCA’s *scienter* requirement—which requires knowledge *or* reckless disregard—with the necessity to show that records or claims were *false*.<sup>136</sup> The FCA’s knowledge element is an independent, additional hurdle for Relator, not a shortcut around proof of falsity.<sup>137</sup> Without evidence linking Relator’s “scheme” evidence to the 291 patients whose files Dr. Steinberg

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<sup>135</sup> *United States v. AseraCare Inc.*, 2015 WL 8486874, at \*6 (N.D. Ala. Nov. 3, 2015) (“Even assuming, arguendo, that the Government could present this testimony to prove falsity . . . , the Government failed to make the necessary connections to the 123 patients to show that the claims were objectively false. For example, the testimony of . . . AseraCare’s Patient Care Coordinator at the Milwaukee agency . . . illustrates the Government’s lack of connection. She testified about how the medical director of that agency, Dr. Mateo, ‘was doing his drawings’ and ‘wasn’t participating’ during the interdisciplinary team meetings. She further testified that she prepared for meetings by setting up Dr. Mateo’s sketch pad, crayons, and coloring pencils and would present papers to Dr. Mateo with ‘little stickies’ where he should sign if he was present to sign them or would use a pre-signed form if he was not at the meeting. But, here is the rub: Dr. Liao identified two patients from Milwaukee as being ineligible—patient # 46 Ingeborg D. and patient # 123 Yvonne Y. The jury did not find that AseraCare’s claims for hospice service for patient # 123 Yvonne Y. were false. The jury found Ingeborg D. was ineligible; however, she was not admitted to hospice until November 4, 2010—two-and-a-half years after [the patient care coordinator] left AseraCare. Furthermore, the court has reviewed Ms. Ingeborg D.’s medical records and cannot find Dr. Mateo’s name in them. Therefore, Ms. Manley’s testimony does not explain why the opinions of the certifying doctors for Ms. Ingeborg D. lack reliability. Thus, the Government has presented nothing more than Dr. Liao’s different opinion as to Ms. Ingeborg D.’s eligibility.”).

<sup>136</sup> *See, e.g.*, Hr’g Tr. at 78 (“We believe . . . evidence of the scheme would allow a jury to infer that those claims submitted were submitted and paid in reckless disregard for the truth or falsity of the information in the claim, even though the evidence of the scheme does not specifically relate to the claims . . . that Steinberg will testify were based on periods when the patients were not eligible for the benefit.”).

<sup>137</sup> 42 U.S.C. §3729(a)(1)(A), (B).

analyzed, there is no evidence that the certifying physicians for the 291 patients were not exercising their best clinical judgments nor that they did not believe the subject patients were terminally ill when they certified them as such, and thus there is no evidence of the falsity required to establish liability.

No reliable evidence is presented by Relator that any patient was not terminally ill. Wall, Lattanzi, and Huffstetler claim they were involved in or observed the certification of patients who were medically ineligible, but eligibility depends on *physician* judgment, and thus, their allegations about patient health cannot support a conclusion that any patient for whom a claim was submitted had a medical prognosis of more than six months.<sup>138</sup> *See Geschrey*, 922 F. Supp. 2d at 703 (“[T]hat Relator Janus, a social worker, and a nurse agreed that the patient was not appropriate for hospice because she could walk, eat, and talk does not suffice to allege that the doctor’s certification that A.W. was appropriate for hospice was fraudulent; it merely alleges that Relator Janus and others disagreed with the doctor’s assessment. Relators have not alleged facts demonstrating that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care.”).

