No. 22-15862

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Marcia Stein and Rodolfo Bone, Relators,
Plaintiffs and Appellants,

and

United States of America, ex rel.,
Plaintiff,

vs.

Kaiser Foundation Health Plan, Inc., et al.,
Defendants and Appellees.

On Appeal from the United States District Court
Northern District of California
Case No. 3:16-cv-05337-EMC
The Honorable Edward M. Chen

REPLY BRIEF OF APPELLANTS MARCIA STEIN AND RODOLFO BONE

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I. INTRODUCTION AND SUMMARY OF ARGUMENT.

The Ninth Circuit *en banc* should reject and disapprove of its prior holdings that the first-to-file rule, 31 U.S.C. § 3730(b)(5), is jurisdictional because they conflict with the Supreme Court's "clear-statement principle" and sister circuits' decisions determining that the first-to-file rule is NOT jurisdictional after applying the clear-statement principle to the first-to-file rule. Accordingly, the District Court improperly granted the Kaiser Appellees' Fed.R.Civ.P. 12(b)(1) first-to-file motion to dismiss Appellants Stein and Bone's (collectively, "Stein") action because the first-to-file rule is not jurisdictional and therefore not the subject matter of a Fed.R.Civ.P. 12(b)(1) jurisdictional motion to dismiss. Further, Stein's FCA claims (other than their Refresh fraud claim) are not barred by the first-to-file rule because they are based on fraud schemes materially different from and independent of the prior actions' FCA frauds. Last, Appellants Stein should have been granted leave to further amend their complaint to the extent any of their claims (other than their Refresh fraud claim) is barred by the first-to-file rule.

II. LEGAL ARGUMENT.

A. BECAUSE THE FIRST-TO-FILE RULE IS *NOT* JURISDICTIONAL UNDER THE SUPREME COURT'S CLEAR-STATEMENT PRINCIPLE, THIS APPEAL REQUIRES *EN BANC* REVIEW TO REJECT AND DISAPPROVE THE NINTH CIRCUIT'S PRIOR HOLDINGS THAT THE FIRST-TO-FILE RULE IS JURISDICTIONAL, AND TO REVERSE THE DISTRICT COURT'S GRANTING OF THE KAISER APPELLEES' FED.R.CIV.P. 12(b)(1) MOTION TO DISMISS.

The Kaiser Appellees do not appear to dispute that the Supreme Court's clear-statement principle applies to the first-to-file rule.[1] Rather, at pages 32-34 of their brief, Appellees argue that Appellants Stein cannot request *en banc* review without having filed a petition requesting *en banc* review. Appellees are wrong.

As discussed in the AOB at pages 20-21, when a three-judge panel is persuaded that prior circuit decision is now erroneous, it has "the right, and perhaps even the duty, to bring the matter to the attention of our colleagues and suggest that an en banc court be convened to reconsider the matter afresh." *Espinosa v. United Student Aid Funds, Inc.,* 530 F.3d 895, 898 (9th Cir. 2008). *See also*, *Atonio v. Wards Cove Packing Co.*, 810 F.2d 1477, 1478-79 (9th Cir. 1987) (en banc) ["We now hold that the appropriate mechanism for resolving an irreconcilable conflict is an en banc decision. *A panel faced with such a conflict must call for en banc review*, which the court will normally grant unless the prior decisions can be distinguished." (*Italics* added.)]

As discussed in the AOB at pages 12-18, the first-to-file rule is NOT jurisdictional (and thus not the subject of a Fed.R.Civ.P. 12(b)(1) jurisdictional

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[1]The first-to-file rule, 31 U.S.C. § 3730(b)(5), states:

> "When a person brings an action under this [*qui tam*] subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action."

motion) because under the Supreme Court's clear-statement principle, the first-to-file rule does not clearly state that the rule is jurisdictional, *Sebelius v. Auburn Reg'l Med. Ctr.,* 568 U.S. 145, 153, 133 S.Ct. 817, 824, 184 L.Ed.2d 627 (2013) (quoting *Arbaugh v. Y & H Corp*., 546 U.S. 500, 515-516, 126 S.Ct. 1235, 163 L.Ed.2d 1097 (2006); *Gonzalez v. Thaler,* 565 U.S. 134, 132 S.Ct. 641, 181 L.Ed.2d 619 (2012). Applying the clear-statement principle, the Courts of Appeals for the District of Columbia, First, Second, Third, and Sixth Circuits held that the first-to-file rule is NOT jurisdictional. *United States ex rel. Heath v. AT&T, Inc.,* 791 F.3d 112, 121 (D.C. Cir. 2015); *United States v. Millenium Labs., Inc.,* 923 F.3d 240, 249-51 (1st Cir. 2019); *United States ex rel. Hayes v. Allstate Ins. Co.,* 853 F.3d 80, 87 (2nd Cir. 2017); *In re Plavix Marketing, Sales Practices and Products Liability Litigation (No. II),* 974 F.3d 228, 232 (3rd Cir. 2020); *United States ex rel. Bryant v. Community Health Systems, Inc.,* 24 F.4th 1024, 1036 (6th Cir. 2021).

As discussed in the AOB at pages 19-21, because the Ninth Circuit held the first-to-file rule was jurisdictional in *United States ex rel. Lujan v. Hughes Aircraft Co.,* 243 F.3d 1181, 1183 (9th Cir. 2001) before the Supreme Court established the clear-statement principle, and in *United States ex rel. Hartpence v. Kinetic Concepts, Inc.,* 792 F.3d 1121, 1130 (9th Cir. 2015) (en banc) (which simply followed *Lujan* without conducting a clear-statement principle analysis) *after* the Supreme Court directed that the clear-statement principle be used to determine if a statute was

jurisdictional, Appellants Stein contend that the present three-justice panel should refer this appeal for *en banc* review so that the Ninth Circuit *en banc* can determine whether the first-to-file rule is jurisdictional in light of the clear-statement principle (and thus the proper subject of Appellees' Fed.R.Civ.P. 12(b)(1) jurisdictional motion), and disapprove of the holdings in *Hartpence* and *Lujan* that the first-to-file rule is jurisdictional. *Espinosa,* 530 F.3d at 898; *Atonio*, 810 F.2d at 1478-79.

B. THE FIRST-TO-FILE RULE AND THE MATERIAL FACTS TEST.

In *Hartpence*, the Ninth Circuit illustrated how a defendant's similar, but factually distinct, fraud schemes against the Government are not barred by the first-to-file rule. In *Hartpence*, the first relator's (Hartpence) *qui tam* FCA complaint alleged that the defendant (a manufacturer of Vacuum Assisted Closure (VAC) Therapy devices that performed negative pressure wound therapy (NPWT)) violated the FCA by misusing the "KX modifier" when billing Medicare and for retaining overpayments it obtained as a result of this scheme. *Hartpence,* 792 F.3d at 1124-25. The second realtor's (Godecke) *qui tam* complaint alleged that the defendant violated the FCA by (a) misusing the KX modifier in submitting claims to Medicare, (b) billing Medicare even though defendant ignored the requirement to receive correct and completed Detailed Written Orders (DWOs) before delivering supplies and beginning therapy, and (c) for retaining overpayments it obtained as a result of these two schemes. *Id.* at 1125-1126.

