JOSEPH H. HUNT
Assistant Attorney General, Civil Division
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
ABRAHAM C. MELTZER
JOHN E. LEE (CBN 128696)
JACK D. ROSS (CBN 265883)
Assistant United States Attorneys
300 N. Los Angeles Street, Room 7516
Los Angeles, California 90012
Tel: (213) 894-3995; Fax: (213) 894-7819
Email: john.lee2@usdoj.gov
MICHAEL D. GRANSTON
ROBERT McAULIFFE
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA E. KRIEG
ZOILA E. HINSON
AMY L. LIKOFF
ADAM R. TAROSKY
Attorneys, Civil Division, U.S. Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 307-0486; Fax: (202) 307-3852
Email: carol.wallack@usdoj.gov
JAMES P. KENNEDY, JR.
United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney (Admitted PHV)
138 Delaware Avenue
Buffalo, New York 14201
Tel: (716) 843-5830; Fax: (716) 551-3052
Email: kathleen.lynch@usdoj.gov
Attorneys for the United States of America

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., *et al.*,

Defendants.

No. CV 16-08697 MWF (SSx)

UNITED STATES' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR REVIEW OF DISCOVERY ORDER

Date: April 8, 2019
Time: 10:00 a.m.
Court: 5A. Hon. Michael W. Fitzgerald

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I. INTRODUCTION

While acknowledging that it shoulders the burden of establishing the relevance of the internal agency deliberations it seeks to compel, Response (Dkt. 338) at 10 n. 4, United has made no effort – either in its submissions to Judge Segal or its opposition to this Motion for Review – to explain the relevance of many of the documents it seeks to compel. Instead, United chooses to focus on internal agency deliberations concerning only a few issues, including the consideration of a FFS Adjuster in the context of Risk Adjustment Data Validation ("RADV") audits. However, even with respect to these issues, United has failed to carry its burden of establishing their relevance.

The documents that United seeks are not relevant to the government's claims or any legitimate defense to United's failure to delete invalid diagnosis codes and to repay billions of dollars in interim payments based on those invalid codes. Instead, United is attempting to coopt this action to launch a program-level challenge to the Medicare Advantage payment system and rates. In essence, United is arguing for a system and rates that never existed. United cannot ignore its obligation to delete invalid diagnosis codes and to repay improperly inflated interim payments under the established system and rates, and then seek to avoid liability for its fraud by challenging them based on its own interpretation of how the agency should implement "actuarial equivalence."

Although United attempts to portray the government as trying to withhold documents it needs to defend its fraudulent conduct, the government has produced and will continue to produce documents and data relating to the allegations in its complaint and the calculation of damages. The government also does not oppose United's pursuit of relevant discovery, such as discovery concerning any actual knowledge that CMS may have had about United's submission of invalid diagnosis codes. The government, however, opposes United's continued efforts to engage in irrelevant and burdensome discovery regarding its grievances with the payment system and rates, especially given that United has acknowledged that this Court lacks subject matter jurisdiction to consider its counterclaims by which it sought to pursue such grievances. (Dkt. 249 at 1.)

II. ARGUMENT

A. Grievances About A Payment System And Rates Are Not A Defense To Engaging In Self-Help And Violating The System's Rules And Regulations

United contends that internal agency deliberations about whether to adopt a FFS Adjuster in the context of RADV audits are somehow relevant to its argument that the reference to "actuarial equivalence" in a Medicare statute, 42 U.S.C. § 1395w-23(a)(1)(C)(i), gives United a free pass to submit false claims to Medicare. But that argument is as a matter of law not a valid defense to any of the government's claims, including its False Claims Act ("FCA") and common law claims.

In this case, United scoured the charts of millions of its beneficiaries to find additional diagnosis codes to submit to CMS for billions of additional risk adjustment payments, while at the same time ignoring the results of those reviews showing that numerous diagnoses previously submitted were not supported by the beneficiaries' medical records. United cannot dispute that, if it had deleted the invalid diagnosis codes based on the results of its chart reviews, CMS's Risk Adjustment System ("RAS") would have *automatically* recalculated and corrected the risk score for each affected beneficiary as part of the final payment reconciliation process after the end of each payment year, and CMS' payment calculation system would have *automatically* corrected the amount of payment that should have been made for each affected beneficiary based on the corrected risk scores. United also cannot dispute that the payment system would have deducted the improperly inflated interim payments from the final reconciliation payment made to United after the end of each payment year.[1]

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[1] United completed its chart reviews prior to the final deadline for submitting diagnoses for each payment year. 42 C.F.R. § 422.310(g). The records that all insurers use to submit diagnosis data have a "Delete Indicator" to identify invalid diagnoses, including those discovered based on their chart reviews. United knows how to delete invalid codes because it used the Delete Indicator many times throughout the years. United knew that following the deadline, CMS would rely on any invalid diagnoses remaining in the system to recalculate each beneficiary's final risk score and determine if adjustments to previously-made interim payments were necessary when making the final reconciliation payment to United. § 422.310(g)(2). When United failed to use the

