UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITEDHEALTHCARE INSURANCE COMPANY, ***et al.*****,** **Plaintiffs,** **v.** **ALEX M. AZAR II,** **Secretary of the Department of Health and Human Services,** ***et al.*****,** **Defendants.**	**Civil Case No. 16-157 (RMC)**

OPINION

Health insurance is provided to most seniors and many disabled Americans through Medicare, paid for by taxes and administered by the Centers for Medicare and Medicaid Services (CMS). As amended, the Medicare statute (formally part of the Social Security Act), includes a "Medicare Advantage" program whereby Medicare-eligible individuals can elect to receive their health insurance coverage through a private insurance company. The insurance company must provide at least the same coverage as traditional Medicare, although it often expands coverage, and is to make its profit from Medicare through efficiencies and other cost-saving methods. The statute requires "actuarial equivalence" between CMS payments for healthcare coverage under Medicare Advantage plans and CMS payments under traditional Medicare. In this case, a large group of insurance companies that provide Medicare Advantage coverage challenged a Final Rule, adopted in 2014, by which the documentation used to set the rates to pay the insurance companies is inconsistent with the documentation used to determine if the insurers have been overpaid. The insurers allege that the Final Rule will inevitably fail to satisfy the statutory mandate of actuarial equivalence.

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There is a history to this dispute over actuarial equivalence. The government previously had proposed an audit program for Medicare Advantage insurers and some insurers challenged its methodology for determining overpayments. Since government records for traditional Medicare payments are used to set rates but are not audited, the insurers contended that imposing a 100% accuracy requirement on their records, on pain of being required to return any "overpayment," would violate the statutory requirement for actuarially equivalent payments between traditional Medicare and Medicare Advantage. Heeding the advice of actuaries, the government ultimately adjusted its audit plan to recognize the different data sets. For the 2014 Final Rule at issue here, however, CMS has refused to make such an adjustment although the different data sets are again in use.

After full briefing and oral argument, this Court concludes that the 2014 Final Rule violates the statutory mandate of "actuarial equivalence" and constitutes a departure from prior policy that the government fails adequately to explain. The Court will grant summary judgment to the Medicare Advantage insurers and vacate the Rule.

I. BACKGROUND

This lawsuit is brought by Medicare Advantage (MA) organizations in the UnitedHealth Group family of companies, the nation's leading provider of Medicare Advantage health benefits plans (collectively, UnitedHealth).[1] Known as Medicare Part C, the Medicare

[1] Plaintiffs are UnitedHealthcare Insurance Company, AmeriChoice of New Jersey, Inc., Arizona Physicians IPA, Inc., Care Improvement Plus South Central Insurance Company, Care Improvement Plus of Texas Insurance Company, Care Improvement Plus Wisconsin Insurance Company, Health Plan of Nevada, Inc., Medica Healthcare Plans, Inc., Oxford Health Plans (CT), Inc., Oxford Health Plans (NJ), Inc., Oxford Health Plans (NY), Inc., Pacificare Life and Health Insurance Company, Pacificare of Arizona, Inc., Pacificare of Colorado, Inc., Pacificare of Nevada, Inc., Physicians Health Choice of Texas, LLC, Preferred Care Partners, Inc., Sierra Health and Life Insurance Company, Inc., UnitedHealthCare Benefits of Texas, Inc., UnitedHealthCare Community Plan of Ohio, Inc., UnitedHealthCare Community Plan of Texas,

Advantage program allows Medicare-eligible individuals to receive healthcare benefits through private insurance companies that have contracted with CMS, a constituent agency of the Department of Health and Human Services (HHS). Alex M. Azar II, HHS Secretary, is sued in his official capacity. CMS administers traditional Medicare and pays its benefits. However, some 20 million Americans, approximately one-third of Medicare-eligible individuals, have opted for Medicare Advantage coverage.

Medicare Parts A, B and C are relevant here. Medicare Part A is mandatory for senior Americans who take Social Security benefits; Part A provides coverage for hospital expenses. Medicare Part B is voluntary and provides partial coverage for doctor expenses. Medicare Part C offers the Medicare Advantage program through which private insurance companies replace CMS and provide full Medicare coverage to beneficiaries.

Initially, Medicare paid all "reasonable costs" ("fee for service") to a hospital caring for a Medicare beneficiary. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994). Over time, that standard has changed and Medicare now pays a hospital based on the "Diagnosis-Related Group" (DRG) shown by the patient's diagnoses at the time of discharge. Medicare Part B also started by paying doctors a reasonable "fee for service," but now pays them according to fee schedules that limit the amount they may charge and be paid for

LLC, UnitedHealthCare Insurance Company of New York, UnitedHealthCare of Alabama, Inc., UnitedHealthCare of Arizona, Inc., UnitedHealthCare of Arkansas, Inc., UHC of California, UnitedHealthCare of Florida, Inc., UnitedHealthCare of Georgia, Inc., UnitedHealthCare of New England, Inc., UnitedHealthCare of New York, Inc., UnitedHealthCare of North Carolina, Inc., UnitedHealthCare of Ohio, Inc., UnitedHealthCare of Oklahoma, Inc., UnitedHealthCare of Oregon, Inc., UnitedHealthCare of Pennsylvania, Inc., UnitedHealthCare of the Midlands, Inc., UnitedHealthCare of the Midwest, Inc., UnitedHealthCare of Utah, Inc., UnitedHealthCare of Washington, Inc., UnitedHealthCare of Wisconsin, Inc., and UnitedHealthCare Plan of the River Valley, Inc.

each defined service. *See United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 968 (D.C. Cir. 1999). Under Part B, doctors must submit diagnosis codes to identify the reason a patient received treatment, but "payments depend only on the services (or durable goods) provided [office visit, examination, shot, etc.] and not in any way on the diagnoses submitted." Defs.' Mem. in Support of Their Cross-Mot. for Summ. J. and Opp'n to Pls.' Mot. for Summ. J. (CMS Mot.) [Dkt. 57-1] at 7.[2] In contrast, Medicare Advantage insurers are not paid based on medical services but "are paid a pre-determined monthly sum for each person they cover, based in part upon the characteristics of the particular beneficiary being covered." *Id.* (internal citation omitted).