After reviewing the pending amended complaints filed by the two relators, *Id.* at 1125, n. 2, *Hartpence* determined that while Godecke's *qui tam* action's KX modifier claim was based on the same material facts as the Hartpence's *qui tam* action's KX modifier claim (as both concerned the defendant's misuse of the KX modifier when billing Medicare), *Id.* at 1131, *Hartpence* also determined that Godecke's *qui tam* action's second claim (billing Medicare even though defendant ignored the requirement to receive correct and completed DWOs) was not based on the same material facts as the first *qui tam* action's KX modifier claim. *Id.* at 1131. *Hartpence* points out that the two fraud schemes involve violations of different Medicare requirements, and "exist completely independent of one another." *Id.* at 1131. Further, *Hartpence* found that dismissal of Godecke's *qui tam* action would not serve the dual purpose of the first-to-file rule ("to promote incentives for whistle-blowing insiders and prevent opportunistic successive plaintiffs") because (a) "allowing claims for related but distinct fraud claims encourages broader investigation and increases the total potential for recovery," and (b) dismissal of Godecke's *qui tam* action does not discourage opportunistic "piggyback claims which would have no additional benefit to the government." *Id.* at 1131. *Hartpence* held that Godecke's *qui tam* action's DWO claim "provided information about a different form of fraud, and without that information the government might not have investigated beyond [defendant's] fraudulent" KX modifier coding practice. *Id.* at

1131-1132. Accordingly, *Hartpence* held that Godecke's *qui tam* action's second and third claims (billing Medicare even though defendant ignored the requirement to receive correct and completed DWOs, and retaining overpayments it obtained as a result of said scheme) were not barred by the first-to-file rule because they "are based on different material facts than the claims contained in . . . the earlier-filed complaint." *Id.* at 1132.

1. The District Court Erroneously Adopted a "Government Notice Standard" as the "Primary Yardstick" for Applying the First-to-File Rule.

During Kaiser's oral argument, the District Court speciously adopted a "Government notice standard" as the "primary yardstick" for the material facts test and fallaciously concluded that *Stein's* sepsis and malnutrition frauds were "within the ballpark enough to give notice" of *Osinek* under its constructive notice "Government notice standard" thereby triggering the bar under the first-to-file rule. 2-ER-63, 65-66, The following excerpts from the District Court's oral argument transcript illustrate the foregoing:

> THE COURT: **And then on the notice point, as I adopted the kind of notice to the defendant, a yardstick for measuring relatedness,** I guess the argument here is, the proof is in the pudding because the investigation that was triggered did exceed or go beyond just the state of California. 2-ER-63 (Emphasis added.)

> THE COURT: But then, **if we're using the notice-to-the-Government kind of yardstick,** and if the allegations here are, given the upcoming and the use of algorithms and all that stuff, why wouldn't that have been enough -- whether

> it did or didn't is not actually necessarily the question -- but why wouldn't that be enough to give -- **I don't know if you call it constructive notice, inquiry notice,** whatever the analogy is -- **the kind of notice to the Government of potential facts that would have uncovered a nationwide problem**? Why isn't that notice, sort of, standard satisfied here? 2-ER-65-66.
>
> THE COURT: That wasn't the only allegation. The other allegation is pressuring doctors to --
> MR. ZINBERG: And --
> THE COURT: -- stand diagnoses and capture high HCCs, and sepsis is one of those.
> MR. ZINBERG: Yes, but as part of their Refresh program. All of that was under the ambit of their Refresh program --
> THE COURT: Well, all right. But --
> MR. ZINBERG: -- where --
> THE COURT: The more you finely cut that, the **more difficult it is against the notice standard,** it seems to me. Again, it doesn't have to be exactly the same; **it's got to be within the ballpark enough to give notice.** 2-ER-81-82 (Emphasis added.)

The District Court's Order did not reference its "notice to the Government standard as a yardstick" but instead referred to citations from *Lujan,* 243 F.3d at 1188-89, *United States ex rel. LaCorte v. SmithKline Beecham Clinical Lab., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998), *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1209 (D.C. Cir. 2011), and *Hartpence*, 792 F.3d at 1125, 1131-32 emphasizing passages that discussed notice to the Government as part of the first-to-file analysis. 1-ER-19. However, the cited passages address claims where the later filed action was merely a slight variation of the first (e.g., *Lujan*), was the same claim but an expansion of the geographic scope (e.g., *Batiste*), or where the court found that the claims were

similar but still separate so that the first-to-file rule is not triggered (e.g., *Hartpence*). None of the cited passages support the District Court's expansive position articulated during oral argument for using an inquiry or constructive style "Government notice yardstick" in applying the material facts test.

To the contrary, the cited passages conclude that the Government is on notice of all relevant facts only when the later filed action is a slight variation of the first-filed action and therefore cannot provide additional material facts. In applying the material facts test, the cited cases used Notice to the Government as a possible conclusion of the material facts test but never its starting point. The material facts test, as applied by the District Court, resembles a throwback to the draconian, pre-1986 Government Notice Bar and a clear departure from the material facts test applied by the Ninth Circuit in *Hartpence.*

C. STEIN'S SEPSIS, MALNUTRITION, AND AORTIC ATHEROSCLEROSIS (AA) FRAUD CLAIMS ARE INDEPENDENT OF AND BASED ON FACTS MATERIALLY DIFFERENT FROM AND THE PRIOR ACTIONS' FRAUD CLAIMS.

1. Overview of Stein's Refresh Fraud Claim and the Prior Filed Actions' Refresh Fraud Schemes.

Stein's Refresh Fraud Claim and *Osinek, Taylor,* and *Arefi* all allege what is referred to as Kaiser's "Refresh Fraud" scheme. The Refresh Fraud involved re-diagnosing of all Kaiser's prior year's HCC diagnoses in the current year. For example, Kaiser's data-mining identified that Patient X was diagnosed with a diabetic

neuropathy during the prior calendar year but had not been diagnosed with a diabetic neuropathy during the current calendar year. Using Kaiser's terminology, the diabetic neuropathy diagnosis was "missing" and the patient's primary care physician ("PCP") needed to "Refresh" the missing diagnosis by adding supporting documentation in the current year of that diagnosis in the patient's medical record. Once Kaiser had identified the missing HCC, Kaiser coders would provide Patient X's PCP with a leading query instructing the PCP to Refresh the missing diabetic neuropathy diagnoses by amending Patient X's medical record, as of the current year's last physician encounter (i.e., the last office visit) to include a medical record entry supporting a diagnoses of diabetic neuropathy. The coder's query frequently provided the exact language required for the medical record addendum. Later this process became streamlined and the required addendum language was pre-populated into Kaiser's electronic medical record system. 8-ER-1764. Kaiser's management carefully tracked the physicians' success of Refreshing the missing HCC diagnoses and went so far as tying physician compensation the physicians' success rate in Refreshing missing HCC diagnoses. 8-ER-1766.