Relator argues that she should survive summary judgment on her scheme evidence alone, contending she is not required to point to specific false records or claims.<sup>139</sup> She concedes that, other than Dr. Steinberg’s testimony, she has “no proof” that corporate pressure or some nurses altering a few identified patient charts “resulted in a particular claim within the relevant period,” and that she has not linked any patient discussed by Wall, Lattanzi, or Huffstetler to a patient file

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<sup>138</sup> These witnesses also testified that they based their eligibility opinions in significant part on LCDs. *See* Rel. Appx. 1549, 1678, 1970. Relator and her hospice expert concede LCDs do not establish a standard. *Resp.* at 3; Steinberg Depo, Def. Appx., at A 973. Relator also produced declarations and affidavits from several VistaCare employees who said ineligible patients were admitted. However, they did not provide any factual support for these conclusory allegations, and did not show that the declarants were qualified to reach such conclusions. *See e.g.*, Rel. Appx. Ex. 27, Ryan Aff., Ex. 28, Castro Decl. The Court will not rely on unsupported, conclusory statements.

<sup>139</sup> *Resp.* at 32–39.

or claim.<sup>140</sup> However, citing to the Fifth Circuit’s decision on a motion to dismiss in *Grubbs*, she argues that she has done enough to raise a fact issue by presenting evidence of a scheme and proving that 93% of Defendants’ patients were covered by Medicare. Although Relator’s contention of a scheme and anecdotal evidence were sufficient to survive a motion to dismiss, without evidence that such practices led to false certifications or claims, Relator cannot prevail on summary judgment.

In *Grubbs*, a case opining on sufficient pleading standards in a false claims case, the court stated, in dicta, that if “at trial a *qui tam* plaintiff proves the existence of a billing scheme and offers particular and reliable indicia that false bills were actually submitted as a result of the scheme—such as dates that services were fraudulently provided or recorded, by whom, and evidence of the department’s standard billing procedure—a reasonable jury could infer that more likely than not the defendant presented a false bill to the government.” 565 F.3d at 189–90. The court stated that, a “plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted,” although “the exact dollar amounts fraudulently billed . . . will in most cases be necessary to sufficiently prove actual damages.” *Id.*

*Grubbs* acknowledged that “[f]raudulent presentment requires proof . . . of the claim’s falsity, not of its exact contents.” *Id.* at 189. The *Grubbs* complaint alleged facts which, if proven, would support a finding of falsity: the defendants stated that they regularly created medical bills to bill Medicare for services that were never provided. *Id.* at 184–85. In *Grubbs*, defendant physicians explained to the relator, a new doctor, that, during weekend on-call shifts, they billed for face-to-face visits that did not occur. *Id.* During the relator’s first weekend on

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<sup>140</sup> Hr’g Tr. at 14, 78.

call, nurses attempted to help him bill for face-to-face visits of patients he did not see. *Id.* at 184. Bills for services not actually provided are factually false, so falsity was not at issue in *Grubbs*. *Grubbs* merely concluded that when the pleadings state that defendants “continually recorded unprovided services,” intentionally creating false bills to defraud Medicare, an inference that those bills were presented is allowed. *Id.* at 190, 192 (“It would stretch the imagination to infer . . . that the defendant doctors go through the charade of meeting with newly hired doctors to describe their fraudulent practice and that they continually record unprovided services only for the scheme to deviate from the regular billing track at the last moment so that the recorded, but unprovided, services never get billed.”).

Here, Relator asks the Court to conclude, from evidence that Defendants had a corporate policy to aggressively seek to enroll and maintain *eligible* patients, that Defendants enrolled and maintained *ineligible* patients. Relator does not explain how Defendants’ alleged policies to (1) admit patients earlier than competitors, before determining their eligibility, and (2) require multiple layers of review before discharging patients ultimately found ineligible, while (3) instructing staff to document evidence supporting eligibility for eligible patients, supports an inference that Defendants billed for ineligible patients. Even if Defendants’ aggressive marketing and enrollment policies were ill-advised, they are not sufficient to prove falsity under *Grubbs* or otherwise. Even “[m]ismanagement . . . of programs that receive federal dollars is not enough to create FCA liability.” *U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 339 (5th Cir. 2008); *see also U.S. ex rel. Willard v. Humana Health Care Plan of Tex. Inc.*, 336 F.3d 375, 381 (5th Cir. 2003) (explaining that liability attaches to a false claim, not “improper internal policies.”); *Barys ex rel. U.S. v. Vitas Healthcare Corp.*, 298 F. App’x 893, 895–96 (11th Cir. 2008) (concluding that “requiring an additional layer of review before a . . . patient is discharged



