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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* KARIN BERNTSEN,

Plaintiffs,

v.

PRIME HEALTHCARE SERVICES, INC., et al.,

Defendants.

No. CV 11-08214 PJW (MG)

UNITED STATES' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE STATISTICAL SAMPLING EVIDENCE

Date: October 27, 2016
Time: 1:30 p.m.
Place: Courtroom 23, 3rd floor
Complaint Filed: June 23, 2016
Trial Date: November 26. 2018

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The United States on behalf of the Department of Health and Human Services (**HHS**) and the Centers for Medicare and Medicaid Services (**CMS**) (collectively, **United States** or **Government**) hereby opposes Defendants' Motion to Exclude Statistical Sampling Evidence, Docket No. 141 (**Evidence Motion** or "**Evid. Mot.**").

I. INTRODUCTION

Prime requests relief that no court has ever granted: a pre-answer, pre-discovery ruling that as a matter of law, the United States is precluded from using an entire category of scientific evidence—"statistical sampling and extrapolation"—to support the falsity of certain claims under the False Claims Act (**FCA** or **Act**). Prime's request is both procedurally improper, *see* Part IV.A, *infra*, and substantively meritless, *see* Part IV.B & C, *infra*. For either reason, it should be denied.

In asking the Court to "exclude" anticipated "evidence" as "unreliable," Prime avoids calling the Evidence Motion what it really is: an *in limine* or *Daubert* motion. Either type of motion would be premature as Prime has yet to answer the Government's Complaint in Intervention, and the evidence Prime seeks to exclude is not yet complete and of record. All Prime has to challenge at this pleading stage is the sample that it surmises the United States used in investigating its claims. But as Prime agreed and the Court ordered, the United States has until January 31, 2018, to complete its expert reports. *See* Joint Rule 26(f) Report § IV, Docket No. 133; Order of Sept. 12, 2016, Docket No. 142. Those reports, the United States anticipates, will specify the purposes for which the Government may introduce statistical evidence and detail the methods employed to define the universe of claims, select a valid sample, address any variability among "different hospitals, patients and physicians," Evid. Mot. at 2–3, draw precise conclusions to quantifiable degrees of scientific certainty, and address other "reliability" concerns that Prime raises. Without the benefit of that and similar information, a ruling on sampling and extrapolation would be premature.

Even if the issue was ripe, however, Prime's argument for the categorical exclusion of sampling and extrapolation as evidence of liability in cases like the present

is meritless. The FCA does not prohibit statistical evidence, and its history and broad remedial purpose are antithetical to that kind of categorical evidentiary restriction. Moreover, the majority of FCA decisions that have addressed sampling and extrapolation in medical necessity cases—including, most recently, two from within this Circuit—have approved their use. *See Cretney-Tsosie v. Creekside Hospice II, LLC*, 2016 WL 1257867, at *6 (D. Nev. Mar. 30, 2016); *United States ex rel. Guardiola v. Renown Health*, 2015 WL 5123375, at *1 (D. Nev. Sept. 1, 2015); *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, 2015 WL 1926417, at *3–4 (M.D. Fla. Apr. 28, 2015); *United States v. Robinson*, 2015 WL 1479396, at *11 (E.D. Ky. Mar. 31, 2015); *United States v. AseraCare, Inc.*, 2014 WL 6879254, at *10 (N.D. Ala. Dec. 4, 2014); *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 567 (E.D. Tenn. 2014). As one such decision explained, "the natural disparity between the claims does not preclude using sampling and extrapolation as evidence of the total number of claims for non-covered services." *Life Care*, 114 F. Supp. 3d at 567. Although conceding that claims for medically unnecessary services can be false, Evid. Mot. at 12, Prime contends that the standard for hospital inpatient care is categorically more "subjective" and "individualized" than the standards in other medical necessity cases that have been litigated using statistical evidence. Prime is wrong, as the District Court for the District of Nevada held. *See Renown Health*, 2015 WL 5123375, at *1 ("statistical sampling" of "inpatient reimbursement claims to Medicare that should have been billed on a less expensive, outpatient basis" is "appropriate").

Recent Supreme Court and Ninth Circuit guidance in analogous contexts bolster the use of sampling and extrapolation as evidence of liability in cases like the present. Just months ago, the Supreme Court held that a "representative or statistical sample, like all evidence, is a means to establish or defend against liability," and "categorical exclusion" of such evidence is improper. *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016). Likewise, the Ninth Circuit recently held that "statistical sampling and representative testimony are acceptable ways to determine liability," *Jimenez v.*

1 *Allstate Ins. Co.*, 765 F.3d 1161, 1167 (9th Cir. 2014), and "*per se*" exclusion of such
2 evidence is improper. *United States v. Gwaltney*, 790 F.2d 1378, 1382 (9th Cir. 1986).
3 More specifically, as in FCA cases involving "fact-intensive" questions of medical
4 necessity, Evid. Mot. at 1, courts in this Circuit have approved of sampling and
5 extrapolation in cases involving an allegedly "unique" Medicare coverage standard,
6 *Bend v. Sebelius*, 2010 WL 4852230, at *4 (C.D. Cal. Nov. 19, 2010); independent
7 "professional judgment," *In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.*,
8 984 F. Supp. 2d 1021, 1032 (C.D. Cal. 2013); and widely variable data, *Prime Media*
9 *Grp., LLC v. Acer Am. Corp.*, 2015 WL 452192, at *4 (N.D. Cal. Jan. 22, 2015).
10 Finally, Prime's assertion that CMS requires case-by-case review of the Medicare
11 claims at issue is incorrect. The procedures employed to make initial payment
12 determinations (and decide initial payment determination appeals) do not dictate the
13 procedures that must be employed to make overpayment determinations. *See Chaves*
14 *Cnty. Home Health Servs., Inc. v. Sullivan*, 931 F.2d 914, 917 (D.C. Cir. 1991). In
15 overpayment proceedings, which are more akin to this action, sampling and
16 extrapolation are expressly permitted by the Medicare Act, 42 U.S.C. § 1395ddd(f)(3),
17 and the Ninth Circuit, which "join[ed] other circuits in approving the use of sampling
18 and extrapolation as part of audits in connection with Medicare and other similar
19 programs, provided the aggrieved party has an opportunity to rebut such evidence."
20 *Ratanasen v. Cal. Dep't of Health Servs.*, 11 F.3d 1467, 1471 (9th Cir. 1993).
21 Prime, of course, will have that opportunity, just not until there is actual evidence
22 to rebut. *See* Joint Rule 26(f) Report § IV (providing for rebuttal expert reports);
23 *Renown Health*, 2015 WL 5123375, at *4 (noting that the provider would have the
24 opportunity to challenge the statistical evidence "through motions *in limine* or at trial");
25 *Prime Media*, 2015 WL 452192, at *4 ("extrapolation from an observed sample to an
26 unobserved population is a classic topic for cross-examination").
27 Ignoring repeated acceptance of statistical evidence especially within the Ninth
28 Circuit, Prime relies on two out-of-Circuit district court decisions involving different

procedural postures and coverage standards, a distinguishable Supreme Court decision that preceded *Tyson Foods*, and erroneous applications of Medicare regulations and guidance, some of which post-date the period relevant to this case. Thus, even on a more developed record, the Evidence Motion would lack merit. But especially before the pleadings have closed and expert reports have been completed, the Court should decline to preclude statistical sampling and extrapolation as a matter of law, and instead, hold the parties to their agreement "to work together to see if they can reach agreement about a statistical sample or samples of claims for use at trial." Joint Rule 26(f) Report § II.