The Refresh fraud scheme resulted in fraudulent and unsupported HCC diagnosis codes because (a) leading coding queries violate ethical coding standards and guidelines as they are generally only used to facilitate upcoding, (7-ER-1531, fn

16, and 1532; 8-ER-1756-1757, 1760), (b) the addendums were untimely,[2] occurring six months or more after the patient encounter, rendering the PCP's statement that he/she had a specific recollection of diagnosing the missing HCC during the last patient encounter, incredulous (7-ER-1531, 8-ER-1760, 62-1764), and (c) the PCP did not provide any medical care or treatment for the Refreshed HCC. 7-ER-1531, 8-ER-1566, 8-ER-1760, 1762-1763.

Stein acknowledged to the District Court that Stein's Refresh Fraud claim is subject to the first-to-file rule. 2-ER-159.

2. Stein's Sepsis, Malnutrition and AA Fraud Claims are Independent of and Based on Facts Materially Different From Osinek's Fraud Claims.

Osinek's Complaint is the first-filed and only alleges a California-based Refresh Fraud scheme as described above. *Osinek's* Complaint does not mention sepsis nor suggests that sepsis was one of the HCC diagnosis that was Refreshed. *Osinek's* Complaint does identify "Cachexia/Protein Calorie Malnutrition" as part of laundry list of 19 high value targets that Kaiser actively data-mined. 8-ER-1758. The terms malnutrition and aortic atherosclerosis (AA) are also found on copies of presentation slides supporting *Osinek's* allegations that Kaiser tied physician compensation and medical group funding to compliance with Refreshing missing HCCs. 8-ER-1770-

[2]Although CMS does not have a specific cutoff period for addendums to correct patients' medical records, addendums are to be made as soon as practicable, typically within 48 hours of the encounter. 7-ER-1530, 8-ER 1756.

1771.

Although Osinek's Complaint conveys that malnutrition and AA were HCCs that Kaiser actively data-mined and were Refreshed by Kaiser medical group physicians, such Refresh Fraud allegations are entirely independent of *Stein's* non-Refresh sepsis, malnutrition and AA fraud schemes.

Like Godecke's claims in *Hartpence*, *Stein's* non-Refresh sepsis, malnutrition and AA fraud schemes involve violations of different Medicare requirements, and "exist completely independent" of *Osinek's* Refresh Frauds. *Hartpence,*792 F.3d at1131. *Osinek's* Refresh Frauds first require Kaiser to identify the prior year's HCC diagnosis that had not been coded in the current year (i.e., a "missing" HCC diagnosis). These missing HCCs are then Refreshed (i.e., re-diagnosed) by Kaiser's medical group's physicians via an untimely and fraudulent medical record addendum of the Medicare Advantage ("MA") patient's medical record. The addendums falsely state that the physician remembers the patient having the specific missing HCC diagnosis but nonetheless forgot to record any clinical findings nor provide any medical treatment for the missing HCC as part of last physician face-to-face encounter with the MA patient. 7-ER-1530-1531, 8-ER-1760-1762.

In contrast, *Stein's* sepsis, malnutrition and AA fraud schemes all concern Kaiser hospitals' deficient coding and documentation policies which allowed the contemporaneous invalid and fraudulent diagnoses of sepsis, malnutrition and AA to

be made on Kaiser hospitals' MA patients. These claims, unlike *Osinek's* claims, do not involve or rely upon a prior year's diagnosis of sepsis, malnutrition, or AA that was added to the current year's diagnosis through an addendum.

The fraudulent conduct alleged in *Osinek's* Refresh fraud scheme and *Stein's* sepsis, malnutrition, and AA fraud schemes are also completely independent of each other and do not overlap. The fraudulent conduct alleged by *Osinek* is the untimely and fraudulent medical record addendums performed by Kaiser medical group physicians to Refresh the missing HCC diagnoses. In comparison, *Stein's* fraudulent conduct is the contemporaneous invalid and fradulent sepsis, malnutrition, and AA diagnoses of Kaiser hospitals' MA patients, knowingly facilitated by Kaiser hospitals' deficient coding and documentation policies,

Like Godecke's claims in *Hartpence, Stein's* independent sepsis, malnutrition and AA fraud schemes should not be first filed barred by *Osinek* because *Stein's* non-Refresh, sepsis, malnutrition and AA fraud claims are based upon different and unrelated material facts than *Osinek's* Refresh fraud scheme. *Hartpence,* 792 F.3d at 1132. Allowing Stein's distinct fraud claims to stand is consistent with the purpose of the first-to-file rule because Stein's sepsis, malnutrition, and AA fraud schemes "provided information about a different form of fraud, and without that information, the government might not have investigated beyond [defendant's] fraudulent" Refresh HCC coding scheme. *Id.* at 1131-1132. Additionally, allowing *Stein's* sepsis,

malnutrition, and AA fraud claims "encourages broader investigation and increases the total potential for recovery," consistent with the objectives of the first-to-file rule. *Id.* In contrast, the dismissal of Stein's non-Refresh claims would be contrary to the purpose of the first-to-file rule because Stein's remaining non-Refresh frauds are not opportunistic nor piggyback claims which provide the Government with no additional benefit barred by the first-to-file rule. See, *Id.* at 1131-1132.

The District Court committed revearsable error by dismissing *Stein's* non-Refresh sepsis, malnutrition and AA claims under the first-to-file bar. The District Court erroneously held that *Stein's* non-Refresh hospital-based fraud claims were the lesser included frauds of *Osinek's* Refresh Fraud scheme and therefore barred under the first-to-file rule. 1-ER-42-43. To reach this conclusion the District Court misconstrued the material facts test by adopting an invalid constructive notice standard as a Government yardstick and limited the material facts analysis to the submission of false HCC diagnoses. 2-ER-63, 65-66, 81-82. Further, to conclude that *Stein's* non-Refresh claims were similar to *Osinek's* Refresh fraud complaint, the District Court unjustifiably expanded the scope of *Osinek's* claims to include hospital-based frauds despite *Osinek's* complete absence of any hospital-based fraud allegations. 1-ER-32, 42-43. This holding stands in stark contrast District Court's decision to limit the geographic scope of *Osinek's* complaint specifically because *Osinek* failed to make any allegations suggesting a nationwide fraud scheme. 1-ER-32.