A Medicare Advantage insurer must provide, at a minimum, the same level of benefits provided by traditional Medicare itself, except for hospice care. *See* 42 U.S.C. § 1395w-22(a). Under a Medicare Advantage policy, the insurance companies pay doctors, other healthcare providers, and hospitals for their services and are reimbursed by CMS on a per-member-per-month rate that is determined beforehand. *See id.* § 1395w-23(a).

By law, CMS must pay Medicare Advantage insurers in a manner that ensures "actuarial equivalence" between payments for healthcare under Medicare and Medicare Advantage plans:

> [T]he Secretary shall adjust the payment amount [of fixed monthly payments to Medicare Advantage insurers] for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . , so as to ensure actuarial equivalence.

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[2] Although all parties used the initials "FFS" (fee-for-service) to reference traditional Medicare (and compare it to Medicare Advantage), this term is "now, something of a misnomer" because CMS has changed its fee structures for hospitals and doctors. *See* CMS Mot. at 4. The Court eschews the use of the acronyms for clarity, except when quoting. *See D.C. Circuit Handbook of Practice and Internal Procedures* 41 (2016).

Id. § 1395w-23(a)(1)(C)(i). Risk factors represent the risk that a given beneficiary, or beneficiary population, will need healthcare from doctors or hospitals in the next year as it may be diagnosed. "A risk adjustment model is required to translate the diagnosis data into expected costs of coverage." CMS Mot. at 14. For this purpose, CMS relies on its model, the CMS Hierarchical Condition Category (CMS-HHC) risk-adjustment model, to "perform that conversion":

> CMS-HCC is a complex regression model built to estimate the costs associated with certain characteristics of Medicare beneficiaries. The inputs to the model are data from individuals who receive their benefits through the traditional, fee-for-service Medicare system. Its outputs are a set of multipliers—that is, "coefficients"—that "represent the marginal (additional) cost" of each medical "condition or demographic factor (e.g., age/sex group, Medicaid status, disability status)." The coefficients are added together to form a "risk score," and then computed against a base payment rate (which varies depending on geography and the bid submitted by the insurer, among other things).

Id. (internal citations omitted).

By this process, CMS calculates the average monthly expenditure for an average beneficiary under traditional Medicare in the past year. The "base rate establishes . . . what it would cost to treat a beneficiary of average risk in a given area." *See* Transcript of Aug. 8, 2018 Motions Hearing (Hearing Tr.) [Dkt. 73] at 5. CMS adds a geographical differential, based on data from the past year, to calculate an average per-capita monthly payment for each county in the nation.

This is no straightforward task. Each traditional Medicare beneficiary has a "demographic risk coefficient" which reflects that person's age, gender, institutional status, and disability status, among others. *See id.* at 4. Additional coefficients represent the health status of the beneficiaries in traditional Medicare, taken from their diagnosis codes as reported to CMS by

their doctors. Using such CMS data, "the model estimates the marginal cost of each disease and cluster of demographic characteristics. . . . By mapping known expenditures . . . , the model calculates the expected cost of each medical condition and demographic factor." CMS Mot. at 17. Using the data from the demographic characteristics, reported diagnoses, and Medicare expenses of the beneficiaries in traditional Medicare, the model can estimate the marginal cost of each condition, disease and cluster of demographic characteristics.

The "average beneficiary" is given a risk score of 1.0, which is then adjusted upwards or downwards according to the risk score determined by an individual's demographic and health status information. For example, if a beneficiary has a condition that CMS has determined based on its Medicare data increases average costs by 20%, that person will have an adjusted risk score of 1.2 and the Medicare Advantage payment rate applicable to that person will be set at 120% of the average benchmark rate. *See, e.g.*, Advance Notice of Methodological Changes for CY 2004 Part C Rates (Mar. 28, 2003) (2004 Advance Notice) at AR3895-97 (describing how CMS uses the model to "associate diseases categories with incremental costs").[3] Thus, the costs in a prior year of the "risk coefficients" in the traditional Medicare system are used to determine the costs of similar risk coefficients for Medicare Advantage beneficiaries. The underlying logic is that developing risk coefficients with data from traditional Medicare, and then adjusting a Medicare Advantage beneficiary's risk score (and the payment to the Medicare Advantage insurer accordingly), will render the cost to CMS under traditional Medicare and the cost to the insurer under Medicare Advantage actuarially equivalent.

[3] CMS publishes annual Advance Notices of changes to its risk-adjustment methodology for the coming year. *See* 42 U.S.C. § 1395w-23(b).

In conducting these analyses, CMS relies entirely on the diagnosis codes submitted by healthcare providers under traditional Medicare. "[T]he risk adjustment model is built on unaudited [traditional Medicare] data . . . which must contain errors." CMS Mot. at 37. Indeed, doctors treating traditional Medicare patients are paid based on their services and not the diagnosis codes they might submit to report why the patient saw the doctor. As UnitedHealth's counsel explained at argument, physicians bill traditional Medicare by procedure, not diagnosis codes, so that "physicians are essentially indifferent to the diagnosis . . . . There's no financial incentive to be particularly careful." Hearing Tr. at 13. "[W]hat matters is the procedure they did." *Id.* at 14; *see also* CMS Mot. at 7 (agreeing that traditional Medicare payments to doctors "depend only on the services . . . and not in any way on the diagnoses submitted"). Given this incentive scheme, it can be no surprise that diagnosis reports for Medicare Part B are considered much less reliable than hospital diagnosis reports for Part A. *See* CMS Mot. at 7 (noting "the quality of the Part B diagnosis data is generally understood to be inferior to the Part A diagnosis data").

Medicare Advantage insurance companies bid annually after CMS issues notice of each county's benchmark rate for the forthcoming year. *See* 42 U.S.C. § 1395w-23(b)(1)(B). The insurers are paid on a per-capita basis for each covered individual, including applicable risk scores. As a result, a Medicare Advantage insurer undertakes to provide insurance coverage at least identical to Medicare at annual fixed rates even though the health care needs of the covered populations, mostly the elderly, vary greatly.