II. STATEMENT OF FACTS

As explained in the Government's Complaint in Intervention, Docket No. 127 ("**CI**"), Medicare is a federally-funded health insurance program that benefits individuals over the age of 65. CI ¶ 28. Medicare Part A covers inpatient hospital, skilled nursing, and home health service. *Id*. Medicare Part B covers other services and supplies, including outpatient hospital and physician services. *Id*. Medicare covers only those services that are "reasonable and necessary for the diagnoses or treatment of illness or injury." CI ¶ 33 (quoting 42 U.S.C. § 1395y(a)(1)(A)). Generally, inpatient hospital services are appropriate for patients who will need hospital care for 24 hours or more. CI ¶ 44. Specific factors inform that decision, including the severity of the signs and symptoms that the patient exhibits, the medical predictability of something adverse happening to the patient, the need for diagnostic studies that are appropriately outpatient services, and the availability of diagnostic procedures when and where the patient presents. CI ¶ 44–45. Observation and other outpatient hospital services are appropriate for patients who present to a hospital Emergency Department (**ED**) and require a period of monitoring or treatment before an admission or discharge decision can be made. CI ¶ 37. The decision to admit or discharge should occur in less than 48 hours, and usually, in less than 24 hours. *Id*. Medicare pays three to four times more for inpatient than observation services. CI ¶ 8.

1 The Complaint in Intervention pleads with particularity a "systematic" scheme by
2 Prime "to increase inpatient admissions of Medicare beneficiaries to Defendant
3 Hospitals without regard to medical need." CI ¶ 4, 48. Prime's "business model" was
4 comprised of "policies and practices" that "discourag[ed] the use of, or even
5 eliminat[ed], observation services," imposed "aggressive quotas to pressure ED
6 physicians to admit more patients," and "criticiz[ed] and penaliz[ed] ED physicians who
7 did not fall in line with the Prime business model." *Id.* Those policies and practices
8 "encroached upon" individual "physicians' medical judgment and discretion about how
9 to treat patients" and caused them "to alter their clinical judgment in favor of admitting
10 Medicare beneficiaries to the hospital." CI ¶¶ 60, 69. The intended result of Prime's
11 scheme was increased unnecessary admissions of Medicare beneficiaries to Prime
12 hospitals and increased "Medicare reimbursements to Prime." CI ¶ 69. Prime's claims
13 for such reimbursements were knowingly false, CI ¶¶ 125–40, and thus, the United
14 States seeks damages and penalties under the FCA, 31 U.S.C. § 3729–33, and the
15 common law. CI ¶¶ 157–73.

16 **III. STANDARD OF REVIEW**

17 Conspicuously absent from the Evidence Motion is a citation to any Federal Rule
18 of Civil Procedure or Evidence that permits the sort of pre-answer, pre-discovery,
19 evidentiary exclusion that Prime seeks. That no such rule exists is cause alone to deny
20 the Evidence Motion.

21 The Evidence Motion also omits discussion of a standard or review. Although
22 Prime asks the Court to "exclude" anticipated "evidence" as "unreliable," it avoids using
23 the words "*in limine*" or "*Daubert*," and for good reason. A motion *in limine* addresses
24 the admissibility of specific evidence at the ***threshold of trial***, *Slagowski v. Central*
25 *Washington Asphalt,* 2014 WL 3001951, at *5 n.5 (D. Nev. July 1, 2014), and *Daubert*
26 applies when a trial judge is faced with an actual "***proffer*** of expert scientific testimony."
27 *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993) (emphasis added).
28 Here, trial is years away, and neither party has proffered any evidence. Undeterred,

Prime encourages the Court to divine a new test. Quoting *Tyson Foods*, Prime contends that the Court may consider pre-answer motions to exclude hypothetical evidence by analyzing "the degree to which" such evidence "is reliable in proving or disproving the elements of the relevant cause of action." Evid. Mot. at 13. In *Tyson Foods* as in *Daubert*, however, the Supreme Court had ***specific*** expert evidence and testimony to evaluate. *Tyson Foods*, 136 S. Ct. at 1043–44. Here, no such evidence exists, and even if it did, Prime's challenges would go to its weight, not its admissibility. *See Bazemore v. Friday*, 478 U.S. 385, 400 (1986) (statistician's "failure" to address certain "variables will affect the analysis' probativeness, not its admissibility"); *Prime Media*, 2015 WL 452192, at *4 ("wide variations" in data do not render extrapolation "inadmissibly unreliable" but go "to the weight the jury should accord" the evidence).

The Court should decline Prime's invitation to create a new standard for its procedurally improper Evidence Motion. Instead, the Court should apply the familiar standard governing pre-answer motions, accepting as true all allegations of material fact in the Complaint in Intervention, construing those facts in the light most favorable to the Government, and remembering that pre-answer relief is "viewed with disfavor." *Broam v. Bogan*, 320 F.3d 1023, 1028 (9th Cir. 2003).

IV. ARGUMENT

The Evidence Motion requests a ruling on sampling and extrapolation "as a matter of law" ***and*** "under the particular circumstances of this case." Evid. Mot. at 25. The particulars of the statistical evidence that the United States expects to introduce, however, are not before the Court. For that reason alone, the Evidence Motion should be denied. Alternatively, the Court should reject Prime's request to exclude as a matter of law an entire category of scientific evidence that courts, juries, and litigants have appropriately relied upon in a myriad of FCA and analogous proceedings.

A. The Evidence Motion is Premature.

Just months ago, the Supreme Court held that a "representative or statistical sample, like all evidence, is a means to establish or defend against liability," and

1 "categorical exclusion" of such evidence is improper. *Tyson Foods*, 136 S. Ct. at 1046.
2 Likewise, the Ninth Circuit recently held that "statistical sampling and representative
3 testimony are acceptable ways to determine liability," *Jimenez*, 765 F.3d at 1167, and
4 "*per se*" exclusion of such evidence is improper. *Gwaltney*, 790 F.2d at 1382.
5 Consistent with those holdings, courts "within the Ninth Circuit have declined to
6 prematurely adjudicate evidentiary issues related to expert testimony." *Renown Health*,
7 2015 WL 5123375, at *4; *see also Jahn v. Equine Servs.*, 233 F.3d 382, 393 (6th Cir.
8 2000) ("A district court should not make a *Daubert* ruling prematurely, but should only
9 do so when the record is complete enough to measure the proffered testimony against the
10 proper standards of reliability and relevance."); *KCG Americas LLC v. Brazilmed, LLC*,
11 2016 WL 900396, at *4 (S.D.N.Y. Feb. 26, 2016) ("fact laden inquiry" is "unsuited" for
12 "pre-answer, pre-discovery" resolution) (citation and quotation marks omitted).
13 Demurring is especially prudent when "broad categories" of evidence are in
14 question. *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 2002 WL 34714563,
15 at *3 (S.D. Cal. Jan. 14, 2002); *see also Colton Crane Co. v. Terex Cranes Wilmington,*
16 *Inc.*, 2010 WL 2035800, at *1 (C.D. Cal. May 19, 2010) ("motions *in limine* should
17 rarely seek to exclude broad categories of evidence, as the court is almost always better
18 situated to rule on evidentiary issues in their factual context"); *Butler v. Home Depot,*
19 *Inc.*, 1997 WL 375285, at *1 (N.D. Cal. Apr. 24, 1997) ("It is premature to determine the
20 admissibility of general categories of evidence" without "considering the specific
21 context in which the evidence is being presented.").
22 Applying these principles, a district court recently considered a motion to employ
23 sampling and extrapolation in a FCA case, like the present, involving Medicare services
24 billed at inappropriate levels of care. *Genoa Healthcare*, 2015 WL 1926417, at *1–4.
25 Because of the large universe of allegedly false claims at issue, the plaintiff moved *in*
26 *limine* to admit "expert testimony on statistical sampling" ***before the sampling had been***
27 ***completed***. *Id.* The district court denied the motion as "premature," while noting that
28 "no universal ban on expert testimony based on statistical sampling applies in a *qui tam*

1 action (or elsewhere)." *Id*. This Court applied similar reasoning to extrapolation: "the
2 proper time to decide on the admissibility of the extrapolation methodology will be
3 ***when the expert testimony including the extrapolation of the data has been submitted***."
4 *Countrywide*, 984 F. Supp. 2d at 1037 (emphasis added).