A quick side by side comparison of *Osinek* and *Stein* quickly shows the lack of overlap or similarity between *Stein's* Non-Refresh fraud claims and *Osinek*'s Refresh Fraud claims. 1-ER-22. Unaided by *Stein's* Complaint, the Government would not have learned of *Stein's* sepsis, malnutrition and AA frauds and would be unable to pursue the separate financial recovery afforded thereby. *Batiste*, 659 F.3d at 1210; Hartpence, 792 F.3d at 1131

3. Stein's Sepsis, Malnutrition and AA Fraud Claims are Independent of and Based on Facts Materially Different From Taylor's Fraud Claims.

Taylor is the second-filed action. *Taylor* makes no sepsis, malnutrition or AA fraud allegations and does not mention sepsis or AA. *Stein's* non-Refresh sepsis, malnutrition, and AA fraud schemes should not be first filed barred by *Taylor's* prior filed complaint because Stein's sepsis, malnutrition, and AA fraud claims are based upon different and unrelated material facts than *Taylor's* allegations. *Hartpence,* 792 F.3d. at 1132. Allowing Stein's distinct fraud claims to stand is consistent with the purpose of the first-to-file rule because Stein's sepsis, malnutrition, and AA fraud schemes "provided information about a different form of fraud, and without that information, the government might not have investigated beyond [defendant's] fraudulent" audit-related and NLP non-Refresh fraud allegations. *Id.* at 1131-1132. Additionally, allowing *Stein's* sepsis, malnutrition, and AA fraud claims "encourages broader investigation and increases the total potential for recovery," consistent with

the objectives of the first-to-file rule. Contrariwise, the District Court's dismissal of Stein's non-Refresh fraud claims is antithetical to the first-to-file rule because Stein's remaining fraud claims provide the Government with an additional benefit and are not opportunistic or piggyback claims appropriately barred by the rule. See, *Id.*

Taylor's Refresh Fraud claim alleges that Kaiser should have known that some of the Refreshed diagnoses were invalid when originally coded in the prior year. 8-ER-1723, 1742-1744. In addition to the Refresh Fraud scheme, *Taylor* alleges Kaiser knowingly accepting HCC data from non-Kaiser hospitals that had high error rates, (8-ER-1718-1721) failed to investigate and redact invalid HCC diagnoses identified from national pre-RADV audits (8-ER-1715-1717) and frauds resulting from Kaiser's electronic medical record using an in-house designed, natural language processing ("NLP") software, intended to aid physicians' medical record documentation but is alleged to purposefully upcode the physicians' inputs to unsupported higher value HCC diagnoses. 8-ER-1744-1746. *Taylor* alleges the NLP software is also defective because it improperly codes HCC diagnoses from the patients problem list, which is an invalid coding practice and was built without the ability to audit the validity of previously submitted claims which would knowingly resulted in the submission of false and unsupported HCC diagnoses. 8-ER-1745.

Taylor alleges that Kaiser's 2009-2010 national Probe Audits identified instances were the history of malnutrition (not a HCC) was incorrectly coded as a

current malnutrition diagnosis (a high value HCC diagnosis) caused by either an electronic medical record system error or Kaiser's coders,[3] 8-ER-1731-1732. However, *Taylor* acknowledged that the probe audits' "sample size is too small for the results to be used for statistically significant extrapolation with respect to the error rates for individual HCCs" and that Kaiser's Probe Audits are merely a "trip-wire" indicating further investigations should be conducted of individual HCCs. 8-ER-1715.

Comparing Taylor's non-Refresh fraud allegations to Stein's sepsis, malnutrition and AA fraud claims makes clear that *Taylor's* non-Refresh fraud allegations do not overlap with *Stein's* sepsis, malnutrition and AA fraud schemes in any manner and are distinct independent allegations that exist separately from Taylor's non-Refresh fraud allegations. First, *Taylor's* complaint does not mention sepsis or AA, nor suggests *Stein's* sepsis or AA fraud schemes, let alone allege any frauds concerning those HCC diagnoses. Second, *Taylor's* reference to malnutrition from the Probe Audits describes a coding error not a fraud scheme. 8-ER-1715. Even if there was sufficient data to allege a malnutrition fraud, the conduct *Taylor* alleged is invalidly coding the "history of" malnutrition as a current HCC diagnoses and is unrelated to *Stein's* malnutrition fraud scheme concerning dieticians illegally making malnutrition diagnoses and the treating physicians failure to record their supporting

[3]Malnutrition was one of 13 medical conditions Taylor referenced that had errors identified by Kaiser's Probe Audits. 8-ER-1723-1734.

clinical findings in the patients' hospital medical record as required.[4] 42 C.F.R. § 422.310(d)(1); 7-ER-1467-1468, 1524-1525.

Stein's sepsis, malnutrition, and AA fraud schemes all involve a different type of fradulent conduct than what is alleged in *Taylor's* Complaint. *Stein's* non-Refresh frauds all concern contemporaneous coding and documentation frauds facilitated by Kaiser hospitals' deficient coding and documentation policies. *Stein* additionally alleges the improper retention of overpayments for failing to identify and return malnutrition and AA overpayments after Kaiser's national compliance office required Kaiser hospitals to discontinue their invalid malnutrition and AA coding policies which caused the submission of false and fradulent claims. 7-ER-1469, 1471-1473, and 1526.

By comparison, *Taylor's* non-refresh fraud allegations concern the failure to redact previously submitted invalid HCC diagnosis codes identified through various audits, failing to identify invalid HCC diagnoses from non-Kaiser hospitals, the failure to initiate audits to investigate signals from the Probe Audits, and invalid coding caused by the natural language processing software utilized by Kaiser's electronic medical record system. 8-ER-1713-1746.

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[4] "All diagnosis codes submitted must be documented in the medical record and documented as the result of a face-to-face visit. The diagnosis must be coded in accordance with the *International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting*." CMS Publication 100-16, Medicare Managed Care Manual, Ch. 7 § 40.

The first-to-file rule should not bar *Stein's* non-Refresh fraud allegations because *Stein's* remaining fraud allegations are based upon different and unrelated material facts, alleges different forms of fraud than *Taylor's* non-Refresh frauds, and provide the Government with the ability to pursue claims it would not have otherwise known about with the potential to obtain additional fi recoveries. Moreover, the lack of similarity between *Stein's* non-Refresh fraud schemes and *Taylor's* non-Refresh fraud allegations demonstrates that *Stein's* later filed complaint is not an opportunistic or piggyback complaint that should be barred under the first-to-file rule.