Humans being human, diagnoses in healthcare records may be miscoded, inappropriately added, or otherwise faulty by accident or mal intent. UnitedHealth suggests that the error rate can be as high as 20%. *See* Compl. [Dkt. 1] ¶ 38; *see also* Hearing Tr. at 28. In the

past, neither CMS nor the insurers made efforts to review proactively the diagnosis codes assigned by healthcare providers. Indeed, as stated above, CMS treats diagnosis codes as categorically valid for its own purposes under traditional Medicare, including for setting rates for Medicare Advantage. Nonetheless, CMS has long required Medicare Advantage insurers to certify "based on best knowledge, information and belief" that the information they provide to CMS, including all diagnosis codes, is "accurate, complete, and truthful." 42 C.F.R. § 422.504(l)(2). CMS contends that this pre-existing regulation, and other existing agency practices, have long required that diagnosis codes submitted by Medical Advantage insurers be supported by underlying medical records (*i.e.*, patient medical charts). UnitedHealth responds that neither this pre-existing regulation, nor any other law or regulation, has previously obligated the insurance companies who provide Medicare Advantage insurance to validate independently the underlying medical records that support diagnosis codes submitted by health care providers.

For more than a decade, CMS has conducted audits of a subsection of insurers in the Medicare Advantage program, through which it has compared the diagnosis codes in bills paid by the insurance companies to the underlying patient medical charts and records, which it requires the insurers to obtain for this purpose. It has then required repayment to CMS of any costs that were based on unsupported diagnosis codes. In 2008, CMS announced that it would begin applying these "Risk Adjustment Data Validation (RADV)" audits to extrapolate the error rate in the audited sample across an entire insurance contract.[4] The insurer would be responsible for returning any overpayment to CMS, based on the extrapolated error rate.

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[4] *See* Policy and Technical Changes to Parts C and D, 74 Fed. Reg. 54,634, 54,674 (Oct. 22, 2009) (2009 Proposed RADV Rule) at AR2409 (summarizing the history of the RADV audit program); Policy and Technical Changes to Parts C and D, 75 Fed. Reg. 19,678, 19,742-53 (Apr. 15, 2010) (2010 RADV Rule) at AR2819; Medicare Advantage Risk Adjustment Data

When CMS sought comments on its new methodology for conducting RADV audits, Medicare Advantage insurers immediately protested that the rates paid for each diagnosis code are based on traditional Medicare records that are not audited or verified in any way; requiring repayment of all amounts seemingly "overpaid" to a Medicare Advantage insurer based on audited records would ignore errors in CMS records and violate the statutory requirement of actuarial equivalence.[5]

This argument ventures deep into the weeds of actuarial science but is not actually disputed by the parties. Nor could CMS really debate it: as a result of the comments it received, CMS adopted a "Fee-for-Service Adjuster" or "FFS Adjuster" to the results of RADV audits of Medicare Advantage insurance contracts. The FFS Adjuster reflects CMS's own estimate of the error rate in risk factors and diagnosis codes submitted by healthcare providers and paid by CMS for its traditional Medicare participants; applied to the results of a RADV audit of a Medicare Advantage insurer, it is designed to achieve actuarial equivalence between the two. Thus, Medicare Advantage providers must return to CMS any audited "overpayments" to the extent that the insurer's errors exceed the estimated error rate in CMS payments under traditional Medicare. *See* Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012) (RADV Final Methodology) at AR5311-15.

Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits: Request for Comment (Dec. 20, 2010) (RADV Methodology Request for Comment) at AR5021-22.

[5] *See generally* Aetna Inc. Comments (Jan. 21, 2011) at AR5036-71; Humana Inc.'s Comments (Jan. 21, 2011) at AR5102-16; UnitedHealthCare Comments (Jan. 21, 2011) at AR5193-5220; *see also* American Academy of Actuaries Comment on RADV Sampling and Error Calculation Methodology (Jan. 21, 2011) (Academy of Actuaries Comment) at AR5235-36.

UnitedHealth asserts that the 2012 FFS Adjuster works to counteract the fact that per-capita payments to Medicare Advantage insurers are based on a less precise set of data—belonging to CMS—than that which is reviewed during an audit. Their argument, and CMS's eventual concurrence, are supported by the American Academy of Actuaries, which strongly advised CMS that it was not actuarially sound to compare unaudited figures to calculate per-capita payments and then audited figures to calculate overpayments. *See* Academy of Actuaries Comment at AR5236 ("This type of data inconsistency not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities.").

The passage of the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), is also directly relevant here. The ACA imposed an obligation on Medicare Advantage insurers to report and return any overpayments that an insurer discovers on its own. *See* 42 U.S.C. § 1320a-7k(d)(1) (2012). This section of the ACA defined "overpayment" as "any funds that a person receives or retains under [Medicare Advantage] to which the person, after applicable reconciliation, is not entitled." *Id.* § 1320a-7k(d)(4)(B). The law further required that any "overpayment . . . be reported and returned [within] 60 days after the date on which the overpayment was identified." *Id.* § 1320a-7k(d)(2). If an insurer in the Medicare Advantage program fails to return such a discovered overpayment within 60 days of identifying it, that failure renders the insurer's initial but faulty claim for payment a violation of the False Claims Act (FCA). *Id.* § 1320a-7k(d)(3) ("Any overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation (as defined in section 3729 (b)(3) of title 31) for purposes of section 3729 of such title."); *cf.* False Claims Act, 31 U.S.C. § 3729(b)(3). Claims for overpayments under the False Claims Act carry the potential

for treble damages, civil penalties, and debarment from Medicare. *See* 31 U.S.C. § 3729(a)(1)(G) (providing for civil penalties and treble damages); 42 C.F.R. § 424.535(a) (describing grounds for revocation of enrollment in the Medicare program). Further, non-government *qui tam* plaintiffs may bring FCA claims in federal court. *See* 31 U.S.C. § 3730(b).

The Affordable Care Act established a basic statutory framework but left several crucial terms undefined. It did not define at what point an insurer might be said to have "identified" an overpayment, thus triggering the 60-day clock; nor did it outline the scope of "applicable reconciliation" or state how "overpayments" and "actuarial equivalence" in payments are related.