In its Response, United claims that it needs wide-ranging discovery to show that, although it would have been paid less if it had deleted the diagnosis codes that it knew were unsupported by the charts it reviewed, its failure to delete those invalid codes did not result in any *overpayment* to United. However, there can only be one way that an insurer might conceivably be deemed NOT to have been overpaid for an invalid diagnosis submitted to Medicare. That is if it were entitled to payment for invalid diagnoses. This is United's argument. It states that its "receipt of payments based on unsupported codes is not improper" and that it was not overpaid "if the diagnostic data it submits to CMS contains a rate of unsupported codes that is comparable to the rate of unsupported diagnosis codes in [fee-for-service] data." Response (Dkt. 338) at 2, 5. In other words, United claims that it is entitled to payment for a certain number or percentage of invalid diagnosis codes equivalent to the number or percentage of invalid codes present in the FFS data used to calibrate the payment model. This is its so-called "coding error rate" argument. United's justification for this argument is its speculation that it was underpaid for *valid* diagnoses and is entitled to payment for *invalid* diagnoses as a means of some sort of compensation. United, however, makes no attempt to explain how a FFS "coding error rate" could accurately provide such compensation.

United also seems to argue that it was not overpaid based on invalid diagnoses because overpayments should not be assessed with respect to individual invalid codes submitted to Medicare for particular beneficiaries, but should instead be assessed in the context of all diagnosis codes submitted for all beneficiaries under a particular contract and the payments by Medicare for valid as well as invalid diagnoses under that contract. In other words, United once again appears to argue that if Medicare does not pay for

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Delete Indicator to withdraw known invalid diagnoses, the final risk scores automatically calculated by CMS' RAS were too high, and the final reconciliation payments automatically calculated by CMS payment system were also too high. By failing to delete known invalid codes, United concealed and avoided its obligation to repay CMS for the improperly inflated interim payments. This is fraud actionable under the reverse FCA provision. 31 U.S.C. § 3729(a)(1)(G). In addition, there was an obvious "payment by mistake" because the payment system did not have accurate information and the Medicare Program is entitled to recover its damages under that common law theory.

invalid codes, it should recalculate the payment rates (that is, the coefficients) and pay more for *valid* codes. But, this time, the overpayment should be determined on a contract-wide basis. This apparently would be some sort of a "payment error rate" adjuster, which would require an audit of all of the diagnoses submitted by United under each of its many contracts to determine which diagnoses were valid and which were not.

United's Response often conflates its arguments about a "coding error rate" adjuster and some sort of "payment error rate" adjuster. However, neither is a viable defense in this FCA case. Indeed, the fundamental problem for United is that Medicare never adopted either one. United is arguing for a payment system that simply does not exist and never existed. Neither the CMS RAS system, which calculates risk scores, nor the CMS payment system ever used a "coding error rate" or a "payment error rate" adjuster to determine whether to recover improperly inflated interim payments based on invalid diagnoses or to determine the amounts of such recoveries. Indeed, there was no need, as the exact amount that Medicare would and should have recovered as part of the final payment reconciliation if United had deleted the invalid diagnosis codes can easily be calculated in the same manner that the RAS and payment systems make risk score and payment calculations. Accordingly, just like those systems, the calculation of damages in this case does not entail the use of any sort of an adjuster for the simple reason that, if United had complied with its obligation to delete the invalid diagnoses and to repay the improperly inflated interim payments for each year, it would not have received the benefit of any sort of adjuster.

United's argument that some sort of FFS "coding error rate" or "payment error rate" adjuster should have been built into the automated systems to ensure "actuarial equivalence" is also without merit. United's assertion that the obligation to delete invalid diagnoses only comes into play relative to some level of coding inaccuracy in FFS data is inconsistent with the Medicare Advantage Program's rules and regulations, which have been in place for more than 15 years. Over this long time period, an insurer's obligation to submit diagnoses supported by medical record documentation and

to delete those diagnoses that are not supported by such documentation has been clearly set forth in program regulations and guidance documents issued by CMS and incorporated into each insurer's contract. At the core of these rules is the fundamental legal principle, recognized by Ninth Circuit law, that the data upon which Medicare payments are based must be valid. *See United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1168, 1169 & 1174-76 (9th Cir. 2016) (holding that, since the beginning of the program in 2000, "[e]ach diagnosis code submitted must be supported by a properly documented medical record" and Medicare Advantage organizations have been required to exercise "good faith" and notify CMS about coding errors, including codes unsupported by patients' medical records); *United States ex rel. Silingo v. Wellpoint, Inc.*, 904 F.3d 667, 673 (9th Cir. 2018) ("[I]f enrollee diagnoses are overstated, then the capitated payments to Medicare Advantage organizations will be improperly inflated."); *see also* United States' First Amended Complaint (Dkt. 171), ¶¶ 66-82 & 87-114 (describing the regulatory and contractual obligation to submit valid diagnoses and delete invalid diagnoses).[2] There was never a regulation or guidance document that permitted insurers to submit some number or percentage of unsupported diagnoses. As explained above, an adjuster was never part of the automated systems.