does not support an inference that patients are being fraudulently re-certified” and that paying “cash bonuses to administrators who maintained high patient populations” was insufficient to support an inference of fraud “without allegations of instances in which these administrators fraudulently re-certified patients”); *AseraCare*, 2016 WL 1270521, at \*4–5 (“[P]ractices that may be improper, standing alone, are insufficient to show falsity without proof that specific claims were in fact false when submitted to Medicare.”).

Further, Relator did not present sufficient evidence tying the alleged scheme to particular records or claims. Relator has not produced “reliable indicia that false bills were actually submitted,” as *Grubbs* suggests is required. 565 F.3d at 189–90. Other than through Dr. Steinberg, she has provided no “dates that services were fraudulently provided or recorded, [or] by whom,” *id.*, instead relying on the percentage of Defendants’ patients who were Medicare patients. At the pleading stage, the complaint in *Grubbs* averred at least one overt act of false billing—including date and physician—for each defendant who allegedly submitted false claims. *Id.*; see *United States v. Solvay*, 2016 WL 1258401, at \*13 (S.D. Tex. Mar. 31, 2016) (“The court agrees, to some extent, with Relators’ contention that they are not required to provide the court . . . with a precise universe of claims to survive summary judgment. . . . However, since the Relators cannot provide any claims data that would be admissible at trial . . . they cannot highlight any evidence of claims submission.”); *Barys*, 298 F. App’x at 895–96 (dismissing a complaint because substantial allegations of a corporate scheme were not tied to particular patients or false claims).

What Relator is missing here is a causal link between Defendants’ policies, a few instances where medical information was allegedly falsified, and actual false or fraudulent certifications and claims. Compare *U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.*,

498 F. Supp. 2d 25, 66 (D.D.C. 2007) (rejecting a relator’s argument that “since there is evidence of a general nature that [defendant] tried to hold patients longer than necessary, and since relator’s experts opine that the average length-of-stay spiked during the . . . period in a way that is statistically significant and not random, then the Court should assume that all patients in the subject range were held too long.”).

Thus, Defendants’ Motion for Summary Judgment is **GRANTED** as to the false claims allegations, and they are **DISMISSED** with prejudice.

#### **F. CLAIM FOR FALSE CERTIFICATION OF COMPLIANCE WITH THE ANTI-KICKBACK STATUTE**

Relator also contends Defendants violated the FCA by falsely certifying compliance with the Anti-Kickback Statute (“AKS”). The AKS criminalizes the knowing or willful paying or offering to pay any remuneration to induce: (1) the referral of an individual for items or services that may be paid for by a federal health care program; or (2) the purchasing, leasing, ordering, or arranging for purchasing, leasing, or ordering any item or service that may be paid for by a federal health care program. 42 U.S.C. § 1320a–7b(b)(1–2); *see U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App’x 890, 893 (5th Cir. 2013); *Thompson*, 125 F.3d at 901. To show an AKS violation, a relator must present evidence that a defendant: (1) knowingly and willfully (2) solicited or received, or offered or paid remuneration (3) in return for, or to induce, referral or program-related business. 42 U.S.C. § 1320a–7b(b)(1–2). The AKS does not create a private right of action, but a violation of it can form the basis of an FCA claim. *Nunnally*, 519 F. App’x at 893; *Thompson*, 125 F.3d at 901; *Bennett*, 2011 WL 1231577, at \*32.