We come to the 2014 Final Rule at issue here. CMS issued a notice of proposed rulemaking in January 2014 and sought comments.[6] CMS proposed to "clarify the statutory definition of overpayment" with a new regulation titled "Reporting and Returning Overpayments," to be codified at 42 C.F.R. § 422.326. *See* 79 Fed. Reg. at 1996, 2055-56 (June 29, 2000) (AR80 at AR139-40).

CMS published its Final Rule on May 23, 2014, and in so doing finalized 42 C.F.R. § 422.326 concerning overpayments.[7] Under the 2014 Overpayment Rule, *any* diagnostic code that is inadequately documented in a patient's medical chart results in an "overpayment." *Id*. at 29,921 (AR1313). Further, an overpayment is "identified" whenever a Medicare Advantage insurer determines, "or should have determined through the exercise of reasonable

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[6] *See* Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918, 1918-2073 (Jan. 10, 2014) (2014 Proposed Rule) at AR1 *et seq.*

[7] *See* Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29,844-968 (May 23, 2014) (2014 Overpayment Rule) at AR1235 *et seq.*

diligence," that it had received an overpayment. *Id*. at 29,923 (AR1315). CMS further defined reasonable diligence as requiring "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." *Id.* UnitedHealth alleges that these obligations apply a simple negligence standard for purposes of False Claims Act liability, which is contrary to the standards in the False Claims Act itself. *See* 31 U.S.C. § 3729(b)(1) (defining "knowing" and "knowingly" to include "actual knowledge," "deliberate ignorance," or "reckless disregard of the truth or falsity of the information"). At oral argument, CMS essentially conceded that the 2014 Overpayment Rule imposed a negligence standard with a purported False Claims Act enforcement mechanism:

> The Court: It's a negligence standard, knew or should have known?
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> [Defense Counsel]: . . . . [T]he rule does interpret the statutory language identified to mean not only literally knew about the overpayment, but also if you for instance have an entirely deficient compliance program and that is the reason, and your failure to have the appropriate compliance program is the reason you didn't learn of an overpayment that you should have learned of, then we will also begin the clock on that . . . .
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> The Court: . . . . The definition of identified doesn't mean knew, it means knew or with reasonable diligence should have known or maybe didn't care to look.
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> [Counsel]: Yes, your Honor.
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> The Court: That's all negligence.
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> [Counsel]: It bears some similarities to negligence, your Honor.
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> The Court: Right. So it's not a knowledge based thing?
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> [Counsel]: Not as it has been interpreted in the overpayment rule.

Hearing Tr. at 34-36.

Most critically for the present challenge, the 2014 Overpayment Rule did not adopt something like an "FFS Adjuster" to recognize that the sources of data are not compatible, *i.e.*, unaudited traditional Medicare records to determine payments to Medicare Advantage insurers and audited medical charts to determine overpayments. UnitedHealth argues that the 2014 Overpayment Rule thus fails to ensure "actuarial equivalence" between CMS's own costs and what CMS pays Medicare Advantage insurers to provide the same coverage. Rather, it subjects the insurers to a more searching form of scrutiny than CMS applies to its own enrollee data, thus resulting in a false appearance of better health among Medicare Advantage beneficiaries compared to traditional Medicare participants and systemic underpayments for healthcare costs to Medicare Advantage insurers. UnitedHealth also argues that the "negligence" standard of liability imposed by the 2014 Overpayment Rule constitutes an unlawful departure from the standard for liability under the False Claims Act.

The original Complaint in this matter was filed January 29, 2016, and CMS filed a motion to dismiss, which the Court denied on March 31, 2017. *See* 3/31/2017 Order [Dkt. 26]; Mem. Op. [Dkt. 25]. The parties proceeded to summary judgment briefing. Defendants filed the Administrative Record on July 14, 2017, *see* Notice of Filing and Serv. of Admin. Record [Dkt. 40], and UnitedHealth moved to supplement it. *See* Mot. for Leave to File Suppl. to the Admin. Record [Dkt. 44]. After full briefing, the Court granted the motion to supplement with two documents related to the FFS Adjuster for RADV Audits, *see* Mem. Op. [Dkt. 68]; 8/1/18 Order [Dkt. 69]; the parties filed a joint appendix to the administrative record including the additional documents. *See* Notice of Submission of Suppl. Joint Appx. [Dkt. 70]; Joint Mot. for Leave to File Corrected Joint Appx. Vol. 2 [Dkt. 71]; 8/7/18 Minute Order (granting motion to file

corrected volume). Summary judgment is now fully briefed,[8] with the addition of a brief *amicus curiae* in support of Plaintiffs, without objection from CMS, by America's Health Insurance Plans. *See* Amicus Brief [Dkt. 62]. The Court heard oral argument from the parties on August 8, 2018. *See* Hearing Tr.

III. LEGAL STANDARD

Summary judgment is available when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it is capable of affecting the outcome of litigation. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Id.*

Summary judgment is the proper stage for determining whether, as a matter of law, an agency action is supported by the administrative record and is consistent with the Administrative Procedure Act (APA). *Richards v. INS*, 554 F.2d 1173, 1177 (D.C. Cir. 1977). The APA provides that "[t]he reviewing court shall . . . hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. §706(2)(A), (C). Arbitrary and capricious review is "narrow." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). The Court is not to "substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Rather, the Court must determine whether the agency "examine[d] the relevant data and articulate[d] a satisfactory

[8] *See* Pls.' Mot. for Summary J. (United Mot.) [Dkt. 47]; CMS Mot.; Mem. in Opp'n to Mot. for Summ. J. [Dkt. 58]; Pls.' Mem. in Opp'n to Cross-Mot. for Summ. J. (Pls.' Opp'n & Reply) [Dkt. 60]; Reply to Opp'n to Mot. for Summ. J. [Dkt. 61]; Defs.' Reply to Opp'n to Cross-Mot. for Summ. J. (Defs.' Reply) [Dkt. 64].

explanation for its action, including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). The Court's review is limited to the administrative record, *Holy Land Found. For Relief and Dev. v. Ashcroft*, 333 F.3d 156, 160 (D.C. Cir. 2003), and the party challenging an agency's action bears the burden of proof, *City of Olmsted Falls v. FAA*, 292 F.3d 261, 271 (D.C. Cir. 2002).