5 Here, like the sampling in *Genoa Health* and extrapolation in *Countrywide*, the
6 statistical analyses that the Government expects to introduce are not yet complete and of
7 record. Despite that dispositive reality, Prime attempts to obtain an advisory opinion on
8 the admissibility of those analyses by challenging the sampling that it surmises the
9 Government conducted in investigating its claims. *See* Evid. Mot. at 11, 22 (noting that
10 the "universe" of alleged false claims "is apparently based on a medical review of only
11 131 patients in the case of inpatient admissions" and implying that sampling "0.17% of
12 the universe of 78,000 claims" is inadequate). The United States has made no
13 representation, however, that it will rely on any pre-complaint sampling in litigating this
14 case. To the contrary, Prime has agreed and the Court has ordered that the Government
15 will have until January 31, 2018, to conduct the analyses upon which it will rely at trial,
16 and to submit expert reports detailing those analyses. *See* Joint Rule 26(f) Report § IV;
17 Order of Sept. 12, 2016. The United States expects that those reports will correct
18 Prime's assumptions about the purposes for which the Government will introduce
19 statistical evidence and assuage Prime's "reliability" concerns.

20 Prime assumes, for example, that the United States will use statistical evidence "to
21 prove the falsity of Prime claims." Evid. Mot. at 1 (emphasis added). That is an
22 overstatement. The Government may rely on sampling and extrapolation as ***some***
23 ***evidence*** of the falsity of ***certain*** claims, but its proof will be significantly more
24 extensive. As this Court has held, the Relator has alleged "a standardized system of
25 meetings, procedures, hospital forms, and training sessions by all Prime hospitals to
26 perpetrate Medicare fraud." Order of Nov. 20, 2014, at 8, Docket No. 102. That system,
27 which included universal elimination of observation status and imposition of admission
28 quotas, resulted in Prime's submission of millions of dollars' worth of false Medicare

1 claims. CI ¶¶ 4, 14, 48. In addition to presenting statistical evidence to support those
2 allegations, the United States plans to introduce, *inter alia*, internal Prime documents,
3 communications between Prime and ED physicians, fact witness testimony, and expert
4 witness testimony about medical reviews of individual claims. *Cf. Dilts v. Penske*
5 *Logistics*, LLC, 267 F.R.D. 625, 638 (S.D. Cal. 2010) ("As to liability, the use of
6 statistical sampling, at least when paired with persuasive direct evidence, is an
7 acceptable method of proof in a class action."). Even Prime acknowledges that such
8 evidence is probative of the falsity of its claims for inpatient services. *See* Evid. Mot. at
9 22 (noting that the Government is "perfectly capable of individually proving the falsity
10 of a sufficient number of false claims to support its charge that Prime Defendants were
11 allegedly engaged in a corporate scheme to unnecessarily admit Medicare patients").
12 Prime also contends that sampling is inappropriate here because of the variability
13 of the data of interest, overlooking the very purpose of inferential statistics: that "a
14 smaller portion of claims" can reliably support an "inference about a larger, ***not entirely***
15 ***identical***, population of claims." *Life Care*, 114 F. Supp. 3d at 566 (emphasis added);
16 *see also In re Chevron U.S.A.*, Inc., 109 F.3d 1016, 1019–20 (5th Cir. 1997) ("The
17 essence of the science of inferential statistics is that one may confidently draw inferences
18 about the whole from a representative sample of the whole."). The science of inferential
19 statistics provides numerous tools for achieving that purpose. To control for potential
20 biases in sample selection, for example, a statistician may rely on random or
21 "probability" sampling. Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* at
22 224–27 (3d ed. 2011) ("Probability sampling ensures that . . . the sample will be
23 representative of the sampling frame."). And to make precise but conservative
24 conclusions about the population despite variability, a statistician may calculate the
25 standard error, the margin of error, and confidence intervals. *Id.* at 243–46 (a "95%
26 confidence interval" may be established by adding and subtracting "twice the standard
27 error," also known as the "margin of error," from the "sample average."). Such
28 calculations permit conclusions to degrees of certainty that exceed the FCA's

1 "preponderance of the evidence," 31 U.S.C. § 3731(d), or "more likely than not,"
2 standard. *Sanchez v. Monumental Life Ins. Co.*, 102 F.3d 398, 404 (9th Cir. 1996).
3 Here, the United States has ample time to employ these and other statistical
4 methods to address Prime's "reliability" concerns. Until the Government has had the
5 opportunity to do so, however, and until the Court has had the benefit of the
6 Government's expert reports and testimony, a ruling on the compatibility of statistical
7 evidence with the facts of this case would be premature. *See Genoa Health*, 2015 WL
8 1926417, at *4 ("Because the margin of error is unknown" a "*Daubert* hearing is
9 premature.").
10 **B. Even if Ripe, the Evidence Motion is Meritless.**
11 Even if the particulars of the evidence Prime seeks to exclude were before the
12 Court, the Evidence Motion would still lack merit. Sampling and extrapolation are
13 consistent with the language, history, and broad remedial purpose of the FCA; numerous
14 cases decided under the Act; recent Supreme Court and Ninth Circuit opinions in
15 analogous contexts; and Medicare laws, regulations, and guidance. Against that weight
16 of authority, Prime relies on two out-of-Circuit district court decisions; a Supreme Court
17 decision that preceded *Tyson Foods*; and erroneous interpretations of select Medicare
18 regulations and guidance.
19 **1. The Language, History, and Purpose of the FCA Support the Use**
20 **of Sampling and Extrapolation in This Case.**
21 The FCA contains no express limitation on statistical evidence. That omission is
22 significant as Congress has amended the Act multiple times since sampling was first
23 raised in a FCA case, *see Life Care*, 114 F. Supp. 3d at 571, and since regulation under
24 the Civil Monetary Penalties Law, a statute referenced in the FCA, 31 U.S.C. §
25 3730(c)(5), authorized sampling as evidence of false Medicare claims. *See* 42 C.F.R. §
26 1003.133 (1986) (authorizing HHS to "introduce the results of a statistical sampling
27 study as evidence of the number and amount" of false Medicare claims). Aware of
28 HHS's use of sampling and extrapolation under that "***alternate*** remed[ial]" scheme to