The District Court committed revearsable error by dismissing *Stein's* sepsis, malnutrition and AA claims under the first-to-file rule. The District Court erroneously held that *Stein's* non-Refresh hospital-based fraud claims were barred under the first-to-file rule because they were the lesser included frauds of *Osinek's* Refresh Fraud scheme. 1-ER42-43. (The District Court did not compare *Stein's* non-Refresh fraud allegations to *Taylor's* claims.) To reach this conclusion the District Court misconstrued the material facts test by adopting an invalid constructive notice standard as a Government yardstick and limit the material facts analysis to the submission of false HCC diagnoses. 2-ER-63, 65-66, 81-82.

A quick side by side comparison of *Taylor* and *Stein* quickly shows the lack of overlap or similarity between *Stein's* Non-Refresh fraud claims and *Taylor's non-*Refresh fraud claims. 1-ER-22. Unaided by *Stein's* Complaint, the Government would

not have learned of *Stein's* sepsis, malnutrition and AA frauds and would be unable to pursue the separate financial recovery afforded thereby. *Batiste*, 659 F.3d at 1210; *Hartpence,* 792 F.3d at 1131.

4. Stein's Sepsis, Malnutrition and AA Fraud Claims are Independent of and Based on Facts Materially Different From Arefi's Fraud Claims.

Arefi is the third and final prior filed action and alleges complex Refresh Fraud allegations and non-Refresh fraud claims. *Arefi* makes no allegations of AA frauds nor makes any reference thereof.

Stein's sepsis, malnutrition, and AA fraud schemes should not be first filed barred by *Arefi's* prior filed complaint because *Stein's* sepsis, malnutrition, and AA fraud claims are based upon different and unrelated material facts than *Arefi's* non-Refresh fraud allegations. *Hartpence,* 792 F.3d. at 1132. Allowing Stein's related but distinct fraud claims to stand is consistent with the purpose of the first-to-file rule because Stein's sepsis, malnutrition, and AA fraud schemes "provided information about a different form of fraud, and without that information, the government might not have investigated beyond [defendant's] fraudulent" audit-related and NLP non-Refresh fraud allegations. *Id.* at 1131-1132. Additionally, allowing *Stein's* sepsis, malnutrition, and AA fraud claims "encourages broader investigation and increases the total potential for recovery," consistent with the objectives of the first-to-file rule. Contrariwise, the District Court's dismissal of *Stein's* non-Refresh fraud claims is

antithetical to the first-to-file rule because *Stein's* remaining fraud claims provide the Government with the additional benefit of pursuing claims it would have otherwise have no knowledge of and the potential of obtaining additional recoveries. Further, because Stein's distinct non-Refresh fraud claims are based upon different forms of fraud and are based upon different material facts, they are not opportunistic nor piggyback claims appropriately barred by the first-to-file rule. See, *Id.*

Arefi's Refresh Fraud allegations (8-ER-1566-1571) include additional allegations of using bogus clinical algorithms to identify unsupported HCC diagnosis to be Refreshed. 8-ER-1566-1570. This is similar to *Osinek's* Refresh fraud claims. 8-ER-1760-1763. One of *Arefi's* bogus clinical algorithms was for cachexia, a wasting syndrome rarely found in the United States, which Refreshed the "history of malnutrition as a current diagnosis of **cachexia.**" 8-ER-1567-1568.

Arefi's non-Refresh fraud scheme describes an electronic medical record fraud caused by Kaiser's use of convergent medical terminology (CMT), which expansively redefined ICD-9 diagnoses for Kaiser electronic medical record system. Arefi alleges CMT is designed to automatically upcode to higher value HCC diagnosis codes when physicians select key terms in Kaiser's electronic medical record system.[5] 8-ER-1565-1866.

[5] *Arefi's* convergent medical terminology claim is similar to *Taylor's* natural language processing claim regarding the mis-mapping of medical terms in Kaiser's electronic medical record to improperly upcode the physicians' diagnoses

A significant portion *Arefi's* complaint is a statistical analysis that discusses the success of "Kaiser Defendants' scheme to fraudulently obtain Medicare risk adjustment payments," presumably as a result of the Refresh and non-Refresh fraud schemes alleged in *Arefi's* complaint. However, *Arefi* does not attempt to apportion Kaiser's over-coding success between the Refresh fraud and the convergent medical terminology frauds alleged. 8-ER-1572-1575. Sepsis and malnutrition are two of the seven HCC examples that Arefi alleges have been successfully over-coded. 8-ER-1573. Last, *Arefi* alleges that Kaiser's upcoding falsely understated its mortality data which caused CMS to issue a Kaiser MA plan a five-star rating and resulted in Kaiser fraudulently receiving a $380 million bonus. 8-ER-1574. *Arefi* used its statistical analysis as the basis for a series of damage calculations (8-ER-1576-1578) which again references septicemia and malnutrition. 8-ER-1577.

Comparing Stein's sepsis, malnutrition and AAfraud schemes to *Arefi* reveals that Stein's non-Refresh fraud claims are based on completely different material facts. Although *Arefi* alleges that Kaiser had a long standing plan to over-diagnose septicemia, among other HCCs, there are no allegations regarding how this occurred except for the Refresh Fraud allegations and Arefi's convergent medical terminology claim. There are no allegations similar to Stein's sepsis fraud claim explaining how Kaiser's medical group intentionally exploited Kaiser hospital's early treatment sepsis protocols to intentionally fail to correct obvious cases of false positive sepsis

diagnoses. 7-ER-1458-1461, 1516-1520.

Similarly, regarding malnutrition, the only relevant material facts *Arefi* alleges, other than the Refresh Fraud scheme and the convergent medical terminology fraud, are instances where the history of malnutrition is falsely diagnosed as a current cachexia diagnosis. This allegation is materially different from Stein's malnutrition fraud allegations. First, Stein's malnutrition fraud claims do not discuss **cachexia** diagnoses. Second, Arefi's complaint makes no allegations similar to *Stein's* nationwide systemic malnutrition fraud involving malnutrition diagnoses illegally made by Kaiser hospital's dieticians and the subsequent failure of the MA patient's treating physician to record their clinical findings supporting a malnutrition diagnoses in the MA patient's hospital medical record as required. See, fn 3, *supra*.

The first-to-file rule should not bar *Stein's* non-Refresh fraud allegations because *Stein's* remaining fraud allegations are based upon different and unrelated material facts, allege a different form of frauds then *Arefi's* non-Refresh frauds, and provides the Government with the ability to pursue claims it would not have otherwise known about with the potential to obtain additional financial recoveries. Moreover, the lack of similarity between *Stein's* non-Refresh fraud schemes and *Arefi's* non-Refresh fraud allegations illustrates that unaided by *Stein's* later filed sepsis malnutrition and AA fraud schemes the Government would not have learned of *Stein's* additional claims resulting in an additional benefit to the Government. See,

Hartpence, 792 F.3d at 1131. Therefore, *Stein's* later filed non-Refresh fraud claims are not opportunistic or piggyback claims that should be barred under the first-to-file rule.