Relator’s AKS claim is not based on any gifts or payments to third parties.<sup>141</sup> Instead, she argues Defendants’ program to bonus employees for “obtaining patients and retaining them

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<sup>141</sup> *Id.*

on census” violated the AKS,<sup>142</sup> contending that the program constitutes paying or offering to pay remuneration “for the purpose of inducing a referral or arranging for a service compensated by Medicare.”<sup>143</sup> Relator contends that Defendants’ offers to pay employees bonuses for hitting admissions targets and census goals is sufficient to support a verdict that claims made while such incentives were in place were based on false certifications of compliance with the AKS.<sup>144</sup>

*i. The Bona Fide Employee Exception*

The AKS states that there is no violation of the statute for a payment “by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” 42 U.S.C. 1320a-7b(b)(3)(B); *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 669 (S.D. Tex. 2013) (Costa, J.). The bona fide employee safe harbor is further codified in 42 C.F.R. § 1001.952(i), which provides that payments to employees “for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs” are not remuneration and therefore cannot form the basis of an Anti-Kickback Act violation. 42 C.F.R. § 1001.952(i).

The bona fide employee exception is an affirmative defense on which Defendants bear the burden of proof. Relator asserts Defendants have not carried that burden, as they have not presented evidence showing the exception applies. However, Relator has stipulated that her AKS theory is based solely on the making of payments to Defendants’ employees. Rel. Resp. Br. [Docket Entry #279-2] at 42 (“VistaCare violated the AKS by routinely paying kickbacks to its own employees.”); Hr’g Tr. at 93 (“Our theory on the kickback claim is this: The evidence in

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<sup>142</sup> Hr’g Tr. at 93.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 93–94.

the summary judgment record . . . demonstrates that for a period of years, [Defendants] had a comprehensive, pervasive program to bonus employees, all of them, at times, but certainly and regularly the sales employees, for the purpose of obtaining patients and retaining them on census.”). Thus, Defendants need not present further evidence showing that they had a bona fide employment relationship with the individuals to whom they provided bonuses. Instead, this question turns on a disputed legal question—can bonuses to Defendants’ own employees constitute an improper payment under the AKS, rendering a certification of compliance false?

Relator claims the bona fide employee exception does not apply, because Defendants have not shown that bonuses to employees were “for employment in the provision of covered items or services.” Rel. Supp. Br. [Docket Entry #404] at 3. Defendants, on the other hand, claim *all* of their employees were employed in the provision of covered services: hospice services eligible for reimbursement under the MHB. Def. Sup. Br. [Docket Entry #405] at 7.

The text of the statute supports Defendants’ position. The statutory exception applies to payments *for employment in the provision of* covered services, not *for providing* covered services. 42 U.S.C. 1320a-7b(b)(3)(B); *see Hericks v. Lincare, Inc.*, 2014 WL 1225660, at \*14 (E.D. Penn. Mar. 25, 2014) (rejecting the argument that the bona fide employee safe harbor did not apply to cash bonuses for referrals paid to employees because bonuses were not “for employment in the provision of covered items or services,” finding that “the [defendant’s] employees [we]re *employed in the provision of* covered items and services” regardless of the specific task compensated by the bonuses). On its face, therefore, the exception protects payments to employees of entities in the business of providing covered services of hospice care, not only for specific direct patient care for which bills can be submitted to Medicare.

Further, the structure of the statute supports this reading of it. If the exception did not apply to payments intended to induce referrals or business for the program, it would be superfluous. The court in *U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center* rejected the argument that a bonus paid to employees to induce referrals was not protected by the safe harbor:

[T]he Bona Fide Employment Exception provides that the normal prohibition on payments to induce referrals does not apply where the payments are made to a (for lack of a better word) legitimate employee. The Relator would change that to read that the prohibition on payments to induce referrals does not apply where the payments are made to a legitimate employee unless they are payments to induce referrals. The exceptions set forth in the Anti-Kickback Statute and accompanying regulations “provide immunity from prosecution for behavior *that might have violated the Anti-Kickback Statute.*” . . . The Relator’s interpretation of the Bona Fide Employment Exception would eviscerate it.

2013 WL 6196562 (M.D. Fl. 2013) (emphasis added).

The codifying regulation’s history makes clear that Relator’s interpretation is incorrect. In adopting the regulation, HHS stated that the exception is based on an assumption that employers, who are responsible for the acts of their employees, will appropriately supervise those employees to prevent referrals of ineligible patients.