Of equal significance, United cannot engage in self-help to avoid existing rules and regulations. The Ninth Circuit has made clear that seeking to invalidate a payment rule (here, the rule requiring the submission of valid diagnoses and deletion of invalid

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[2] Although United claims that its arguments based on "actuarial equivalence" are new and were never considered by the Ninth Circuit, the application of *stare decisis* focuses on the *issue* decided by the Court – not the *arguments* presented to the Court. *In re Osborne*, 76 F.3d 306, 309 (9th Cir. 1996). *Swoben* involved the very same defendant and the very same chart review programs now before this Court, the Ninth Circuit plainly addressed an insurer's legal obligation to code accurately, and that ruling is binding in this case, even if United purports to have new arguments for why it was not obligated to code accurately. 848 F.3d at 1176-79 (rejecting United's prior arguments). The Magistrate Judge erred in allowing United to litigate this case upon an entirely blank state and allowing discovery on issues decided by the Ninth Circuit, in violation of *stare decisis*. *Morrow v. Balaski*, 719 F.3d 160, 181 (3d Cir. 2013) ("the very point of stare decisis is to forbid us from revisiting a debate every time there are reasonable arguments to be made on both sides").

diagnoses) is no defense to a knowing violation of the rule. *Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d 765, 769 (9th Cir. 1997) ("If the Hospitals did indeed knowingly submit false claims in order to receive payment for devices not covered under the 1986 rule, the invalidity of the rule will be no defense.") (citing and following *Bryson v. United States*, 396 U.S. 64, 68 (1969), and *Dennis v. United States*, 384 U.S. 855, 867 (1966)).[3] United cannot simply ignore its obligation to delete invalid diagnosis codes or to repay improperly inflated interim payments based the established payment system and rates, and then, after being sued under the FCA, seek to avoid liability for its fraud by challenging that system and those rates based on its own interpretation of how the agency should have implemented "actuarial equivalence."

United also cannot meaningfully distinguish its challenge to the Medicare Advantage payment system and rates from the challenge to the medical device payment rule in *Cedars-Sinai*. The only argument United musters in its response is that this case is based on a reverse false claim, which makes no difference at all. This case is *not* about a defendant that innocently obtained an "overpayment" and then later learned that it submitted invalid data. Rather, United knew about the invalid diagnosis data *before* it obtained the final payment for each payment year and *still* did not withdraw the invalid diagnoses (that is, the false claims) before it obtained that final payment. In that sense, this case is nearly identical to *United States v. Bourseau*, 531 F.3d 1159 (9th Cir. 2008), which involved "interim payments made to defendants under Medicare, and defendants' obligation to provide a [truthful] cost report each year so the government agency could make appropriate reconciliation payments based on those reports." *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, 2018 WL 1363487, at *11 (C.D. Cal. Feb. 12

[3] In its Response, United does not address *Cedars-Sinai* at all. Instead, it tries to distinguish *Dennis* and *Bryson* by contending that they involved prosecutions without any reference to the underlying requirement that was challenged as invalid. Dkt. 338 at 24. Even if United were correct about *Dennis* and *Bryson*, which it is not, *Cedars-Sinai* involved the violation of a rule that defendant later challenged as invalid: Defendant asserted that the Medicare coverage rule it was charged with violating was not issued in accordance with the APA, but the Ninth Circuit rejected this defense. 125 F.3d at 767.

2018) (*citing Bourseau*, 531 F.3d at 1162). The defendants in *Bourseau* submitted false costs on their cost reports and thereby concealed and avoided their obligation to repay CMS for improperly inflated interim payments through a final reconciliation process, in violation of the reverse FCA provision. Likewise, United failed to delete known invalid codes and thereby concealed and avoided its obligation to repay CMS for improperly inflated interim payments through a final reconciliation process. United's misconduct is also akin to the knowing submission of false claims.[4] There is no substantive distinction such that challenging payment rules would be permissible in a reverse false claims case, but not permissible in an affirmative false claims case.[5]