The District Court committed revearsable error by dismissing *Stein's* non-Refresh sepsis, malnutrition and AA claims under the first-to-file bar. The District Court erroneously held that *Stein's* non-Refresh hospital-based fraud claims were barred under the first-to-file rule because they were the lesser included frauds of *Osinek's* Refresh Fraud scheme. 1-ER42-43. To reach this conclusion the District Court misconstrued the material facts test by adopting an invalid constructive notice standard as a Government yardstick and limit the material facts analysis to the submission of false HCC diagnoses. 2-ER-63, 65-66, 81-82.

A quick side by side comparison of *Arefi* and *Stein* quickly shows the lack of overlap or similarity between *Stein's* remaining Non-Refresh fraud claims and Arefi's fraud claims. 1-ER-22. Unaided by *Stein's* Complaint, the Government would not have learned of *Stein's* sepsis, malnutrition and AA frauds and would be unable to pursue the separate financial recovery afforded thereby. *Batiste*, 659 F.3d at 1210; *Hartpence*, 792 F.3d at 1131.

/ / /

/ / /

D. IN THE EVENT THAT STEIN'S SEPSIS FRAUD, MALNUTRITION FRAUD, OR AORTIC ATHEROSCLEROSIS FRAUD CLAIMS ARE BARRED BY THE FIRST-TO-FILE RULE, THE DISTRICT COURT ERRED BY REFUSING TO ALLOW APPELLANTS TO FURTHER AMEND THEIR COMPLAINT.

In the event the Court upholds the dismissal of Stein's Sepsis, Malnutrition or AA claims, Stein should be permitted to file a further amended complaint to correct any deficiency in her complaint.

III. CONCLUSION.

The District Court erred in granting Kaiser's Fed.R.Civ.P. 12(b)(1) motion to dismiss and (a) holding that the first-to-file rule is jurisdictional, and (b) dismissing Stein's Sepsis fraud, Malnutrition fraud, and Aortic Atherosclerosis fraud claims under the first-to-file rule, requiring that said rulings be reversed.

The Ninth Circuit's holdings in *United States ex rel. Hartpence v. Kinetic Concepts, Inc.,* 792 F.3d 1121 (9th Cir. 2015) (en banc) and *United States ex rel. Lujan v. Hughes Aircraft Co.,* 243 F.3d 1181 (9th Cir. 2001) that the False Claims Act's first-to-file rule, 31 U.S.C. § 3730(b)(5), is jurisdictional should be rejected and disapproved in light of the Supreme Court's "clear-statement principle" in *Gonzalez v. Thaler,* 565 U.S. 134, 132 S.Ct. 641, 181 L.Ed.2d 619 (2012) and related decisions, and sister circuit decisions. Accordingly, this appeal should be reviewed and decided by the Ninth Circuit *en banc*.

Alternatively, the District Court abused its discretion by denying Appellants

Stein leave to file a further amended complaint to allege their Sepsis fraud, Malnutrition fraud, and Atherosclerosis fraud claims because a further amendment would not result in futility for lack of merit, would not cause undue delay in the litigation, would not prejudice Appellees, and is not sought in bad faith.

Accordingly, Appellants respectfully request the Court reverse the District Court's May 5, 2022 Order and November 15, 2022 Judgment.

Respectfully Submitted,

THE ZINBERG LAW FIRM
A Professional Corporation

HANAGAMI LAW
A Professional Corporation

Dated: April 17, 2023

By: */s/William K. Hanagami*
William K. Hanagami
Attorneys for Plaintiffs and Appellants,
Marcia Stein and Rodolfo Bone

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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§ 3730. Civil actions for false claims

Effective: December 27, 2022
Currentness

(a) Responsibilities of the Attorney General.--The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.--(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure.[1] The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.--(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government

has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.--(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting[2] Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) Certain Actions Barred.--(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2)(A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 13103(f) of title 5.

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

(f) Government not liable for certain expenses.--The Government is not liable for expenses which a person incurs in bringing an action under this section.

(g) Fees and expenses to prevailing defendant.--In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

(h) Relief from retaliatory actions.--

(1) In general.--Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any

other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

(2) Relief.--Relief under paragraph (1) shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

(3) Limitation on bringing civil action.--A civil action under this subsection may not be brought more than 3 years after the date when the retaliation occurred.

CREDIT(S)

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 978; Pub.L. 99-562, §§ 3, 4, Oct. 27, 1986, 100 Stat. 3154, 3157; Pub.L. 100-700, § 9, Nov. 19, 1988, 102 Stat. 4638; Pub.L. 101-280, § 10(a), May 4, 1990, 104 Stat. 162; Pub.L. 103-272, § 4(f)(1)(P), July 5, 1994, 108 Stat. 1362; Pub.L. 111-21, § 4(d), May 20, 2009, 123 Stat. 1624; Pub.L. 111-148, Title X, § 10104(j)(2), Mar. 23, 2010, 124 Stat. 901; Pub.L. 111-203, Title X, § 1079A(c), July 21, 2010, 124 Stat. 2079; Pub.L. 117-286, § 4(c)(36), Dec. 27, 2022, 136 Stat. 4358.)

Notes of Decisions (2635)

Footnotes

1 See, now, Rule 4(i) of the Federal Rules of Civil Procedure.

2 So in original. Probably should be “Accountability”.

31 U.S.C.A. § 3730, 31 USCA § 3730
Current through P.L. 117-327. Some statute sections may be more current, see credits for details.

End of Document

Rule 12. Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing

(a) TIME TO SERVE A RESPONSIVE PLEADING.

(1) *In General.* Unless another time is specified by this rule or a federal statute, the time for serving a responsive pleading is as follows:

(A) A defendant must serve an answer:

(i) within 21 days after being served with the summons and complaint; or

(ii) if it has timely waived service under Rule 4(d), within 60 days after the request for a waiver was sent, or within 90 days after it was sent to the defendant outside any judicial district of the United States.

(B) A party must serve an answer to a counterclaim or crossclaim within 21 days after being served with the pleading that states the counterclaim or crossclaim.

(C) A party must serve a reply to an answer within 21 days after being served with an order to reply, unless the order specifies a different time.

(2) *United States and Its Agencies, Officers, or Employees Sued in an Official Capacity.* The United States, a United States agency, or a United States officer or employee sued only in an official capacity must serve an answer to a complaint, counterclaim, or crossclaim within 60 days after service on the United States attorney.

(3) *United States Officers or Employees Sued in an Individual Capacity.* A United States officer or employee sued in an individual capacity for an act or omission occurring in connection with duties performed on the United States' behalf must serve an answer to a complaint, counterclaim, or crossclaim within 60 days after service on the officer or employee or service on the United States attorney, whichever is later.