1 the FCA, 31 U.S.C. § 3730(c)(5) (emphasis added), it would have been anomalous for
2 Congress to prohibit sampling and extrapolation under "the Government's ***primary***
3 litigative tool for combating fraud." S. Rep. No. 99-345, at 2 (1986). And in fact, in
4 amending the FCA, Congress has moved in the opposite direction, striving to "make the
5 statute a more useful tool against fraud in modern times." *Id.*; *see also Life Care*, 114 F.
6 Supp. 3d at 558 (noting that the FCA has "evolved with the ever-changing landscape of
7 technology and new methods and mechanisms for committing fraud"). That broad
8 remedial purpose requires liberal interpretation of the Act and provides additional
9 support for the use of statistical evidence in FCA cases like the present. *United States v.*
10 *Neifert-White Co.*, 390 U.S. 228, 232 (1968); *cf. Tyson Foods*, 136 S. Ct. at 1047
11 (finding sampling consistent with the "remedial nature" of the Fair Labor Standards Act
12 and the "great public policy which it embodies") (citation and quotation marks omitted).
13 Given the "sheer scale" of Medicare and similar federal programs, "it is often not
14 practicable to do a claim-by-claim review of each allegedly false claim in a complex
15 FCA action." *Life Care*, 114 F. Supp. 3d at 571; *see also Ill. Physicians Union v. Miller*,
16 675 F.2d 151, 157 (7th Cir. 1982) ("in view of the enormous logistical problems of
17 Medicaid enforcement, statistical sampling is the only feasible method available"). If
18 FCA liability could only be established in that manner, fraud would pay. "Armed with
19 the knowledge that the government could not possibly pursue each individual false
20 claim, large-scale perpetrators of fraud would reap the benefits," and "the deterrent
21 effect" of the FCA "would be circumscribed." *Life Care*, 114 F. Supp. 3d at 571*; see*
22 *also Robinson*, 2015 WL 1479396, at *11 (requiring full claim-by-claim review would
23 "frustrate the purposes of the FCA because it would likely encourage anyone who
24 fraudulently submitted claims to Medicare to do so in extremely large quantities so as to
25 prevent the government from logistically being able to bring suit"); *cf. In re Multidistrict*
26 *Vehicle Air Pollution*, 591 F.2d 68, 73 (9th Cir. 1979) (prohibiting proof of damages by
27 inferential evidence "would be an inducement to make wrongdoing so effective and
28 complete in every case as to preclude recovery, by rendering the measure of damages

uncertain") (quoting *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 264 (1946)). An unscrupulous provider might decide, for instance, that a modest civil settlement is a small price to pay for the windfall that presenting scores of false claims would provide. Conversely, it is easy to imagine cases where recovering funds paid on false claims would cost the Government more than the false claims themselves.

When the Ninth Circuit approved of "sampling and extrapolation as part of audits in connection with Medicare," it had these policy concerns in mind:

> To deny public agencies the use of statistical and mathematical audits methods would be to deny them an effective means of detecting abuses in the use of public funds. Public officials are responsible for overseeing the expenditure of our increasingly scarce public resources and we must give them appropriate tools to carry out that charge.

Ratanasen, 11 F.3d at 1471; *see also Rogan*, 517 F.3d at 453 (requiring claim-by-claim review of allegedly false Medicare claims "is a formula for paralysis"); *Yorktown Med. Labs., Inc. v. Perales*, 948 F.2d 84, 90 (2d Cir. 1991) (precluding extrapolation would "hamstring" efforts by Medicaid agencies "to eliminate fraud").

Here, by Prime's own estimation, as many as 78,000 claims are potentially at issue. Evid. Mot. at 11. Paying for individual expert reviews of all of those claims would likely cost the Government more than it could hope to recover in this action. And even if universal review was possible, presenting that review to a jury on a claim-by-claim basis would require months, and probably years, of trial.

Prime's answer to these policy concerns is transparently self-serving, and indeed, troubling: "neither the government nor relator are ***required*** to pursue ***all*** potential false claims submitted by the Prime Defendants." Evid. Mot. at 22 (emphases added). Contrary to Prime's wish, the United States has a responsibility to Medicare beneficiaries and American taxpayers to pursue recovery of all the public funds that it has alleged were paid out as a result of false claims. *See Ratanasen*, 11 F.3d at 1471. A premature evidentiary ruling denying it of "appropriate tools" for doing so, *id.*, would render Prime' exposure grossly out of proportion to its alleged wrongdoing; assure

1 Medicare providers that they can submit false claims with relative impunity; cripple
2 Government efforts, like the present, to recoup public funds spent on medically
3 unnecessary services; and worst of all, undermine the broad remedial purpose of the
4 FCA. The Court should not interpret the Act to permit such results.

5 **2. Cases Decided under the FCA Support the Use of Sampling and**
6 **Extrapolation in This Case.**

7 Cases decided under the FCA bolster this interpretation of the Act. Numerous
8 courts, including two in this Circuit, have permitted sampling as evidence of liability in
9 FCA cases involving questions of medical necessity.

10 *Renown Health* involved conduct nearly identical to the present. There, the
11 provider "submitted false inpatient reimbursement claims to Medicare that should have
12 been billed on a less expensive, outpatient basis." 2015 WL 5123375, at *1. The
13 District Court for the District of Nevada held that "statistical sampling of claims was
14 appropriate" as evidence of "how many claims were improperly submitted for
15 reimbursement," reasoning that sampling "would make this litigation more efficient and
16 less costly," and the provider would retain "the right . . . to question or attack the
17 reliability" of the sampling "through motions *in limine* or at trial." *Id.* at *1, 4 (quoting
18 *Arrendondo v. Delano Farms Co.*, 2014 WL 5106401, at *10 (E.D. Cal. Oct. 10, 2014)).

19 Another District of Nevada decision, *Creekside Hospice*, involved medically
20 unnecessary hospice services. 2016 WL 1257867, at *2–3. Medicare covers such
21 services only if a physician certifies that the beneficiary is terminally ill, meaning "the
22 individual has a medical prognosis that his or her life expectancy is 6 months or less."
23 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3. Despite what Prime incorrectly
24 characterizes as the "inherently subjective" and "patient-specific" nature of that standard,
25 Evid. Mot. at 16, the district court allowed the United States to rely "upon the
26 extrapolation made by its experts" from "what it contends is a statistically valid random
27 sample to prove its claims." *Creekside Hospice*, 2016 WL 1257867, at *6.
28

1 Numerous other courts have reached similar conclusions. *Life Care*, for example,
2 involved medically unnecessary rehabilitation therapy provided to Medicare
3 beneficiaries in skilled nursing facilities. 114 F. Supp. 3d at 551–53. Medicare covers
4 the "Ultra High" level of such therapy only if a physician or practitioner certifies that in
5 his or her medical opinion, the beneficiary required skilled nursing or rehabilitation
6 services on a daily basis, the services could only be provided in a skilled nursing facility
7 or hospital, and the services addressed a condition for which the patient received
8 treatment during a qualifying hospital stay. *Id.* (citing 42 U.S.C. § 1395f(a)(2)(B); 42
9 C.F.R. § 409.31(b)). Like Prime, Life Care contested "the use of statistical sampling in
10 establishing liability because of the individualized factors that affect an analysis of each
11 patient's care," including "age; gender; pre-hospital condition/prior level of function; . . .
12 condition upon admission to skilled nursing facility;" and "whether the patient was
13 terminally ill." *Id.* at 566. Rejecting that and related arguments, the district court wrote:

14 [T]he fact that these factors exist and are likely unique to each patient does
15 not necessarily preclude the use of statistical sampling. Statistical sampling
16 has been used in litigation for decades, and Defendant's argument regarding
17 the individuality of each claim in the sample is not unique to this litigation.
18 In fact, Defendant's argument highlights the very nature of statistical
19 sampling: that a smaller portion of claims will be used to draw an inference
20 about a larger, not entirely identical, population of claims. If all of the
21 claims were exactly the same in every respect, there would be no need for
22 statistical sampling and extrapolation in litigation because each individual unit would be identical, and it would be relatively simple to formulate a mathematical calculation for a large number of claims . . . . The large number of allegedly false claims at issue in this action leads to the natural effect that the claims are unique to one another in some respects . . . . However, as long as the statistical sample is a valid sample that is representative of the universe of claims, the natural disparity between the claims does not preclude using sampling and extrapolation as evidence of the total number of claims for non-covered services.