When proposing the rule codified at 42 C.F.R. § 1001.952(i), HHS did not define “covered items or services,” but, in discussing the bona fide employee safe harbor, it stated:

This statutory exemption *permits an employer to pay an employee in whatever manner he or she chooses for having that employee assist in the solicitation of Medicare or State health care program business.* The proposed exemption follows the statute in that it applies only to bona fide employee-employer relationships. . . .

[M]any commenters suggested that we broaden the exemption to apply to independent contractors paid on a commission basis. We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision. We believe that *if individuals*

*and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.*<sup>145</sup>

A contrary reading would make all payments to hospice providers' sales, marketing, and other staff for involvement in patients securing hospice services from their employer illegal for Medicare providers, leaving such providers unable to promote their businesses by rewarding employees based on success.

The cases cited by Relator do not persuade the Court otherwise. Relator relied on several criminal cases, which the Court finds unpersuasive in this case. In *United States v. Njoku*, 737 F.3d 55 (5th Cir. 2013) and in the unpublished case of *United States v. Jackson*, 220 Fed. App'x. 317 (5th Cir. 2007), there is no discussion of the bona fide employee exception, and it is not at all clear that the affirmative defense was ever raised. The defendants in *United States v. St. Junius*, 739 F.3d 193, 199 (5th Cir. 2013) were independent contractors, not employees, and in another unpublished case, *United States v. Robinson*, 505 Fed. App'x. 385, 387–88 (5th Cir. 2013), the court concluded the individuals who received payments were not bona fide employees.

Relator also relies on *United States v. Starks*, in which the Eleventh Circuit stated that defendants were not bona fide employees, but, even if they were, “they were not providing ‘covered items or services,’” because they “received payment . . . only for referrals and not for any legitimate service for which the Hospital received any Medicare reimbursement.” 157 F.3d 833, 839 (11th Cir. 1998). *Starks* engaged in no substantive analysis of the exception, and commented on the “covered items or services” clause without relying on it—the defendants in

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<sup>145</sup> Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 FR 3088-01 (Jan. 23, 1989) (emphasis added).

that case clearly were not bona fide employees, clandestinely receiving checks or cash for their referrals in parking lots to avoid detection. *See United States v. Crinel*, 2015 WL 3755896, at \*5 (E.D. La. 2015) (disagreeing with *Starks* and stating that the *Starks* court engaged in no substantive analysis of the statute). Here, it is uncontested that the payments at issue were to bona fide employees.

The Court also is not persuaded by *United States v. Borrasi*, where the Seventh Circuit held that where “at least part of the payments to [a defendant were] ‘intended to induce’ him to refer patients,” the bona fide employee safe harbor did not apply. 639 F.3d 774, 781 (7th Cir. 2011); *see also United States v. Luis*, 966 F. Supp. 2d 1321, 1330 (S.D. Fl. 2013) (finding it “irrelevant whether the [defendants] were bona fide employees paid for ‘covered items or services’ because the payments to them were, at least in part, for their illegal patient referrals”). As *Crinel* concluded, this reading “focuse[s] on the wrong statutory provision,” and does not give independent meaning to the safe-harbor provision, as it states that “if a particular payment violates a substantive provision of the anti-kickback statute, the safe-harbor provision does not apply. This reading allows the rule to swallow the exception.” 2015 WL 3755896.

Finally, Relator relies on a 1992 letter concerning hospitals acquiring physician practices, from the Associate General Counsel of the HHS Office of the Inspector General to an assistant in the Office of the Associate Chief Counsel of the IRS. The letter includes a footnote stating: “payments to employees which are for the purpose of compensating such employees for the referral of patients would likely not be covered by the employee exemption.”<sup>146</sup> This Court finds that prediction of likelihood to be the equivalent of dictum, and that, in this Courts’ view, is inaccurate. The only other case of which the Court is aware considering the letter found it

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<sup>146</sup> Letter from D. McCarty Thornton, Associate General Counsel, HHS OIG, to T.R. Sullivan, IRS, (Dec. 22, 1992), at n. 2, available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm>.