(4) *Effect of a Motion.* Unless the court sets a different time, serving a motion under this rule alters these periods as follows:

(A) if the court denies the motion or postpones its disposition until trial, the responsive pleading must be served within 14 days after notice of the court's action; or

(B) if the court grants a motion for a more definite statement, the responsive pleading must be served within 14 days after the more definite statement is served.

(b) HOW TO PRESENT DEFENSES. Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

(1) lack of subject-matter jurisdiction;
(2) lack of personal jurisdiction;
(3) improper venue;
(4) insufficient process;
(5) insufficient service of process;
(6) failure to state a claim upon which relief can be granted; and
(7) failure to join a party under Rule 19.

A motion asserting any of these defenses must be made before pleading if a responsive pleading is allowed. If a pleading sets out a claim for relief that does not require a responsive pleading, an opposing party may assert at trial any defense to that claim. No defense or objection is waived by joining it with one or more other defenses or objections in a responsive pleading or in a motion.

(c) MOTION FOR JUDGMENT ON THE PLEADINGS. After the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings.

(d) RESULT OF PRESENTING MATTERS OUTSIDE THE PLEADINGS. If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

(e) MOTION FOR A MORE DEFINITE STATEMENT. A party may move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response. The motion must be made before filing a responsive pleading and must point out the defects complained of and the details desired. If the court orders a more definite statement and the order is not obeyed within 14 days after notice of the order or within the time the court sets, the court may strike the pleading or issue any other appropriate order.

(f) MOTION TO STRIKE. The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter. The court may act:

(1) on its own; or
(2) on motion made by a party either before responding to the pleading or, if a response is not allowed, within 21 days after being served with the pleading.

(g) JOINING MOTIONS.

(1) *Right to Join*. A motion under this rule may be joined with any other motion allowed by this rule.

(2) *Limitation on Further Motions*. Except as provided in Rule 12(h)(2) or (3), a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion.

(h) WAIVING AND PRESERVING CERTAIN DEFENSES.

(1) *When Some Are Waived*. A party waives any defense listed in Rule 12(b)(2)–(5) by:

(A) omitting it from a motion in the circumstances described in Rule 12(g)(2); or

(B) failing to either:

(i) make it by motion under this rule; or

(ii) include it in a responsive pleading or in an amendment allowed by Rule 15(a)(1) as a matter of course.

(2) *When to Raise Others*. Failure to state a claim upon which relief can be granted, to join a person required by Rule 19(b), or to state a legal defense to a claim may be raised:

(A) in any pleading allowed or ordered under Rule 7(a);

(B) by a motion under Rule 12(c); or

(C) at trial.

(3) *Lack of Subject-Matter Jurisdiction*. If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.

(i) HEARING BEFORE TRIAL. If a party so moves, any defense listed in Rule 12(b)(1)–(7)—whether made in a pleading or by motion—and a motion under Rule 12(c) must be heard and decided before trial unless the court orders a deferral until trial.

(As amended Dec. 27, 1946, eff. Mar. 19, 1948; Jan. 21, 1963, eff. July 1, 1963; Feb. 28, 1966, eff. July 1, 1966; Mar. 2, 1987, eff. Aug. 1, 1987; Apr. 22, 1993, eff. Dec. 1, 1993; Apr. 17, 2000, eff. Dec. 1, 2000; Apr. 30, 2007, eff. Dec. 1, 2007; Mar. 26, 2009, eff. Dec. 1, 2009.)

Title 42 - Public Health
Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services
Subchapter B - Medicare Program
Part 422 - Medicare Advantage Program
Subpart G - Payments to Medicare Advantage Organizations

Source: 70 FR 4729, Jan. 28, 2005, unless otherwise noted.
Authority: 42 U.S.C. 1302 and 1395hh.
Source: 63 FR 18134, Apr. 14, 1998, unless otherwise noted.

Editorial Note: Nomenclature changes to part 422 appear at 70 FR 4741, Jan. 28, 2005.

§ 422.310 Risk adjustment data.

(a) ***Definition of risk adjustment data.*** Risk adjustment data are all data that are used in the development and application of a risk adjustment payment model.

(b) ***Data collection: Basic rule.*** Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) ***Sources and extent of data.***

(1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Items and services covered under the original Medicare program.

(ii) Medicare covered items and services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) ***Other data requirements.***

(1) MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. CMS may specify abbreviated formats for data submission required of MA organizations.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

(5) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data, MA organizations must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance.

(e) ***Validation of risk adjustment data.*** MA organizations and their providers and practitioners are required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings for payment year 2018 and subsequent payment years.

(f) ***Use and release of data*** —

(1) ***CMS use of data.*** CMS may use the data described in paragraphs (a) through (d) of this section for the following purposes:

(i) To determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c);

(ii) To update risk adjustment models;

(iii) To calculate Medicare DSH percentages;

(iv) To conduct quality review and improvement activities;

(v) For Medicare coverage purposes;

(vi) To conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research;

(vii) For activities to support the administration of the Medicare program;

(viii) For activities conducted to support program integrity; and

(ix) For purposes authorized by other applicable laws.

(2) ***CMS release of data.*** Regarding data described in paragraphs (a) through (d) of this section, CMS may release the minimum data it determines is necessary for one or more of the purposes listed in paragraph (f)(1) of this section to other HHS agencies, other Federal executive branch agencies, States, and external entities in accordance with the following:

(i) Applicable Federal laws;

(ii) CMS data sharing procedures;

(iii) Subject to the protection of beneficiary identifier elements and beneficiary confidentiality, including—

(A) A prohibition against public disclosure of beneficiary identifying information;

(B) Release of beneficiary identifying information to other HHS agencies, other Federal executive branch agencies, and States only when such information is needed; and

(C) Release of beneficiary identifying information to external entities only to the extent needed to link datasets.

(iv) Subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data.

(v) Risk adjustment data other than data described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section will be released without the redaction or aggregation described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section, respectively.

(3) Risk adjustment data will not become available for release under this paragraph (f) unless—

(i) The risk adjustment reconciliation for the applicable payment year has been completed;

(ii) CMS determines that data release is necessary under paragraph (f)(1)(vi) of this section for emergency preparedness purposes before reconciliation; or

(iii) CMS determines that extraordinary circumstances exist to release the data before reconciliation.

(g) ***Deadlines for submission of risk adjustment data.*** Risk adjustment factors for each payment year are based on risk adjustment data submitted for items and services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate. CMS may adjust these deadlines, as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting items and services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

(i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.