III. ANALYSIS

A. Statutory Requirement of "Actuarial Equivalence"

The statutory provision at issue states that "the Secretary shall adjust the payment amount" of fixed monthly payments to Medicare Advantage insurers "for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status . . . so as to ensure actuarial equivalence." 42 U.S.C. § 1395w-23(a)(1)(C)(i). A traditional rule of statutory interpretation renders the use of "shall" a mandatory obligation. *See Anglers Conserv. Network v. Pritzker*, 809 F.3d 664, 671 (D.C. Cir. 2016) (citing Antonin Scalia & Bryan A. Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 112 (2012)).

UnitedHealth argues that the 2014 Overpayment Rule violates the statutory mandate of "actuarial equivalence." CMS responds that Medicare Advantage insurers are paid "a sum equal to the cost that CMS would expect to bear in providing traditional Medicare benefits to a given beneficiary" and there is thus "equivalence between an expected cost, on the one hand, and a known payment, on the other." CMS Mot. at 36.

In its briefs, CMS fails adequately to address the actuarial problem posed by the 2014 Overpayment Rule because of the different data sources on which it rests; the same actuarial problem was recognized and mitigated by CMS in 2012 with the FFS Adjuster for

RADV audits but, surprisingly, omitted in 2014. The record is clear that payments for care under traditional Medicare and Medicare Advantage are both set annually based on costs from unaudited traditional Medicare records, but the 2014 Overpayment Rule systemically devalues payments to Medicare Advantage insurers by measuring "overpayments" based on audited patient records. This distinction makes an actuarial difference.

In plain English, doctors treating patients under traditional Medicare bill CMS by the procedure involved and not by diagnosis code(s). While the doctors are required to enter diagnosis codes, that information is irrelevant to payment. As far as the record reveals, the diagnosis codes in traditional Medicare are never verified because they do not matter to payment. "[T]he risk adjustment model is built on unaudited data about traditional, fee-for-service Medicare beneficiaries, which must contain errors." CMS Mot. at 37. However, those very same diagnosis codes are presumed to have been accurate when CMS inputs all the data concerning beneficiaries of traditional Medicare into its regression model, which ultimately computes a value for each diagnosis. In consequence, the rates at which CMS pays Medicare Advantage insurers are based on flawed data across the millions of people in traditional Medicare. Yet the 2014 Overpayment Rule ignores those flaws when defining an "overpayment."

It is critical to appreciate that CMS does not claim that it audits traditional Medicare patient records; to the contrary, it accepts their diagnosis codes as given. *See* CMS Mot. at 7 (agreeing that traditional Medicare payments to doctors "depend only on the services . . . and not in any way on the diagnoses submitted"). It is also critical to appreciate that CMS does not show more errors or fraud in the charts of Medicare Advantage beneficiaries than in the charts of traditional Medicare beneficiaries. But the effect of the 2014 Overpayment Rule,

without some kind of adjustment, is that Medicare Advantage insurers will be paid less to provide the same healthcare coverage to their beneficiaries than CMS itself pays for comparable patients. This inequity is inevitable because CMS sets Medicare Advantage rates based on costs that are presumed, based on traditional Medicare diagnosis codes, to be associated with particular health status information that is not verified in underlying patient records. The same unverified diagnosis is, under the 2014 Overpayment Rule, treated as an overpayment that must be repaid, thus reducing the reimbursement to a Medicare Advantage insurer while requiring no such reduction in payment under traditional Medicare. Similarly auditing CMS records for errors or fraud could resolve the difference, if the audits were timely and if CMS were able to construct a legitimate program to carry out such audits. *See* Hearing Tr. at 26 (Plaintiffs' counsel explaining that CMS data is not audited prior to determining risk coefficients). This statement is not made to denigrate CMS but to recognize the difficulty involved.

Neither party cites, and the Court has not located, any case in which a court has defined the precise meaning of "actuarial equivalence" as used in 42 U.S.C. § 1395w-23(a)(1)(C)(i). Congress used the same language in the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1054(b)((1)(H)(iii)(I), (c)(3); and the D.C. Circuit has construed its meaning in that context. In *Stephens v. U.S. Airways Grp., Inc.*, 644 F.3d 437 (D.C. Cir. 2011), the Circuit "assume[d]" that "Congress intended that term of art to have its established meaning," that "[t]wo modes of payment are actuarially equivalent when their present values are equal *under a given set of actuarial assumptions*." *Id.* at 440 (emphasis added). The Seventh Circuit has found that ERISA requires "actuarial equivalence between a lump sum and an accrued pension benefit," and determined that this comparison was comparable to equivalence

"between a present and a future value." *Berger v. Xerox Corp. Ret. Income Guar. Plan*, 338 F.3d 755, 759 (7th Cir. 2003).

The term also appears in the Medicare Part D statute, which provides that certain prescription-drug coverage is subject to an "actuarial equivalence requirement" that is described in implementing regulations as "a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with . . . CMS actuarial guidelines." 42 C.F.R. § 423.4; *see also* 42 U.S.C. § 1395w-113(b)(5). According to CMS, the Medicare Part D provision requires "actuarial equivalence to compare the expected value [of covered prescription drugs] to the beneficiary (or, seen differently, the expected cost to the insurer) of different benefit plans." CMS Mot. at 29.

Based on these references to actuarial equivalence, CMS argues that the term "means to equate either an expected value with a known value (as in the case of an annuity and a lump sum payment) or two expected values (as in the case of benefit plans)." *Id.* at 30. In particular, CMS insists that the risk adjustment model for determining Medicare Advantage payment rates for each diagnostic code results in actuarial equivalence between the per capita payments to the insurers and payments for services by traditional Medicare. In this argument, CMS happily ignores the requirements of the 2014 Overpayment Rule that an insurer repay within 60 days *any* overpayment, no matter its degree, about which it knew or "should have determined through the exercise of reasonable diligence." 42 C.F.R. § 422.326(c).