B. *Azar* Does Not Preclude Any Issues Here

United cannot rely on Judge Collyer's decision in the *Azar* APA action to avoid liability for its knowing failure to delete invalid diagnoses codes and causing Medicare to make improperly inflated final payments. Response (Dkt. 338) at 11. Unlike this FCA case, the question in *Azar* was whether the 2014 Overpayment Rule, 42 C.F.R. § 422.326, reflected arbitrary and capricious agency action or violated the Medicare Act. There were no allegations that any Medicare Advantage organization with actual knowledge, reckless indifference, or deliberate ignorance failed to delete invalid diagnosis codes, and thereby concealed its obligation to pay CMS. Early on, Judge Collyer concluded that "any decision in [the APA case] will not answer the most relevant questions in the FCA Cases [which include] whether a government contractor knowingly engaged in fraud . . . ." *UnitedHealthCare Ins. Co. v. Price*, 255 F. Supp. 3d 208, 210 (D.D.C. 2017). She explained that "[a]ll parties agree that the allegedly

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[4] In *Bourseau*, the district court also held that the false cost reports were also actionable as affirmative false claims. 531 F.3d at 1164.

[5] Furthermore, an "obligation" under the FCA is much more than the "retention of any overpayment." 31 U.S.C. § 3729(b)(3). It is also an "established duty, whether or not fixed, arising from an express or implied contractual … relationship, from a fee-based or similar relationship, [or] from statute or regulation." For example, and as noted above, the relevant regulations obligate MAOs to repay CMS for improperly inflated interim payments resulting from known invalid diagnoses through a final reconciliation process. 42 C.F.R. § 422.310(g)(2).

fraudulent conduct in *Poehling* and *Swoben* predates the 2014 Overpayment Rule, and that the Rule is not at issue in either FCA Case." *Id*. And most importantly, Judge Collyer was clear that her decision concerning the validity of the Overpayment Rule in *Azar* does not apply to insurers like United that "knowingly or recklessly … bill CMS for erroneous diagnosis data." *UnitedHealthCare Ins. Co. v. Azar*, 330 F. Supp. 3d 173,189 (D.D.C. 2018); *see also Price*, 255 F. Supp. 3d at 211 (noting that the APA case "does not concern the actions of United in any way").

Judge Collyer explained that her decision did not apply to cases involving the FCA and the Overpayment Statute, 42 U.S.C. § 1320a-7k(d)(1), because violations of these statutes require that an insurer acts with actual knowledge of or with deliberate ignorance or reckless disregard to the invalidity of diagnosis codes submitted to Medicare. In contrast, Judge Collyer construed the "reasonable diligence" standard in the Overpayment Rule as a negligence standard that imposed an obligation on insurers to engage in proactive compliance activities to ensure that all diagnosis codes that they submit for payment under a particular contract are valid. 330 F. Supp. 3d at 190-91 ("In summary, the FCA and the ACA require actual knowledge, deliberate ignorance, or reckless disregard before liability can be found. The standard in . . . the FCA . . . is certainly not the standard in the 2014 Overpayment Rule . . . ."). It was this affirmative obligation to ensure contract-wide perfect coding that made the Overpayment Rule equivalent to RADV extrapolated audits determining contract-wide overpayments. *Id*. at 176 ("the insurers contend that imposing a 100% accuracy requirement on their records . . . would violate the statutory requirement of actuarially equivalent payments"); at 186 (stating that "RADV audits …are conducted for the same purpose as the 2014 Overpayment Rule" and finding that the Overpayment Rule required proactive compliance activities to identify invalid diagnoses); and at 191 ("the 2014 Overpayment Rule extends far beyond the False Claims Act and, by extension, the Affordable Care Act"). And it was only in the context of requiring contract-wide perfect coding accuracy that Judge Collyer believed some sort of adjuster was necessary.

Based on the limited issue that was decided and ruled upon in *Azar*, United cannot meet its burden of showing issue preclusion based on that case. As the party seeking issue preclusion, United "bears the burden of showing with clarity and certainty what was determined by the prior judgment." *Clark v. Bear Stearns & Co.*, 996 F.3d 1318, 1321 (9th Cir. 1992). Moreover, United bears the burden of showing that the issues in the two cases are identical. *Littlejohn v. United States*, 321 F.3d 915, 923 (9th Cir. 2003); *In re Magnacom Wireless*, 503 F.3d 984, 996 (9th Cir. 2007) (no preclusive effect in light of how district court in prior case limited the scope of the litigation). As the Supreme Court stated in *United States v. Stauffer Chem., Co.*, 464 U.S. 165, 169 (1984), for defensive collateral estoppel to apply against the government, the issue sought to be re-litigated must be identical to the issue already litigated. United cannot satisfy these burdens here.[6] Because the *Azar* decision addresses different issues, it is not identical to this case and thus is not binding.