(ii) After the final risk adjustment data submission deadline, which is a date announced by CMS that is no earlier than January 31 of the year following the payment year, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

(3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

[73 FR 48757, Aug. 19, 2008, as amended at 79 FR 29956, May 23, 2014; 79 FR 50358, Aug. 22, 2014; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 88 FR 6665, Feb. 1, 2023]

Medicare Managed Care Manual
Chapter 7 – Risk Adjustment

Table of Contents
(Rev. 118, 09-19-14)

Transmittals for Chapter 7

10 - Introduction
(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

This manual chapter addresses the policies and operations related to the data collection for, calculation of, and use of risk scores in Part C and Part D payments through 2011. For detailed information on payment policies and formulas, refer to Chapter 8 for Part C payment (a chapter for Part D payment is forthcoming). CMS risk adjusts Part C payments made to Medicare Advantage (MA) plans and Program of All Inclusive Care for The Elderly (PACE) organizations, and Part D payments made to Part D sponsors, including Medicare Advantage-Prescription Drug plans (MA-PDs) and standalone Prescription Drug Plans (PDPs).

20 - Purpose of Risk Adjustment
(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

Risk adjustment allows CMS to pay plans for the risk of the beneficiaries they enroll, instead of an average amount for Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs. Risk adjustment is used to adjust bidding and payment based on the health status and demographic characteristics of an enrollee. Risk scores measure individual beneficiaries' relative risk and risk scores are used to adjust payments for each beneficiary's expected expenditures. By risk adjusting plan bids, CMS is able to use standardized bids as base payments to plans.

30 - Statutory and Regulatory Authority for Risk Adjustment
(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The Medicare Advantage (MA) program provides Parts A and B services under Part C of Title XVIII of the Social Security Act ("the Act"). CMS administers risk adjusted payments to MA organizations in accordance with Subpart G of 42 CFR §422.304. This regulatory provision is based on sections 1853, 1854, and 1858 of the Act. CMS risk adjusts Part C payments made to MA plans under Section 1853(a) (3) of the Act; these rules are codified at 42 CFR 422.310. CMS risk adjusts payments to PACE organizations under 1894(d) (2).

MA plans include MA-only plans, MA-PD plans, regional plans, employer group health plans, and Special Needs Plans (SNPs). CMS risk adjusts certain demonstration plan payments, such as the Part C payments made to the dual demonstration plans (Wisconsin Partnership Program, MassHealth Senior Care Options, and Minnesota Senior Health Options and Minnesota Disability Health Options), and Social Health Maintenance Organizations (SHMOs).

CMS risk adjusts Part D payments to Medicare Advantage Prescription Drugs plans (MA-PDs), standalone Prescription Drug Plans (PDPs), and PACE organizations under 1860(d); these rules are codified at 42 CFR 423.

40 - Role and Responsibilities of Plan Sponsors
(Rev. 118; Effective: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010); Implementation: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010))

MA organizations, PACE organizations, 1876 Cost HMOs/Competitive Medical Plans (CMPs), and starting in 2012, Health Care Prepayment Plans (HCPPs) like the United Mine Workers of America Health and Retirement Funds, must submit risk adjustment data, as required by CMS.

This section provides a high-level checklist of plan requirements. Detailed information about risk adjustment data collection, submission, reporting, and validation are outlined in later sections within this chapter.

Risk Adjustment Data Submission Requirements – Plan Sponsors (Medicare Advantage Organizations (MAOs), PACE organizations, and 1876 Cost HMO/CMPs) must:

- Ensure the accuracy and integrity of risk adjustment data submitted to CMS. All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to *International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting*.

- Implement procedures to ensure that diagnoses are from acceptable data sources. The only acceptable data sources are hospital inpatient facilities, hospital outpatient facilities, and physicians. Plan sponsors are responsible for determining provider type based on the source of the data.

- Submit the required data elements from acceptable data sources according to the coding guidelines.

- Submit all required diagnosis codes for each beneficiary and submit unique diagnoses at least once during the risk adjustment data-reporting period. Submitters must filter diagnosis data to eliminate the submission of duplicate diagnosis clusters.

    - For Part B-only beneficiaries enrolled in a plan, the plan sponsor must submit diagnosis codes under the same rules as for a beneficiary with both Parts A and B. The plan should also submit *diagnosis* codes for Part A services provided under a non-Medicare contract.

  If upon conducting an internal review of submitted diagnosis codes, the plan sponsor determines that any diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted diagnosis codes as soon as possible.

- Receive and reconcile CMS Risk Adjustment Reports in a timely manner. Plan sponsors must track their submission and deletion of diagnosis codes on an ongoing basis.

- Once CMS calculates the final risk scores for a payment year, plan sponsors may request a recalculation of payment upon discovering the submission of inaccurate diagnosis codes that CMS used to calculate a final risk score for a previous payment year and that

had an impact on the final payment. Plan sponsors must inform CMS immediately upon such a finding.

50 - History of Risk Adjustment

(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The Balanced Budget Act of 1997 (BBA) mandated that a risk adjustment payment methodology, incorporating information on beneficiaries' health status, be implemented in the Medicare+Choice (M+C) program (now the Medicare Advantage program) no later than January 2000. Under the BBA, risk adjustment of M+C payments was initially to be based only on data from enrollees' inpatient hospital stays, with later implementation of risk adjustment based on data from additional sites of care. CMS selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method to be implemented in 2000. This model recognizes diagnoses for which inpatient care is most frequently appropriate and which are predictive of higher future costs.

To assist managed care organizations, CMS provided for a gradual phase-in of risk adjusted payment, initially adjusting only a portion of the total payment based on the PIP-DCG methodology - and later the CMS Hierarchical Condition Category (HCC) methodology - with the remainder still adjusted under the pre-BBA method based only on demographic information. This phase in was intended to provide more stable payments to M+C organizations.

The phase in schedule was as follows:

<table>
<tr><td>Payment year</td><td>MA plans</td><td>Evercare*</td><td>SHMO*</td><td>PACE and dual demonstrations*</td></tr>
<tr><td>2000-2003</td><td>10% risk/90% demographic</td><td>100% demographic</td><td>100% demographic</td><td>100% demographic</td></tr>
<tr><td>2004</td><td colspan="3">30% risk/70% demographic</td><td>10% risk/90% demographic</td></tr>
<tr><td>2005</td><td colspan="2">50% risk/50% demographic</td><td colspan="2">30% risk/70% demographic</td></tr>
<tr><td>2006</td><td colspan="2">75% risk/25% demographic</td><td colspan="2">50% risk/50% demographic</td></tr>
<tr><td>2007</td><td colspan="2" rowspan="2">100% risk/0% demographic</td><td colspan="2">75% risk/25% demographic</td></tr>
<tr><td>2008 and later</td><td colspan="2">100% risk/0% demographic</td></tr>
</table>

*Note: For MA plans (formerly M+C plans), the demographic-only portion of the payment was adjusted for age, gender, Medicaid eligibility, institutional status, and working aged status. For certain demonstrations, the non-risk portion of the payment may have involved a demonstration-specific payment methodology.

ESRD risk adjustment was implemented at 100% in 2005. Part D risk adjustment was implemented at 100% in 2006.