“inapposite” to cases involving “bona fide employees receiving payment from their employer while working for that employer.” *Hericks*, 2014 WL 1225660, at \*14.

Relator’s interpretation reads the bona fide employee exception out of the statute and is inconsistent with the text, structure, and purpose of the exception. No binding case law supports such an interpretation, and the Court rejects it. Therefore, because Relator relies on bonuses paid to Defendants’ bona fide employees for employment in the provision of hospice services, Relator cannot prevail on her AKS theory.

***ii. Insufficient Proof That Any AKS Violation Led to an FCA Violation***

Even if paying bonuses to legitimate employees were a violation of the AKS, that is not enough to show a violation of the FCA. An FCA claim dependent on the AKS needs to meet all of the other elements of an FCA claim. *Nunnally*, 519 F. App’x at 894–95; *see also U.S. ex rel. Hartwig v. Medtronic, Inc.*, 2014 WL 1324339, at \*12 (S.D. Miss. Mar. 31, 2014). In other words, Relator must show not only that Defendants paid, or offered to pay, remuneration in exchange for referrals, but also that payments led to false certifications or claims. *See Nunnally*, 519 F. App’x at 894–95. Relator has not provided any evidence of false certifications for submitted claims.

First, Relator “has not provided reliable indicia that [Defendants] actually falsely certified compliance” with the AKS. *Bennett*, 2011 WL 1231577, at \*33. Courts have found claims properly stated where they cite “Medicare enrollment application Form CMS 855–As, . . . [which] expressly certif[y] compliance with the AKS.” *Parikh*, 977 F. Supp. 2d at 665. However, at summary judgment, Relator cannot rely on mere assertions that such certifications exist, and her evidence does not include any certifications of AKS compliance. Even if she were not required to provide the certifications themselves, she has not provided reliable indicia of such



certifications, as she has not identified individuals who made such certifications, or dates on which they were made. *See Nunnally*, 519 F. App'x at 894 (noting the complaint failed “to allege with particularity an actual certification to the Government that was a prerequisite to obtaining the government benefit”); *Bennett*, 2011 WL 1231577, at \*33 (dismissing a complaint where the relator “fail[ed] to identify any hospitals or physicians who certified compliance with the antikickback statute”); *U.S. ex rel. Kennedy v. Aventis Pharms.*, 610 F. Supp. 2d 938, 945 (N. D. Ill. 2009) (the relators “identified a number of hospitals to which Aventis allegedly gave kickbacks” but failed to allege “that one or more of the hospitals falsely certified, in connection with a Medicare claim, that it had complied with the anti-kickback statute; the failure to identify “any certification by a hospital,” caused dismissal).

Second, Relator did not sufficiently link the payment of a bonus to a referral, patient, or claim. The extent to which a relator must tie a particular claim to a particular kickback is unresolved. *Parikh*, 977 F. Supp. 2d at 665. However, the Fifth Circuit has indicated that an FCA violation based on an AKS violation must involve some connection between kickbacks, referrals, and claims. *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 894 (5th Cir. 2013). Even at the pleading stage, the Fifth Circuit has held that alleging a violation “requires pleading that [a defendant] knowingly paid remuneration to specific [referral sources] in exchange for referrals” and that a referral was “actual[ly] induce[d].” *Id.*; *U.S. ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1107 (7th Cir. 2014), *cert. denied*, 136 S. Ct. 49 (2015) (“To comply with Rule 9(b) [relator] would have had to allege either that the pharmacy submitted a claim to Medicare (or Medicaid) on behalf of a specific patient who had received a kickback, or at least name a [individual] who had received a kickback”). Yet

Relator points to no evidence that any particular bonus led to a referral, which in turn led to a false certification of compliance with the AKS.