Of particular assistance here, the D.C. Circuit specifically noted that two figures are actuarially equivalent only when they share "a given set of actuarial assumptions." *Stephens*, 644 F.3d at 440. In the *Stephens* context and here, this Court interprets "given" to mean "the same," as in two figures are actuarially equivalent when they share the same set of actuarial

assumptions. Different assumptions behind the elements of a calculation would, necessarily, result in actuarially non-equivalent results.

CMS is the insurer for traditional Medicare. Under the 2014 Overpayment Rule, however, the "expected cost" to the government insurer for traditional Medicare, *i.e.*, CMS, would be less than the "expected cost" to a private insurance company offering Medicare Advantage coverage. The problem would immediately arise when a Medicare Advantage insurer found its payments from CMS lower than traditional Medicare payments for comparable patients, due to reductions for *any* "overpayments" as defined by the 2014 Overpayment Rule. The use of unaudited CMS data, with its known and unknown errors, to set the rates by which Medicare Advantage insurers are paid and then the use of audited data to define "overpayments" will lead to this result. *See* Academy of Actuaries Comment at AR5235 ("An underlying principle of risk-adjustment systems is that there needs to be consistency in the way the model was developed and how it is used. The [model's] risk-adjustment factors were developed with FFS data that, to the best of our knowledge, were not validated or audited for accuracy.").

RADV audits, of course, are conducted for the same purpose as the 2014 Overpayment Rule: to identify those claims for medical care that are not supported by medical diagnoses. In the context of an RADV audit, a contract-wide "error rate" is extrapolated from a sample and extended to an entire contract; a Medicare Advantage insurer may be required to return monies to CMS based on the extrapolated error rate. In that context, CMS heeded the advice of actuaries and adopted the FFS Adjuster to achieve actuarial equivalence between Medicare Advantage and traditional Medicare. Under an RADV audit, therefore, an "overpayment" is shown when, and only when, the error rate for a Medicare Advantage contract is greater than the CMS error rate. *See* RADV Final Methodology at AR5314 ("[T]o determine

the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster . . . as an offset to the preliminary recovery amount.”).

The base rate for the “average Medicare beneficiary” and specific rates for diagnosis codes are determined using unverified CMS data. From this uncontested fact, UnitedHealth argues that relying on audited data to identify alleged overpayments to Medicare Advantage insurers is actuarially unsound and violates the statute. It contends that the statutory mandate of actuarial equivalence requires CMS to use the “same methodology” for each. *See* 42 U.S.C. § 1395w-23(b)(4)(D). According to the argument, CMS cannot subject the diagnosis codes underlying Medicare Advantage payments to a different level of scrutiny than it applies to its own payments under traditional Medicare without impermissibly skewing the calculus: by doing so, it ensures that there will *not* be actuarial equivalence between traditional Medicare payments and Medicare Advantage payments for comparable patients.

CMS fails to respond adequately. The agency has been explicit that the 2014 Overpayment Rule requires “proactive compliance activities” and other measures to ensure that overpayments, defined as any unsupported diagnosis, are identified and repaid promptly. 79 Fed. Reg. at 29,923 (AR1315). Given its definitions and this proactive obligation, the “expected” value of payments from CMS for healthcare costs under Medicare Advantage plans will be lower than the “expected” payments CMS itself will make under traditional Medicare, since CMS does not audit or engage in similar self-examination for accuracy of its own records. The consequence is inevitable: while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed. *See* Academy of Actuaries Comment at AR5235.

The Court finds that the 2014 Overpayment Rule establishes a system where "actuarial equivalence" cannot be achieved.

B. Statutory Requirement of "Same Methodology"

UnitedHealth argues that the 2014 Overpayment Rule violates other statutory requirements as well. In computing expenditures for traditional Medicare (information that determines patient risk scores and Medicare Advantage payment rates), CMS must "us[e] the same methodology as is expected to be applied in making payments" to Medicare Advantage plans. 42 U.S.C. § 1395w-23(b)(4)(D). UnitedHealth insists that CMS fails to comply with this mandate because the "methodology" applied in "making payments" to the insurers involves reconciliation based strictly on audited diagnosis codes for Medicare Advantage patients, in sharp contrast to unverified diagnosis codes for traditional Medicare patients from which payment rates were set. The argument also raises the question of the meaning of "applicable reconciliation" contemplated by the statute. *Id.* § 1320a-7k(d)(4)(B). The logic of the earlier discussion of "actuarial equivalence" commands the results here.[9]

For present purposes, the fly in the ointment is that CMS recognized the actuarial need to apply an FFS Adjuster to the RADV audit program because of its failure, as proposed, to maintain actuarial equivalence in payments between traditional Medicare and Medicare Advantage but CMS refused to maintain such actuarial equivalence in the 2014 Overpayment Rule. Yet without some adjustment, the entire Rule would fail. Whether analyzed as a direct

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[9] The parties argue about the validity of CMS risk factors and risk scores, which, as stated, form the basis for (unaudited) CMS payments to traditional Medicare beneficiaries and payments to Medicare Advantage plans (subject to RADV audits and to the 2014 Overpayment Rule). Going back to these basics and redefining all the risk factors and all the diagnostic codes to account, within that structure, for actuarial equivalence may be the preferred approach but the very heart quakes at the thought, if one or more actuarially-sound "adjusters" might resolve the obvious dissonance in the 2014 Overpayment Rule.

question of the statutory requirement of actuarial equivalence or an indirect question of the requirements of explicit statutory language concerning "same methodology," the result is the same: the 2014 Overpayment Rule fails to recognize a crucial data mismatch and, without correction, it fails to satisfy 42 U.S.C. § 1395w-23(b)(4)(D).

C. Arbitrary and Capricious

It is established law that an agency must provide a legitimate reason for departing from or rejecting a previous rule. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). This principle also applies to changes to an agency's policy. *See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 1001 (2005) ("[T]he Commission is free within the limits of reasoned interpretation to change course *if it adequately justifies the change*.") (emphasis added). UnitedHealth complains that the 2014 Overpayment Rule departs from prior CMS policies and pronouncements without rationale or justification and is therefore arbitrary and capricious. It identifies four categories of prior statements by CMS that arguably established an agency position that is contrary to the 2014 Overpayment Rule.