Cedars-Sinai compels this conclusion. In that case, a group of hospitals brought an APA action successfully challenging a rule banning Medicare coverage for certain medical devices. *Id.* at 767. A relator filed a separate action under the FCA claiming that many hospitals had violated the coverage ban. The relator attempted to intervene in the APA case, but the district court denied his intervention motion. On appeal, the Ninth Circuit held that although the coverage ban was at the center of both cases, "the district court [had] correctly decided that the issue in [the APA] case and the . . . *qui tam* case are different." *Id.* at 769. The Ninth Circuit explained that the "issue in [the APA] case is whether HCFA's 1986 rule was validly promulgated [while] the issue in the Seattle

[6] United also cannot satisfy the third *Littlejohn* factor that the "issue in the prior litigation must have been a critical and necessary part of the judgment in the earlier action." This failure is notable because *Azar's* ruling on the actuarial equivalence issue was unnecessary to its outcome because of the ruling that the agency's failure to explain why it did not include an adjuster as part of the Overpayment Rule when it proposed one for RADV audits was arbitrary and capricious. 330 F. Supp. 3d at 190 ("The Court finds that CMS was arbitrary and capricious in adopting the 2014 Overpayment Rule without explaining its departure from prior policy.") (footnote omitted).

qui tam case is whether any of the Hospitals knowingly submitted false claims for payment." *Id.* The Ninth Circuit then concluded that, "[b]ecause these issues are distinct, the identity of the issues is not met," and the APA action could proceed. *Id.*

Here, the relationship between *Azar* and this case is even more attenuated. This case is not about the Overpayment Rule under review in *Azar*.[7] Plaintiffs' claims are not based on noncompliance with the Overpayment Rule, and Plaintiffs do not rely on the "reasonable diligence" standard in that Rule. In bringing this action, the government does not seek to impose a scienter standard which might be interpreted as requiring perfect coding accuracy on a contract-wide basis. Nevertheless, United itself decided to review its beneficiaries' medical records to find additional diagnosis codes, and United determined which beneficiaries' charts to review as part of its chart review program. Having scoured those records for additional diagnosis codes to submit for increased payments, United cannot lawfully turn a blind eye to and ignore the negative results of those reviews. *See Swoben*, 848 F.3d at 1179 ("[T]his is not a case about whether Medicare Advantage organizations have to take affirmative steps to verify risk adjustment data. The defendants indisputable took such steps by conducting retrospective reviews. This is a case about whether such organizations, having adopted affirmative verification procedures, have to conduct them in good faith.").

C. The Documents And Data That United Requests Do Not Relate To And Cannot Be Used To Determine Any Sort Of Adjuster In This Case

United seeks a vast quantity of internal agency documents relating to CMS's consideration and study of a "payment error rate" adjuster for contract-wide RADV audits and overpayments based on such audits and all the data that was relied upon or used by CMS as part of its consideration and study of a "payment error rate" adjuster. United is not entitled to such documents or data in this case because this case has

[7] Thus, United is not entitled to the irrelevant documents that it demands relating to this Overpayment Rule, including its demands for all documents relating to the proposal of this rule (Request for Production [RFP] 27), the final adoption of the rule (RFP 28), and the "reasonable diligence" standard in that rule. (RFP 33).

nothing to do with a contract-wide audit or contract-wide overpayments. Thus, even if a "payment error rate" adjuster were a valid concept in the contract-wide audit and overpayment context (which CMS disputes in the report of its recent study), that concept does not apply here and the documents and data are irrelevant. As previously stated, the government's claims are not based on any audits of United's contracts and the government is not basing its damages on any contract-wide audits or overpayments.

United also seeks these internal agency documents and data relating to the agency's consideration of a "payment error rate" adjuster and a vast quantity of other data that have no relevance to its argument that it is entitled to a free pass for a certain number or percentage of invalid diagnosis codes. First, CMS has never proposed using a "coding error rate" adjuster. Indeed, CMS has unambiguously stated that the FFS Adjuster discussed in the context of the extrapolated RADV audits "was *never* intended to set a permissible rate for the submission of erroneous diagnosis codes." 83 Fed. Reg. at 55,038 (emphasis added).[8] The "payment error rate" adjuster described in the 2012 RADV methodology memo was focused on a potential offset to the contract-wide overpayment amount.[9] As explained in the 2012 memo, the contract-wide overpayment amount for a RADV audit was to be determined based on the results of a review of a random sample of beneficiaries and their medical records and extrapolation of those

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[8] The two internal deliberative documents that United cites in footnote 7 of its Response do not address the use of a "coding error rate" adjuster. The documents reflect internal agency deliberations concerning speculation by insurers that unaudited FFS diagnosis data may have caused the coefficients for some unspecified HCCs to be too low and, if so, whether a *payment error rate adjuster* (not coding error rate adjuster) should be used for extrapolated contract-wide administrative audit overpayment calculations. These two documents do not conclude that any coefficients were too low or that any payment adjuster was necessary even in the context of an extrapolated contract-wide administrative audit. They simply discuss – before CMS completed any study – what a payment error rate adjuster might be.