Third, Relator did not direct the Court to evidence of *any* claim that was false based on an AKS violation, asking the Court to assume that all claims submitted while Defendants were paying incentive bonuses were false. In *Nunnally*, the court affirmed dismissal of an FCA action in part because the complaint did “not identify a single claim submitted . . . for services rendered pursuant to an illegal referral, let alone one for which [the defendant] expressly certified its compliance with federal law.” 519 F. App’x at 894; *Hericks*, 2014 WL 1225660, at \*1, 7 (dismissing a claim because, although relator pled defendants provided remuneration to specific physicians, and those physicians referred patients, the relator did “not connect these referrals to any claims made to Medicare”). Here, Relator has engaged in years of discovery, but has not presented evidence of such a claim. The Court will not assume the key element Relator is required to prove.

The mere fact that 93% of Defendants’ patients are Medicare patients is not sufficient to show Defendants submitted claims that falsely certified compliance with the AKS. Courts regularly reject FCA claims which rely on probability arguments like Relator’s. *See e.g., U.S. ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 857 (7th Cir. 2006) (affirming the district court’s decision to grant summary judgment because, although the relator proved it was “statistically unlikely” that improper practices had not led to false claims, the relator had not provided evidence linking the practice to any claim); *Hockett*, 498 F. Supp. 2d at 66. For example, in *Hericks*, the court found a relator failed to state a claim when she alleged claims were false because they “were submitted when [defendant’s] illegal practices were in effect, and [did] not explain how the[ ] submissions related to any specific illegal activity.” 2014 WL

1225660, at \*8. The court found that the relator's "claim that roughly 60% of [defendant's] revenue comes from Medicare and Medicaid is not indicative of wrongdoing and does not lead to the conclusion that most of [defendant's] revenues derive from fraudulent activity." *Id.* The same is true here.

Because Defendants have established the bona fide employee safe harbor applies, and because Relator has failed to provide evidence linking any AKS violation to a false or fraudulent certification or claim, Defendants' Motion for Summary Judgment on Claim II is **GRANTED**, and Relator's claim based on alleged AKS violations is **DISMISSED** with prejudice.

### **G. RETALIATION**

Relator asserts claims for retaliation under the FCA, 31 U.S.C. § 3730(h), and the Texas Medicare Fraud Prevention Act ("TMFPA"), Tex. Hum. Res. Code § 36.115(a), alleging she was discharged because she engaged in protected activity. The FCA and TMFPA both prohibit an employer from retaliating against an employee because of lawful acts, including investigating, initiating, testifying, or assisting in an action filed "in furtherance of an action" under either statute.<sup>147</sup> The "in furtherance" language in both provisions requires a "nexus" between the protected activity and the filing or potential filing of a *qui tam* suit."<sup>148</sup> Relator must prove (1) she engaged in protected activity; (2) her employer knew about the activity; and (3) her employer retaliated against her because of the protected activity. *Robertson v. Bell Helicopter Textron*, 32 F.3d 948, 951; *see also McKenzie v. BellSouth Telecomms.*, 219 F.3d 508, 514 (6th Cir. 2000).

The retaliation provisions of the FCA protect whistleblowers who voice concerns "about

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<sup>147</sup> Tex. Hum. Res. Code § 36.115(a); 31 U.S.C. § 3730(h).

<sup>148</sup> *See United States v. City of Dallas, Tex.*, 2011 WL 4912590 (N.D. Tex. Sept. 27, 2011) *report and recommendation adopted sub nom. Moore v. City of Dallas, Tex.*, 3:09-CV-1452-O, 2011 WL 4907303 (N.D. Tex. Oct. 14, 2011) (evaluating TMFPA action based upon the same evidence and arguments offered with respect to FCA retaliation claim); *see also United States v. Thorek Hosp. & Med. Ctr.*, 2007 WL 2484333 at \*4 (N.D. Ill. Aug. 29, 2007) (evaluating FCA action and Illinois Whistleblower Reward and Protection Act actions together).

the company defrauding the government.” *Robertson*, 32 F.3d at 951. Without a suggestion from the employee that she is “attempting to expose illegality or fraud within the meaning of the FCA,” activity is not of the “protected” variety. *Id.* The protected activity need not be *clearly* in furtherance of a *qui tam* action, *id.*, but must include steps “towards the exposure of the false claims, such as investigating or complaining about the fraud.” *Guerrero*, 2012 WL 899228, at \*4; *See Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 479 (5th Cir. 2012).