The first, most recent, and most apt is the stated rationale on which CMS ultimately included the FFS Adjuster in the RADV audit process, as explained in the official notice of the methodology CMS would use to extrapolate payment errors to a contract-wide error rate. *See* RADV Final Methodology at AR5311-15. After notice and comment on the proposed audit process, including from the American Academy of Actuaries, CMS explained:

> CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. . . . *The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the [MA] risk-adjustment model (FFS claims).* The actual

> amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

RADV Final Methodology at AR5314-15 (emphasis added). 42 U.S.C. § 1395w-23(b)(4)(D). (At oral argument, counsel for CMS stated that the anticipated audit, whose goal is to "publish[] a finalized FFS adjuster," is not concluded. *See* Hearing Tr. at 31-32.) UnitedHealth urges the Court to find that this CMS explanation of the need for an FFS Adjuster for audits, due to the different data sources from which pay rates and error rates are determined, is a singular and strong demonstration of the inadequacies of the 2014 Overpayment Rule, which is based on the same dissimilar data sources but lacks such an adjustment.

Second, UnitedHealth points to two notices from CMS that recognized the differences in data for traditional Medicare and Medicare Advantage healthcare coverage. It notes the CMS rationale for applying a "Coding Intensity Adjustment" to Medicare Advantage insurers. Medicare Advantage plans contain more diagnosis codes than does traditional Medicare, which could lead to overpayments relative to traditional Medicare costs for the same patient. CMS implemented a Coding Intensity Adjustment to adjust for the higher prevalence of diagnosis codes in Medicare Advantage plans. When it did so, CMS emphasized that it was concerned about the imbalance in the number of diagnosis codes between traditional Medicare and Medicare Advantage and not "improper coding." Advance Notice of Methodological Changes for CY 2009 Parts C and D Rates and Policies (Feb. 22, 2008) (2009 Advance Notice) at AR4231 ("We do not assume that the coding pattern differences that we found in our study are the result of improper coding. . . . However, because MA coding patterns differ from FFS coding patterns, the normalization factor (which is calculated based on FFS coding) does not currently adjust for these different coding patterns."). In addition, UnitedHealth points to a CMS 2010 rate announcement for Medicare Advantage plans which recognized that because "MA

payment methodology is based on fee-for-service payments" by traditional Medicare, such "plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid." Announcement of CY 2010 Parts C and D Rates and Policies (Apr. 6, 2009) at AR4335.

Third, UnitedHealth argues that an Advance Notice for 2004 defined "diagnosis" as "keyed to the presence of a diagnosis code in the claims data," which definition is contradicted by the 2014 Overpayment Rule that declares that a "diagnosis" must be supported by underlying medical charts. *See* 2004 Advance Notice at AR3903.

CMS dismisses these earlier statements as only "varied comments about the purpose of the coding difference adjuster, made in an effort to explain why insurers' search for every supportable diagnosis would lead to overpayment." CMS Mot. at 35. It insists that the agency "has always understood a certification of the 'accuracy' and 'truthfulness' of risk adjustment data to require that any reported diagnosis be substantiated" by underlying records. *Id.* at 35 (citing 42 C.F.R. § 422.31(d), (e)); *see also* 79 Fed. Reg. at 29,921-22 (AR1313-14).

The CMS argument does not misstate its regulations but misses the point. UnitedHealth does not contend that Medicare Advantage insurers should be permitted knowingly or recklessly to bill CMS for erroneous diagnosis codes. Instead, it argues that the Medicare statute requires CMS to pay for the healthcare of Medicare Advantage beneficiaries in the same manner, and by the same standards, by which CMS pays for traditional Medicare beneficiaries. That means, for the millions of Americans covered by Medicare and Medicare Advantage, that there are error rates; UnitedHealth argues that it should not be subject to lesser payments, False Claims Act liability, or debarment for errors over these huge populations that are fewer than those errors made by CMS itself.

CMS fails to address the central issue here. The question is whether the documents cited by UnitedHealth constitute an agency policy or position from which the 2014 Overpayment Rule deviated without a reasoned explanation. More specifically, UnitedHealth argues that the analysis in the RADV Final Methodology constituted an agency decision or policy that recognized the necessity of an FFS Adjuster-type procedure to account for discrepancies between the documentation for setting payments to Medicare Advantage insurers and that used for determining whether an "overpayment" had occurred. As to this argument, CMS is essentially silent.

Agency policies and practices may take many forms and still be sufficiently established so that any change in the policy must be explained. *Republic Airline Inc. v. U.S. Dept. of Transp.*, 669 F.3d 296 (D.C. Cir. 2012), provides a good example. That case involved the transfer of "slot exemptions," by which airlines operate out of high-traffic airports. Specifically, after a corporate acquisition, the new parent corporation planned to use an existing slot exemption exactly as it had been used before the acquisition took place. Because the corporate entity operating the flight had "ceased to exist as a carrier," the Department of Transportation (DOT) decided that the new entity's use of the predecessor's slot exemption would constitute a transfer in violation of federal law. *Id.* at 301 (quoting DOT letter). In isolation, its reasoning was not illogical but the D.C. Circuit overruled it nonetheless. Since DOT had previously permitted slot exemptions to continue in use after similar corporate changes, its decision that *Republic Air* resulted in an impermissible "transfer" was found to be arbitrary and capricious. *Id.* at 300-02.

This Court comes to the same conclusion. Having recognized that actuarial equivalence, mandated by statute, required an FFS Adjuster for purposes of defining

overpayments because of dissimilar data for RADV audits, CMS provides no legitimate reason for abandoning that statutory mandate in the context of the 2014 Overpayment Rule. The Court finds that CMS was arbitrary and capricious in adopting the 2014 Overpayment Rule without explaining its departure from prior policy.[10]

D. False Claims Act Liability

1. Negligence Standard

UnitedHealth further complains that the 2014 Overpayment Rule unlawfully imposes a negligence standard on Medicare Advantage insurers to identify and report "overpayments," which is inconsistent with the standards of the False Claims Act to which it would otherwise align enforcement. CMS objects, contending that the standard adopted in the 2014 Overpayment Rule, including its requirement of "reasonable diligence," is indistinguishable from the CMS 2000 Rule that required Medicare Advantage insurers to certify to the accuracy of risk adjustment data. *See* Medicare + Choice Program, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (2000 Rule) (AR2006)). CMS insists that the 2014 Overpayment Rule only "prevents . . . willful ignorance (or reckless disregard), but no more." CMS Mot. at 44.