[9] Even in the context of extrapolated RADV audits, CMS no longer intends to use any adjuster. In its Technical Appendix to its FFS Adjuster Study, CMS explained why even a payment error rate adjuster is conceptually and theoretically incorrect. *See* Technical Appendix to FFS Adjuster Study (Dkt. 307-3) at 1 (explaining that the statistical foundation that would result in a consistent underpayment bias is "largely non-existent") and at 12 (explaining why recalibrating the HCC coefficients based on audited FFS data would not automatically increase risk scores and payments).

sample results to the entire contract.[10]

Contrary to United's characterization of their testimony, *see* Response (Dkt. 338) at 6:1-5, 14:4-6, the only two CMS witnesses who have been deposed in this case did not agree with United's "coding error rate" argument or testify that there were any documents relating to the use of such an adjuster. Plaintiffs already addressed United's mischaracterization of these witnesses' testimony in their Partial Summary Judgment reply brief. *See* Dkt. 272 at 20-21. In short, United never asked either witness about a "coding error rate" adjuster. Furthermore, Mr. Grant testified that the existence of any error as to the HCC model's prediction of costs does *not* mean that insurers can refuse to correct invalid diagnoses. *Id*. at 21. Although Mr. Grant advocated for a payment error rate adjuster when he worked for the insurers (not CMS), he was clear in his testimony that he never believed that insurers were entitled to a free pass on submitting unsupported diagnosis codes and he never advocated for a coding error rate. *Id*.

Because CMS never proposed a "coding error rate" adjuster, the Magistrate Judge clearly erred in concluding that documents relating to the proposed RADV FFS Adjuster payment error rate adjuster were somehow relevant to United's "coding error rate" argument. United falsely states that the government knows that these documents would bolster its argument. Response (Dkt. 338) at 6:9. To the contrary, the government knows that the documents have nothing to do with a "coding error rate," and so does United because, after CMS issued its 2012 RADV memo, United continued to delete numerous invalid diagnosis without ever asking for a "coding error rate" adjuster.

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[10] The government filed a copy of CMS's study with the Court. (Dkt. 307.) United contends that this filing was an admission of the study's relevance and, thus, justifies its requests for all documents and data relating to the study. That is incorrect. The government filed it to correct United's misstatement to the Court that the adjuster proposed in the 2012 RADV memo was a "coding error rate" adjuster. Similarly, the government's service of subpoenas on two industry associations for documents relating to this adjuster issue is not an admission that the discovery is relevant to a legitimate defense in this case. The government served the subpoenas because these associations possess documents that will refute the legitimacy of this defense and, as long as this illegitimate defense remains in the case, the government will refute it.

Second, none of the vast amount of documents and data requested by United regarding the development, evaluation, and calibration of the risk adjustment model (the CMS-HCC model) relate to an adjuster. Even if the number or percentage of unsupported diagnoses in the FFS data were somehow relevant to this action, recalibrating the model will not provide such coding error rate information. And, determining the error rates for the FFS diagnosis codes used to calibrate the model requires a review of the medical records for the FFS beneficiaries. CMS reviewed some of these records as part of its recent study and published the error rates in the report it posted on its public website. Accordingly, United's "coding error rate" argument does not justify its numerous and overly broad and burdensome requests for all documents and data relating to the development and evaluation of the CMS-HCC model and the calibration and various recalibrations of the payment rates (that is, coefficients) for the model since 2004 or for all data used over the last 15 years to calibrate and recalibrate the coefficients.[11]

D. Internal Agency Documents Relating To CMS' General Knowledge About Chart Reviews And The Validity Of Diagnosis Coding Are Irrelevant

This Court has already recognized that CMS's continued payments despite generalized knowledge of one-way chart reviews and problems with the validity of diagnosis coding is not the issue here. The Court stated that, in assessing "materiality,"

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[11] For example, United fails to justify the production of "[a]ll data fields included in the following Limited Data Set ('LDS') Files: 1) 100% Denominator File, 2) 5% Carrier Standard File. 3) 100% Inpatient Standard Analytical File, and 4) 100% Outpatient Standard Analytic File" for dates of service years 2005 through 2015 (RFP 8); "Documents [from 1997 to 2017] sufficient to show the methodology by which the Government calculates Risk Adjustment Factors [*i.e.*, coefficients]" (RFP 24); "[a]ll Documents related to the development and operation of the CMS-HCC Risk Adjustment Model [from 2004 to 2017], including but not limited to Documents identifying and explaining the specific data used to calibrate the CMS-HCC Risk Adjustment Model" (RFP 100); "[a]ll Documents [from 2004 to 2017] sufficient to show how the data were selected and which records were specifically selected to create the 5% Medicare Standard Analytic files . . . used to develop, calibrate, and recalibrate the CMS-HCC Risk Adjustment Model" (RFP 101); or "[a]ll data [for payment years 2004 to 2017] from all fields included in the 5% Fee-For-Service Medicare file used to develop, calibrate, or recalibrate the CMS-HCC Risk Adjustment Model" (RFP 102).