Whether Defendants retaliated against Relator turns on disputed questions of fact. Relator testified that she complained to numerous supervisors and Defendants’ human resources department expressing concerns that Defendants were admitting and maintaining ineligible patients, and that employees were committing fraud in connection with Medicare.<sup>149</sup> The Court previously held that, because Relator “characterized her concerns as involving fraud that violated federal and state regulations,” her allegations, if proven, could show that she engaged in a protected activity and that Defendants knew she engaged in a protected activity.<sup>150</sup> There is also sufficient evidence of a connection between Relator’s protected activity and her termination. She provided uncontroverted evidence that she had never received a negative performance review before raising these concerns, and that she was demoted and fired within months of doing so.<sup>151</sup> The issue thus turns on Relator’s and other Defendants’ employees’ credibility, and thus it cannot be resolved at summary judgment.<sup>152</sup>

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<sup>149</sup> Rel. Appx. 1645–72.

<sup>150</sup> Opinion, [Docket Entry #91] at 11.

<sup>151</sup> Rel. Appx. 1645–72.

<sup>152</sup> The Fifth Circuit recently made clear that an FCA retaliation claim is analyzed under the *McDonnell Douglas* burden-shifting standard. *Diaz*, No. 15-50655 at 4 n. 3. The relator must provide evidence of retaliation, then the defendant must show a non-retaliatory motive, and the burden shifts back to the relator to show that the defendant’s explanation is pretextual. The Fifth Circuit affirmed summary judgment against a relator on a retaliation claim because the relator did not allege pretext. *Id.* at 5–6. Here, relator alleges pretext and provides evidence sufficient for a jury to find Defendants’ explanation—reducing social workers due to overstaffing—pretextual: she was the only social worker with a master’s degree and the most senior social worker at her location.

Despite Defendants' arguments to the contrary, the FCA does not require Relator to prevail on her false claims causes of action to succeed on her retaliation claim. *See U.S. ex rel Bias v. Tangipahoa Parish Sch. Bd.*, No 15-30193 (5th Cir., Mar. 9, 2016) (allowing plaintiff to proceed on his retaliation claim, although his only other FCA claim had settled and been dismissed); *Diaz v. Kaplan Higher Ed.*, No. 15-50655 (5th Cir., Apr. 13, 2016) (allowing plaintiff to proceed on only a retaliation claim under the FCA).<sup>153</sup>

Defendants argue that the alleged violation of the TTMFPA should be dismissed for all the reasons the FCA retaliation claim should be dismissed and because absent a predicate violation of the FCA, pendent state law claims arising under the TMFPA should be dismissed. As Relator has presented sufficient evidence to survive summary judgment on her federal retaliation claim, her claims under the TMFPA also survive summary judgment. Therefore, Defendants' Motion for Summary Judgment is **DENIED** as to retaliation.

## VI. CONCLUSION

Defendants' Motions to Strike the Testimony of Drs. Kriegler and Steinberg are **GRANTED** in part, Defendants' Motion for Summary Judgment is **GRANTED** as to all Relator's claims except retaliation, and Relator's Motions are **DENIED** as moot.

**SO ORDERED.**

June 20, 2016.

  
BARBARA M. G. LYNN  
CHIEF JUDGE

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<sup>153</sup> Defendants also argued that Relator's retaliation claims should be dismissed because Relator had not adequately explained the damages she claims resulted from the alleged retaliation. The Court rejected this argument at the hearing. Hr'g Tr. at 90; *CQ, Inc. v. TXU Min. Co., L.P.*, 565 F.3d 268, 279 (5th Cir. 2009).