Back to basics. The ACA requires that "[a]n overpayment must be reported and returned" within "60 days after the date on which the overpayment was identified." 42 U.S.C.

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[10] UnitedHealth further urges the Court to find that "it is inherently arbitrary and irrational to calibrate a payment model using one type of data and then operate the model using a different type of data." United Mot. at 32. As discussed above, the Court recognizes and gives substantial weight to the American Academy of Actuaries' analysis of why it is actuarially unsound to "apply the risk-adjustment model in a way that is inconsistent with the way it was developed." Academy of Actuaries Comment at AR5235. Further, "'unexplained departure from prior agency determinations' is inherently arbitrary and capricious." *Nat'l Treasury Emps. Union v. Fed. Labor Relations Auth.*, 404 F.3d 454 (D.C. Cir. 2005) (quoting *Am. Fed. of Gov't Emps., Local 2761 v. FLRA*, 866 F.2d 1443, 1446 (D.C. Cir. 1989)). The Court contents itself with finding that the failure of the 2014 Overpayment Rule to ensure actuarial equivalence violates the statute and its unexplained departure from prior agency policy is arbitrary and capricious.

§ 1320a-7k(d)(2). The 2014 Overpayment Rule provides: "The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment." 42 C.F.R. § 422.326(c). In the preamble to the 2014 Overpayment Rule, CMS explained that such reasonable diligence "at a minimum . . . would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." 79 Fed. Reg. at 29,923 (AR1315). Failure to do so could place a Medicare Advantage insurer at risk of liability under the False Claims Act.

In contrast, the False Claims Act—which the ACA refers to for enforcement, *see* 42 U.S.C. § 1320a-7k(d)(3)—imposes liability for erroneous ("false") claims for payment submitted to the government that are submitted "knowingly." "Knowingly" is a term of art defined in the FCA to include false information about which a person "has actual knowledge," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).[11] In summary, the FCA and the ACA require actual knowledge, deliberate ignorance, or reckless disregard before liability can be found. This, indeed, is the standard CMS itself once adopted: the preamble to the 2000 Rule required certification to the "best knowledge, information, and belief" of an insurer, with a sanction only in cases of "[a]ctual knowledge of falsity," "reckless disregard," or "deliberate ignorance." *See* 2000 Rule, 65 Fed. Reg. at 40,268 (AR2006). The

[11] The ACA does not use the term "knowingly" but defines it by cross-reference to the FCA. *See* 42 U.S.C. § 1320a-7k(d)(4)(A) ("The terms 'knowing' and 'knowingly' have the meaning given those terms in section 3729(b) of Title 31.").

standard in the 2000 Rule (or the FCA or the ACA) is certainly *not* the standard in the 2014 Overpayment Rule, however much CMS might want to make it so.

"Congress clearly had no intention to turn the FCA, a law designed to punish and deter fraud, into a vehicle for either 'punish[ing] honest mistakes or incorrect claims submitted through mere negligence' or imposing 'a burdensome obligation' . . . rather than a 'limited duty to inquire.'" *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274-75 (D.C. Cir. 2010) (quoting S. Rep. No. 99-345, at 6, 19 (1986)). With these proscriptions in mind, the 2014 Overpayment Rule extends far beyond the False Claims Act and, by extension, the Affordable Care Act. Not being Congress, CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation.

2. Definition of "Identified"

UnitedHealth also notes that the proposal for the 2014 Overpayment Rule stated that a Medicare Advantage insurer would have "identified" an overpayment when "it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment." 2014 Proposed Rule at 1997 (AR81). However, the final 2014 Overpayment Rule stated that a Medicare Advantage insurer would have "identified" an overpayment when "it has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment." 42 C.F.R. § 422.326(c). The proposed language was consistent with the 2000 Rule, the FCA and the ACA's reference to the FCA. The CMS proposal intimated nothing about what Medicare Advantage insurers should have known, nor about "proactive compliance activities." While CMS argues that there is no new requirement, its change of standards is obvious. *Cf.* 2000 Rule,

65 Fed. Reg. at 40,268 (AR2006) (providing for sanctions only if insurers certify information despite their "actual knowledge," "reckless disregard," or "deliberate ignorance" of its falsity).

A regulation "violates the APA, if it is not a 'logical outgrowth' of the agency's proposed regulations." *Ass'n of Private Sector Colleges and Univs. v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012). In such cases, the regulated parties must be afforded "an opportunity to comment on new regulations." *Id.* "A final rule is a logical outgrowth if affected parties should have anticipated that the relevant modification was possible." *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014). In point of fact, regulated insurers apparently did not anticipate that CMS might ultimately define "identified" to include overpayments about which an insurer should have known because of "proactive compliance activities." In the position of insurance companies that do not regularly see patient medical records, but only doctor bills, Medicare Advantage insurers argued that "identified" overpayments should be identified as ones that are "known" to the insurer. UnitedHealth draws attention to its own comment on the Proposed Rule argued that "an identified overpayment should be limited to actual knowledge of an overpayment." UnitedHealth Group Comment (Mar. 7, 2014) at AR1040. Agencies may not "pull a surprise switcheroo on regulated entities" by adopting an interpretation that significantly departs from the one proposed. *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). The Court agrees that CMS did so here, and that 2014 Overpayment Rule imposed a distinctly different and more burdensome definition of "identified" without adequate notice.

IV. CONCLUSION

For the foregoing reasons, the Court will grant UnitedHealth's Motion for Summary Judgment, Dkt. 47; deny CMS's Cross-Motion for Summary Judgment, Dkt. 57; and vacate the 2014 Overpayment Rule. A memorializing Order accompanies this Opinion.

Date: September 7, 2018

ROSEMARY M. COLLYER
United States District Court