it would consider CMS' "actual knowledge" of Defendants' invalid diagnoses and what CMS did to "change the risk adjustment payments" if and when it had such "actual knowledge." *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, 2018 WL 1363487 at *12 (C.D. Cal. Feb. 12, 2018) (Dkt. 212 at 21). Despite this ruling, United continues to seek broad discovery as to all documents about CMS' generalized knowledge of chart reviews and problems with diagnosis coding, including documents relating to audits and investigations of other insurers, deletes made by other insurers, overpayments repaid by other insurers, and risk adjustments compliance activities engaged in by other insurers.[12] Furthermore, despite this ruling, the Magistrate Judge ordered the production of all documents relating to CMS' generalized knowledge about chart reviews because it would be "material." Mem. Decision and Order ("Discovery Order") (Dkt. 324) at 32:10-12. That part of the Magistrate Judge's Discovery Order was clearly erroneous.

[12] For example, United seeks "[a]ll Documents relating to the preliminary and final results of any audits or reviews conducted by or on behalf of the Government, including CMS and HHS OIG, of diagnosis codes submitted to the Medicare Program for Risk Adjustment payments, including, but not limited to, RADV Audits" (RFP 5); "[a]ll Documents relating to the Government's knowledge as to whether MA Plans were validating the accuracy of diagnosis codes submitted on claims data to CMS for purposes of Risk Adjustment" (RFP 17); "[a]ll Documents relating to the Government's knowledge as to whether MA Plans were deleting diagnosis codes submitted on claims data to CMS for purposes of Risk Adjustment that were not supported by a medical record" (RFP 18); "[a]ll Documents relating to the Government's knowledge as to whether MA Plans 'look both ways" (RFP 19); "[a]ll Documents relating to the Government's knowledge of MA Plans' efforts to exercise 'reasonable diligence' to report and return overpayments to CMS as described in 79 Fed. Reg. 29,844, 29,923" (RFP 20); "[a]ll Documents reflecting or relating to whether MA Plans validate or validated the accuracy of diagnosis codes submitted on claims data to CMS for purposes of Risk Adjustment and whether MA Plans 'look both ways' when reviewing medical charts" (RFP 38); "[a]ll Documents relating to discussions between the Government and MA Plans regarding the voluntary retention or return of potential or actual overpayments as a result of MA Plan review of Risk Adjustment data" (RFP 40); "[a]ll Documents relating to discussions between the Government and MA Plans regarding Chart Reviews, compliance obligations with respect to Risk Adjustment, diagnosis coding and medical record documentation" (RFP 41); "Documents sufficient to show the dollar value of diagnosis codes deleted by all MA Plans" (RFP 47); all documents relating to the processing of deletes by other insurers and to communications with other MAOs about deletes (RFPs 2, 3, and 4 [Second Set]); and "[a]ny Documents relating to any meetings between CMS and any Person related to Risk Adjustment" (RFP 18 [Second Set]).

As part of this erroneous ruling, the Magistrate Judge not only ignored this Court's prior decision in this case but also the Ninth Circuit's ruling in *Swoben* that CMS' decision not to finalize its proposed medical record review rule was not relevant to the obligation of insurers to delete known invalid diagnoses codes. The Magistrate Judge only cited the first part of the Ninth Circuit's discussion of this issue. Discovery Order (Dkt. 324) at 32:14-22. There is no mention of the Ninth Circuit's ultimate ruling that the regulatory requirements that existed before the proposed rule continued to exist despite CMS not finalizing the proposed rule and that these requirements included the obligation of insurers to implement appropriate procedures to ensure that they have submitted valid payment data and to delete known invalid diagnoses. *Swoben*, 848 F.3d at 1169-70. For instance, the regulatory and contractual obligation to implement effective compliance programs has continued to exist. An insurer that intentionally or recklessly disregards the negative results of its blind chart reviews (results showing that it submitted invalid data) cannot possibly have complied with this obligation. Under these circumstances, as the Ninth Circuit concluded, the proposed medical record review rule was unnecessary to require the insurer to look both ways at the results of its chart reviews, add supported codes, and delete unsupported codes. The doctrine of *stare decisis* precludes re-litigation of this issue.[13]