23 *Id.* at 566–57 (citations omitted).
24 *Robinson*, another medical necessity case, involved optometry services provided
25 to Medicare beneficiaries. 2015 WL 1479396, at *1–3. In denying the provider's
26 motion for summary judgment, the district court rejected arguments similar to Prime's,
27 including that "the necessity of each claim at issue is a subjective determination made by
28 the medical professional on a patient-by-patient basis," and the "use of samples in order

1 to extrapolate liability" is "improper as a matter of law" because "individualized proof"
2 is required. *Id*. at *5, 10; *see also Genoa Healthcare*, 2015 WL 1926417, at *4
3 (declining to conduct *Daubert* hearing before statistical sampling was complete in case
4 involving the medical necessity of rehabilitation care while noting that "no universal ban
5 on expert testimony based on statistical sampling applies in a *qui tam* action");
6 *AseraCare*, 2014 WL 6879254, at *10 (rejecting motion for summary judgment as to all
7 claims outside the Government's statistical sample in action involving the medical
8 necessity of hospice services because "[s]tatistical evidence ***is*** evidence" and questions
9 about the weight of that evidence are "for the jury") (emphasis in original).

10 Against this weight of FCA authority, Prime relies on two out-of-Circuit district
11 court decisions. Unlike the Evidence Motion, *United States ex rel. Wall v. Vista Hospice*
12 *Care, Inc.*, 2016 WL 3449833 (N.D. Tex. June 20, 2016), involved challenges to the
13 reliability and admissibility of ***actual*** experts' reports and testimony. For that reason
14 alone, *Vista Hospice Care* is distinguishable. Furthermore, although the district court
15 decided that statistical evidence was impermissible in the "context" of the case, it did not
16 hold that such evidence was impermissible in all FCA cases, or even in all FCA cases
17 involving "the clinical picture of individual patients." *Id*. at *12 (distinguishing *Life*
18 *Care* and *Robinson*); *id*. at *12 n.100 (noting that certain "evidence" may "mak[e] the
19 sample a reasonable basis for extrapolation to the whole"); *id*. at *14 (criticizing the
20 expert's failure to address certain variables but noting that he "could have"). And even
21 if *Vista Hospice Care* was decided at the pleading stage and involved the same coverage
22 standard at issue here, the decision should be rejected as inconsistent with the FCA and
23 cases decided under it by courts in this Circuit.

24 *United States ex rel. Michaels v. Agape Senior Community*, 2015 WL 3903675
25 (D.S.C. June 25, 2015), should likewise be rejected. The district court's analysis of the
26 sampling question was conclusory, equivocal, and secondary to a separate legal question.
27 The primary question in *Agape Senior Community* (currently on appeal in the Fourth
28 Circuit) was whether the United States was entitled to object to the settlement of a *qui*

tam action in which it had not intervened. *Id*. at *3–9. The district court held that it was, denied the provider's motion to enforce the settlement over the Government's objection, and *sua sponte* certified the question for interlocutory appeal. *Id*. Then, the district court offered an advisory opinion on sampling and extrapolation. *Id*. It suggested that if its denial of the provider's motion to enforce the settlement was overturned, it would find the Government's objection to the settlement "unreasonable" because it was based on "some form of statistical sampling," which the district court had rejected in a two-paragraph order. *Id*. Instead of expounding on that summary rejection,[1] the district court surveyed cases "on each side of the issue;" found that although "some cases are suited for statistical sampling, this "is not such a case;" and certified that question, too, for interlocutory appeal. *Id*. For these reasons, the Court should reject *Vista Hospice Care* and *Agape Senior Community* as distinguishable and contrary to the broad acceptance of statistical evidence under the FCA and in the Ninth Circuit.

3. The Supreme Court's Recent *Tyson Foods* Decision Supports the Use of Sampling and Extrapolation in This Case.

The use of sampling and extrapolation in this case is also consistent with the Supreme Court's recent decision in *Tyson Foods*. As noted, *Tyson Foods* held that sampling and extrapolation are "means to establish or defend against liability," and their "categorical exclusion" is improper. 136 S. Ct. at 1046. Rather, the permissibility of such evidence depends on whether it is "reliable in proving or disproving the elements of the relevant cause of action." *Id*. That question, in turn, depends on "facts and circumstances" particular to each case, such as whether the data to be sampled is related by a "common policy." *Id*. at 1048–49. *Tyson Foods* involved a class of employees seeking overtime pay. *Id*. at 1041. Because the employees "did similar work" and were

[1] In pertinent part, the two-paragraph order stated: "The Court has carefully reviewed the briefs on the topic and researched the topic thoroughly. The Court heard extensive oral argument regarding statistical sampling on October 10, 2014 . . . . After additional consideration and research on statistical sampling, the Court believes that based on the facts of this case, statistical sampling would be improper." *Agape Senior Community*, No. 0:12-cv-034666, Docket No. 255 (Mar. 16, 2015).

1 "paid under the same policy," the Supreme Court held that "the experiences of a subset
2 of employees can be probative as to the experiences of all of them." *Id*. In so holding,
3 the Supreme Court rejected the employer's argument, reminiscent of Prime's, that the
4 "person-specific inquiries into individual work time" necessary to determine liability
5 rendered sampling and extrapolation unreliable. *Id*. at 1046.

6 Similar reasoning has been applied in a FCA case. In *United States ex rel.*
7 *Loughren v. UnumProvidert Corp.*, a health insurance company caused over 450,000
8 insureds to submit false claims for Social Security Disability Insurance (**SSDI**). 604 F.
9 Supp. 2d 259, 260–61 (D. Mass. 2009). The company filed a *Daubert* motion to
10 preclude proof of those claims by sampling and extrapolation. *Id*. At the time of the
11 *Daubert* motion, it was unclear whether each insurance examiner made a "separate
12 subjective evaluation" about "the decision whether to require a claimant to file an
13 application" for SSDI, or whether the company "had a ***general policy*** of requiring a
14 claimant to file an application" before they were entitled to benefits. *Id*. Evidence at
15 trial suggested that the company had a "***policy and practice*** of coercing its insureds" to
16 request SSDI "as soon as they were disabled for six months" regardless of other
17 eligibility considerations. *Id*. Relying on that evidence, the district court concluded that
18 "extrapolation is a reasonable method for determining the number of false claims so long
19 as the statistical methodology is appropriate."[2]

20 Here, like the employees in *Tyson Foods* and the insurance examiners in
21 *UnumProvident*, all physicians at all Prime hospitals operated under the same Prime
22 policies. As this Court has already held, the Relator has alleged "a ***standardized system***
23 of meetings, procedures, hospital forms, and training sessions by ***all*** Prime hospitals to
24 perpetrate Medicare fraud." Order of Nov. 20, 2014, at 8 (emphases added). Upon
25 acquiring a new hospital, Prime implemented policies that "encroached upon" individual
26
27
28

[2] The district court proceeded to apply *Daubert* to the proffered evidence and concluded that the statistical methodology employed by the expert was unreliable because it failed to account for "the overlapping nature" of the sampling. *Id*. at 269.