E. The United States' Common Law Claims Do Not Justify Discovery Of Internal Agency Deliberations

United attempts to fault the government for not having addressed its payment by mistake claim in its motion for review. Response (Dkt. 338) at 16. The simple explanation is that the Magistrate Judge did not premise any part of her ruling on this

[13] Many of United's other discovery requests also seek irrelevant documents for other reasons as well. These topics have been addressed elsewhere, and the United States will not repeat those arguments here. For example, United seeks discovery into the RADV audit sampling and extrapolation methodology (RFP 1), even though this case has nothing to do with RADV audits (*see, e.g.*, Dkt. 272 at 32-35), and discovery relating to the coding intensity adjuster (RFP 23), even though that is not a valid defense in this action. (*see, e.g.*, Dkt. 272 at 37-43).

claim. In its briefing to the Magistrate Judge, the government explained that because United failed to delete or or otherwise notify CMS about the specific diagnosis codes that were unsupported by its chart reviews, there was no way for any agency official to know which codes were invalid. Mot. to Compel (Dkt. 310) at 67. In the course of the routine automated claims payment system, agency officials do not verify diagnosis codes – nor could they given that beneficiary medical records are not part of the claims submission process. *See Silingo*, 904 F.3d at 672-73 ("[W]ith data for millions of people being submitted each year, CMS is unable to confirm diagnoses before calculating capitation rates…."). Instead, the RAS and payment system rely on the diagnosis codes that an insurer submits and on the insurer's obligation to submit valid diagnoses. Here, the payment system mistakenly made improperly inflated final payments to United based upon invalid diagnoses. *See supra* footnote 1 and accompanying text. Medicare is entitled to recover those mistaken payments. No amount of discovery regarding the agency's internal deliberations will change these fundamental features of this automated payment process showing that payments were mistaken.

United's arguments regarding unjust enrichment also fail. United cannot defend against the unjust enrichment claim by arguing that whether it was unjustly enriched by the improperly inflated final payments should take into account whether United was underpaid on a contract-wide basis because some payment rates (that is, coefficients) for some medical conditions (that is, HCCs) may have been too low. Response (Dkt. 338) at 17 (making a population-based argument). As previously explained, this case has nothing to do with contract- or population-wide overpayments or underpayments. United also fails to offer any legal authority for the novel proposition that, in order to determine whether its enrichment from the specific invalid claims (that is, specific invalid diagnoses) paid by Medicare was unjust, the Court must conduct an across-the-board accounting based on any claims United purports to have against Medicare based on "too low" payment rates for valid claims (that is, valid diagnoses). Moreover, what is "unjust" is that, after United elected to forego bringing an APA case to challenge the

purportedly "too low" payment rates and instead entered into numerous contracts for payments based on those rates, it is now seeking to employ such a challenge to defend its enrichment for the payment of invalid claims.

III. CONCLUSION

Every year, as required by statute, CMS published a notice announcing the payment rates for the following year for every demographic factor and medical condition. These notices described the methodology for the calculation of the rates. Insurers had the right to comment on the initial notices and then to challenge the final notices in an APA action. United never made such a challenge, even though it knew that unaudited FFS data was used to calculate the payment rates. Instead, every year, United executed numerous contracts with CMS agreeing to comply with the program requirements and to be paid billions of dollars pursuant to the published payment rates. At the same time, United knowingly ignored the results of its own chart reviews showing that it had submitted numerous invalid diagnoses, failed to delete those invalid diagnoses, and thereby concealed and avoided its obligation to repay billions of dollars in interim payments based on those invalid codes. United cannot now use this case to remedy purported grievances it might have had about the payment system or the rates. Nor can it refuse to comply with established payment rules and regulations as a means of self-help. And discovery into these invalid defenses is irrelevant. For the foregoing reasons, the United States respectfully requests that the Court set aside the Magistrate Judge's Discovery Order as clearly erroneous.

Respectfully submitted,

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JOSEPH H. HUNT
Assistant Attorney General
NICOLA T. HANNA
United States Attorney
DAVID M. HARRIS
DAVID K. BARRETT
ABRAHAM C. MELTZER
JACK D. ROSS
Assistant United States Attorneys

MICHAEL D. GRANSTON
ROBERT McAULIFFE
EDWARD CROOKE
CAROL L. WALLACK
JUSTIN DRAYCOTT
PAUL G. FREEBORNE
JESSICA E. KRIEG
ZOILA E. HINSON
AMY L. LIKOFF
ADAM R. TAROSKY
Civil Division, Department of Justice

JAMES P. KENNEDY, JR.
United States Attorney
KATHLEEN ANN LYNCH
Assistant United States Attorney

/S/ John E. Lee

JOHN E. LEE
Assistant United States Attorney
Attorneys for the United States of America