1 "physicians' medical judgment and discretion," and made inpatient admission decisions
2 uniform and profitable. CI ¶¶ 60, 69. Specifically, "Prime, acting through Reddy and
3 others, would inform physicians and staff that the hospital would no longer use
4 observation for Medicare beneficiaries." CI ¶ 51. To assure company-wide
5 implementation, Prime simply removed the "observation services" check box from ED
6 and attending physician order forms. CI ¶ 52. Similarly, upon acquiring a hospital,
7 Prime would implement "a policy of directing ED physicians to admit insured patients
8 from the ED if their evaluation or treatment would take longer than two hours." CI ¶ 58.
9 The "no observation" and "two hour" policies were a universal success: billings for
10 observation care at newly acquired Prime hospitals would decrease dramatically while
11 billings for inpatient care would increase. CI ¶¶ 61–63.
12 Prime also "introduced arbitrary admission benchmarks or quotas that Defendant
13 Hospitals should admit as inpatients 20 to 30% of the insured patients who presented at
14 the ED." CI ¶ 64. To monitor the satisfaction of those quotas, Prime leadership
15 scrutinized reports of admission rates by individual Prime hospitals, CI ¶¶ 73–80, and
16 even by individual physicians. CI ¶¶ 87–90. If a hospital's or physician's admission
17 numbers fell below expectations, Prime took action, "second-guessing" physicians'
18 "medical judgment," pressuring them "to alter their clinical judgment in favor of
19 admitting Medicare beneficiaries," and threatening that they would find themselves "off
20 the schedule." CI ¶¶ 12(c), 69, 94. As these policies were common to all Prime
21 hospitals, a subset of inpatient admission claims is probative of them all.
22 Prime's reliance on the Supreme Court's pre-*Tyson Foods* reservation about "Trial
23 by Formula" is misplaced. *See* Evid. Mot. at 13 (quoting *Wal-Mart Stores, Inc. v.*
24 *Dukes*, 564 U.S. 338, 367 (2011)). Unlike this case and *Tyson Foods*, *Wal-Mart*
25 involved pay and promotion decisions that were "generally committed to local
26 managers' broad discretion." *Tyson Foods*, 136 S. Ct. at 1048. Moreover, unlike the
27 Complaint in Intervention, the plaintiffs in *Wal-Mart* had not identified "a common
28 mode of exercising [that] discretion that pervades the entire company." *Id*. (quoting

1 *Wal-Mart*, 564 U.S. at 355–56). Thus, the Supreme Court concluded in *Tyson Foods*,
2 *Wal-Mart* "does not stand for the broad proposition that a representative sample is an
3 impermissible means of establishing classwide liability." *Id*. at 1046, 1048.

4 **4. Decisions by Ninth Circuit Courts in Analogous Contexts**
5 **Support the Use of Sampling and Extrapolation in This Case.**

6 Ninth Circuit courts in analogous cases have reached similar conclusions. In
7 particular, courts in this Circuit have approved of sampling and extrapolation as evidence
8 of liability in cases involving an allegedly "unique" Medicare coverage standard,
9 independent "professional judgment," widely variable data, and even proof beyond a
10 reasonable doubt.

11 In June of this year, the Ninth Circuit distinguished *Wal-Mart* and applied the
12 Supreme Court's guidance in *Tyson Foods* that "the need for individualized liability
13 determinations" does not preclude the "use of expert statisticians and statistical surveys."
14 *Vauquero v. Ashley Furniture Indus., Inc.*, 824 F.3d 1150, 1155 (9th Cir. 2016). And
15 just two years ago, the Ninth Circuit held that notwithstanding *Wal-Mart*, "circuit courts
16 including this one have consistently held that statistical sampling and representative
17 testimony are acceptable ways to determine liability." *Jimenez*, 765 F.3d at 1167.

18 Consistent with those principles, this Court approved the use of sampling and
19 extrapolation in a Medicare overpayment action involving medically unnecessary
20 chiropractic services. *Bend v. Sebelius*, 2010 WL 4852230, at *1–2 (C.D. Cal. Nov. 19,
21 2010). Like Prime, the provider suggested that chiropractic services are "unique" and
22 "inherently more subjective" than other services covered by Medicare. *Id*. at *4–5.
23 Finding "no reason to treat statistical sampling for chiropractic services any different
24 than statistical sampling for other Medicare services," this Court denied the provider's
25 challenge to the overpayment decision. *Id.*

26 Similarly, this Court approved the use of sampling in a civil suit involving the
27 adherence of loans in residential mortgage-backed securities to underwriting guidelines
28 disclosed to investors. *Countrywide*, 984 F. Supp. 2d at 1032. Countrywide moved to

1 exclude the investors' loan sampling plans on the ground that they prevented accurate
2 evaluation of "questions of gradation, like reasonable professional judgment" of
3 individual underwriters evaluating individual loans. *Id.* Unpersuaded, this Court denied
4 Countrywide's motion, holding that the investors' sampling plans satisfied Federal Rule
5 of Evidence 702. *Id.*; *see also Assured Guar. Mun. Corp. v. Flagstar Bank*, 920 F. Supp.
6 2d 475, 512 (S.D.N.Y. 2013); *In re Wash. Mut. Mortgage-Backed Sec. Litig.*, 2012 WL
7 2995046, at *6 (W.D. Wash. July 23, 2012).

8 In another analogous case, an advertising company argued that although
9 extrapolation may be valid in the abstract, it was inappropriate to establish contract
10 overcharges because "***wide variations*** exist between the amounts of overcharges on
11 various invoices." *Prime Media Grp.*, 2015 WL 452192, at *4 (emphasis added).
12 Rejecting that argument, the district court held that "[e]xtrapolating results from a
13 sample to a population is a routine statistical technique and indeed is often necessary in
14 the face of an incomplete or intractably large data set." *Id.* Like several of the FCA
15 decisions discussed in Part IV.B.2, *supra*, the district court reasoned that variability does
16 not render statistical analysis "inadmissibly unreliable" but "goes to the weight the jury
17 should accord" the evidence. *Id.*

18 And even in a criminal action, where proof of liability must be "beyond a
19 reasonable doubt," the Ninth Circuit permitted the Government to establish tax evasion
20 using extrapolation from a "representative sample" of 12 of the accused's bank deposits
21 over a two-year period. *United States v. Stone*, 770 F.2d 842, 844–45 (9th Cir. 1985).

22 **5. The Medicare Act and Medicare Regulations and Guidance**
23 **Support the Use of Sampling and Extrapolation in This Case.**

24 As under the FCA and the Supreme Court and Ninth Circuit cases discussed
25 above, statistical sampling and extrapolation are approved methods of proof in
26 administrative overpayment and civil monetary penalties proceedings. The Medicare
27 Act authorizes the "use of extrapolation to determine overpayment amounts to be
28 recovered by recoupment, offset, or otherwise" upon a determination by HHS that "there

is a sustained or high level of payment error" or "documented educational intervention has failed to correct the payment error." 42 U.S.C. § 1395ddd(f)(3); *see also* 42 C.F.R. § 405.1064 (providing standard of review by Administrative Law Judge (**ALJ**) where appeal from a Qualified Independent Contractor (**QIC**) "involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration"). An overpayment determination, like "a credible allegation of fraud," which includes "[p]atterns identified through provider audits," 42 C.F.R. § 405.370(a), is also a basis for suspending payments to a Medicare provider. 42 C.F.R. § 405.371(a). In that context, too, Medicare has employed "the principles of statistical sampling . . . to determine what percentage of claims in a given universe of suspended claims are payable." CMS Pub. 100-08, Medicare Program Integrity Manual (**MPIM**), Ch. 8 § 3.2.3.1(A) (Rev. 377).

Similarly, regulations promulgated under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a (**CMPL**), authorize the HHS Office of the Inspector General (**OIG**) to "introduce the results of a statistical sampling study as evidence of the number and amount" of false Medicare claims "presented or caused to be presented" by the respondent provider. 42 C.F.R. § 1003.133; *see also* 42 C.F.R. § 402.109 (HHS or OIG "may introduce the results of a statistical study to show the number and amount of claims subject to sanction under this part"). So prevalent is the use of inferential statistics in overpayment and penalties proceedings that the MPIM devotes an entire chapter to sampling and extrapolation methods. *See* MPIM, Ch. 8.[3]

Judicial decisions have only bolstered these authorities. Federal courts, including the Ninth Circuit, have approved "the use of sampling and extrapolation as part of audits in connection with Medicare." *Ratanasen*, 11 F.3d at 1471. As this Court recently observed, "statistical sampling has been used by Medicare since February 1986 and has withstood numerous due process challenges." *Bend*, 2010 WL 4852230, at *4; *see also*

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[3] Prior to May 27, 2011, Chapter 8 of the MPIM was found in Chapter 3. *Miniet v. Sebelius*, 2012 WL 2930746, at *6 n.9 (S.D. Fla. July 18, 2012).

Gentiva Healthcare Corp. v. Sebelius, 723 F.3d 292, 297 (D.C. Cir. 2013) (rejecting Medicare provider's contention that HHS failed to satisfy a statutory prerequisite before relying on extrapolation to establish overpayments); *Miniet*, 2012 WL 2930746, at *5 (same); *Chaves Cnty. Home Health v. Sullivan*, 931 F.2d 914, 916 (D.C. Cir. 1991) (rejecting Part A provider's constitutional, statutory, and regulatory challenges to "sample adjudication" used to establish overpayments); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 16–23 (E.D.N.Y. 2012) (rejecting five specific challenges to sampling and extrapolation performed to establish overpayments to Part B provider); *Webb v. Shalala*, 49 F. Supp. 2d 1114, 1123 (W.D. Ark. 1999) (rejecting Part B provider's "arguments that the statistical analysis" used to establish overpayments "was flawed"); *Mile High Therapy Ctrs., Inc. v. Bowen*, 735 F. Supp. 984, 985–86 (D. Colo. 1988) (rejecting Part B provider's argument that "the use of a statistical sample" to establish overpayments "violated the Medicare Act" and the "Medicare Carrier's Manual").[4]

Without acknowledging these authorities, Prime repeatedly contends that CMS requires: (a) Medicare contractors to "review the appropriateness of Part A hospital admissions on a ***case-by-case basis***," and (b) Prime to "administratively appeal CMS denials of inpatient admission claims on a ***case-by-case basis***." Evid. Mot. at 18 (emphases added); *see also id.* at 22–23.[5] Those contentions conflate routine initial payment determination (and appeal)—where the task is promptly to process valid claims—with overpayment audits—where statute, regulation, and guidance explicitly

[4] Sampling and extrapolation have also been consistently approved for use in establishing ***Medicaid*** overpayments. *See, e.g., Yorktown Medical Lab.*, 948 F.2d at 89–90 (rejecting Medicaid provider's claim that "any extrapolation from the sample to the entire universe of claims" violates "due process rights" by sanctioning "unidentified unacceptable practices"); *Ill. Physicians Union*, 675 F.2d at 156 (concluding that "the use of sampling and extrapolation" to establish Medicaid overpayment was "proper"); *State of Ga. Dep't of Human Res. v. Califano*, 446 F. Supp. 404, 409–10 (N.D. Ga. 1977) (approving the use of sampling to establish Medicaid overpayments and noting that "mathematical and statistical methods are well recognized as reliable and acceptable evidence in determining adjudicative facts").

[5] Interestingly, if Defendants still find the "burden" of case-by-case appeal too great, Evid. Mot. at 22–23, they may now request that their outstanding ALJ-level appeals be decided using sampling and extrapolation. *See* HHS, Office of Medicare Hearings and Appeals, "Statistical Sampling Initiative," http://www.hhs.gov.

1 authorize sampling and extrapolation because the task is to detect payment trends. *See*
2 42 U.S.C. § 1395ddd(f)(3); 42 C.F.R. §§ 402.109, 405.370(a); 405.371(a); 405.1064,
3 1003.133; MPIM, Ch. 3 § 5.2, Ch. 8. After all, separate reviewers processing (and
4 hearing appeal of) separate individual claims cannot evaluate and remedy ***patterns*** like
5 "a ***sustained*** or high level of payment error," 42 U.S.C. § 1395ddd(f)(3) (emphasis
6 added), but an auditor reviewing a representative sample of those claims can.

7 An argument similar to Prime's was made by a Part A provider and rejected by the
8 District of Columbia Circuit in *Chaves County Home Health*. There, the provider
9 challenged an overpayment determination on the ground that a "sample audit on post-
10 payment review" was "incompatible" with "the individualized adjudication scheme for
11 initial payment determinations." 931 F.2d at 916. The Court of Appeals found no such
12 incompatibility, noting that HHS merely "***supplemented*** individualized pre-payment
13 review of claims with a sampling procedure on post-payment review ***of providers***
14 ***suspected of overbilling***." *Id*. at 917 (emphases added); s*ee also United States v. Lahey*
15 *Clinic Hospital, Inc*., 399 F.3d 1, 17 (1st Cir. 2005) (noting that in addition to "the
16 scheme set up by the Medicare Act and the Secretary of HHS," Congress "has provided
17 the government ***two other independent methods*** to recover overpayments," including
18 "civil money penalties for knowing violations of the Medicare Act" under the CMPL,
19 and recovery of payments "made on the basis of a false or fraudulent claim" under the
20 FCA) (emphasis added).

21 Thus, that Medicare contractors have reviewed and Prime has appealed
22 (successfully or otherwise[6]) thousands of initial payment determinations on a claim-by-
23 claim basis, *see* Evid. Mot. at 23, does not mean that the Government is precluded from
24 conducting post-payment audits of samples of those claims to support overpayment,
25
26 [6] The Evidence Motion incorrectly represents that "Prime's success rate of appeal has been nearly 100% with 4,277 appeals pending at various stages." Evid. Mot. at 23.
27 Neither the Evidence Motion nor the Declaration of Akila Pasupulati explain how that rate was calculated, and recent data from the AdQIC, the CMS contractor responsible for
28 analyzing appeals of Medicare claim denials, shows that Prime's actual "success rate" is below 50 percent. *See* Declaration of Amy Sheehan ¶¶ 4–8.

1 penalties, or FCA actions, or that such audits are "entirely unnecessary in this case." *Id*.
2 And in any event, Prime's attempt to inject disputes of fact into its pre-answer motion
3 should be rejected. *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010)
4 (scope of review on pre-answer motion "is limited to the Complaint" and documents it
5 references that are "central to the plaintiff's claim" and indisputably authentic.)
6 The Evidence Motion's quotations of Federal Register excerpts and Medicare
7 manuals are similarly unavailing. Some of the quoted sources post-date the period
8 relevant to this case. For example, guidance in 78 F.R. 50496, which the Evidence
9 Motion quotes extensively (and in one instance mistakenly refers to as "7***3*** FR"), *see*
10 Evid. Mot at 17–19, 23, relates to changes to the inpatient prospective payment system
11 applicable to discharges "***on or after October 1, 2013***." 78 F.R. 50496, 50496 (Aug. 19,
12 2013) (emphasis added). And even if they were applicable, none of the sources Prime
13 cites suggest a Medicare coverage standard that is categorically less compatible with
14 sampling than the standards at issue in the medical necessity cases discussed in Part
15 II.B.2 & 5, *supra*, where sampling and extrapolation were permitted.
16 **C. Precluding Sampling and Extrapolation Will Neither Limit Prime's**
17 **Ability to Defend Itself Nor Make This Litigation More Efficient.**
18 Prime raises two additional concerns, neither of which outweighs the statutes,
19 regulations, judicial decisions, and public policies supporting the use of statistical
20 evidence in this case. First, Prime suggests that sampling and extrapolation implicate its
21 ability to defend this action. Evid. Mot. at 2–3. They do not. Prime will remain able,
22 *inter alia*, to contest conclusions about specific claims in the Government's sample, to
23 "take issue with the statistical validity of an extrapolation from the sample," and to raise
24 "challenges based on particular claims in the non-sample universe." *Chaves Cnty. Home*
25 *Health Servs.*, 931 F.2d at 921. Prime may also retain its own experts to develop
26 competing samples and present alternative analyses in rebuttal expert reports. *See* Joint
27 Rule 26(f) Report § IV. And as with any evidence, Prime may argue the weight that
28 should be accorded to statistical evidence at the appropriate time. *See, e.g.*, *Prime*

Media, 2015 WL 452192, at *4. More fundamentally, there is simply no basis to assume that sampling will be worse for Prime than universal review; it is as likely to be better. *See Long v. Trans World Airlines, Inc.*, 761 F. Supp. 1320, 1329 (N.D. Ill. 1991) ("the likelihood that extrapolation would produce a lower total for damages" than individual review of the universe of claims "is the same as the likelihood that it would produce a higher total").

Second, Prime argues that statistical evidence will make this litigation ***less*** orderly and efficient because if such evidence is permitted, Prime will mount a "claim by claim defense . . . based on individual claim reviews." Evid. Mot. at 3. As discussed, however, Prime has many other means of defending itself. Accordingly, it is difficult to understand how ***precluding*** statistical evidence will make this litigation ***more*** orderly and efficient—*cf. Renown Health*, 2015 WL 5123375, at *1 ("statistical sampling of claims . . . would make this litigation more efficient and less costly")—especially as the parties have agreed that if the Evidence Motion is denied, they will "work together to see if they can reach agreement about a statistical sample or samples of claims for use at trial." Joint Rule 26(f) Report § IV.

V. CONCLUSION

For the foregoing reasons, the Court should deny the Evidence Motion and hold the parties to that agreement.

Dated: October 6, 2016

Respectfully submitted,

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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* KARIN BERNTSEN,

Plaintiffs,

v.

PRIME HEALTHCARE SERVICES, INC.; *et al.*,

Defendants.

Case No. CV 11-08214 PJW

DECLARATION OF AMY SHEEHAN IN SUPPORT OF UNITED STATES' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE STATISTICAL SAMPLING EVIDENCE

Date: October 27, 2016
Time: 1:30p.m.
Place: Courtroom 23, 3rd Floor
Complaint Filed: June 23, 2016
Trial Date: November 26. 2018

DECLARATION OF AMY SHEEHAN

I, Amy Sheehan, declare and state as follows:

1. I am a resident of South Carolina employed by Q^2 Administrators as the Project/Program Director, AdQIC. The AdQIC is a contractor to the Centers for Medicare and Medicaid Services (CMS), a component of the United States Department of Health and Human Services (HHS). I have a Masters in Human Resources from the University of South Carolina and a Bachelors Degree in Business and Marketing from Converse College. Q^2A was one of eight Qualified Independent Contractors (QICs) chosen by the Department of Health and Human Services, Centers for Medicare and Medicaid Services, to implement a new system for appealing Medicare claim denials. In 2004, Q^2A became the first Administrative QIC (AdQIC) under the new appeals system. The AdQIC is the QIC that provides administrative services and support to CMS and other QICs by analyzing appeal outcomes and managing case files, among other functions. One of the functions performed by the AdQIC is to collect, consolidate, store, maintain, and distribute information regarding the receipt, processing, and disposition of reconsideration requests, as well as to review reconsideration data for statistical and analytical purposes. The AdQIC is also tasked with responding to requests for reports and providing assistance in generating special reports on specific issues for CMS. To achieve this task, we have access to AdQIC databases containing information regarding Medicare claims appeals, including requests for reconsideration by a QIC, appeals for review by Office of Medicare Hearings and Appeals (OMHA) administrative law judges (ALJs), and requests for review by Medicare Appeals Council of the Departmental Appeals Board (DAB). Data may also be obtained and supplemented through the Medicare Appeals System (MAS), the repository for Medicare appeals data.

2. CMS has established a five level appeals process for Medicare claim denials. The first level is a request for redetermination which is made to the Medicare contractor that reviewed and denied the claim; however, a different person from the one

1 who processed the claim reviews the claim. The second level is to a QIC. QICs have
2 their own physicians and other health professionals to independently review and assess
3 the medical necessity of items and services billed on the claim. The third level is to an
4 ALJ at OMHA. The fourth level is to the Medicare Appeals Council, which is part of
5 the HHS Departmental Appeals Board (DAB). The fifth level is to federal district court.
6 3. The AdQIC Reporting team identified relevant appeals through the
7 Medicare Appeals System (MAS) that were filed by the following fourteen hospitals
8 owned by Prime Healthcare that are located in California:
9 a. Prime Healthcare Paradise Valley
10 b. Prime Healthcare Services Encino, LLC d/b/a Encino Hospital Medical
11 Center
12 c. Prime Healthcare Services – Garden Grove, LLC d/b/a Garden Grove
13 Hospital & Medical Center
14 d. Prime Healthcare Anaheim d/b/a West Anaheim Medical Center
15 e. Prime Healthcare Huntington Beach
16 f. Prime Healthcare La Palma d/b/a La Palma Intercommunity Hospital
17 g. Veritas Health Services d/b/a Chino Valley Medical Center, Inc.
18 h. Prime Healthcare Services – San Dimas LLC d/b/a San Dimas
19 Community Hospital
20 i. Desert Valley Hospital, Inc.
21 j. Prime Healthcare Centinela, LLC d/b/a Centinela Hospital Medical
22 Center
23 k. Prime Healthcare Services – Sherman Oaks, LLC d/b/a Sherman Oaks
24 Hospital
25 l. Alvarado Hospital, LLC
26 m. Prime Healthcare Services – Montclair, LLC d/b/a Montclair Hospital
27 Medical Center
28

n. Prime Healthcare Services – Shasta, LLC

4. At the QIC level, the AdQIC has identified 6,262 appeals of claim denials of inpatient hospital services for the providers listed in paragraph 3 above, with dates of service between January 1, 2006 and September 30, 2013. The QIC entered a decision favorable to the hospital on 1,054 of those claims, a partially favorable decision on 3 claims, and upheld the claim denials on the remaining 5,205 appeals, or 83.1% of the total.

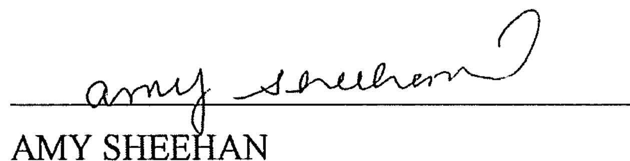
5. The Prime hospitals appealed almost all of the claim denials that the QIC upheld to the ALJ level at OMHA.

6. Our records show that over 3,000 of those appeals are pending at OMHA.

7. Our records show that 1,980 of the claims have been decided by ALJs with the following disposition: 821 decisions favorable to the hospital, 50 decisions that were partially favorable to the hospital, 562 decisions that were unfavorable to the hospital, 511 claims that were dismissed, and 16 claims that were remanded to a lower level in the appeals process. Thus, overall, for the claims appealed to the ALJ level that have been addressed to date, the Prime hospitals have successfully appealed approximately 44%.

8. Our records show that the Prime hospitals listed in paragraph 3 have, since 2012, appealed 67 claim denials that were upheld by the ALJ to the Medicare Appeals Council. Fifty-four of the 67 claims are pending. Of the 13 that have been decided, 1 decision was partially favorable to the hospital, 3 were unfavorable to the hospital, 1 case was vacated, and the remaining 8 were dismissed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on October 6, 2016 in Columbia, South Carolina.



AMY SHEEHAN