UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITEDHEALTHCARE INSURANCE COMPANY,
185 Asylum Street
Hartford, CT 06103-0450;

AMERICHOICE OF NEW JERSEY, INC.,
333 Thornall Street
9th Floor
Edison, NJ 08837;

ARIZONA PHYSICIANS IPA, INC.,
1 East Washington Street
Suite 900
Phoenix, AZ 85004;

CARE IMPROVEMENT PLUS SOUTH CENTRAL INSURANCE COMPANY,
351 West Camden Street
Suite 100
Baltimore, MD 21201;

CARE IMPROVEMENT PLUS OF TEXAS INSURANCE COMPANY,
4350 Lockhill-Selma Road
Suite 300
San Antonio, TX 78249;

CARE IMPROVEMENT PLUS WISCONSIN INSURANCE COMPANY,
9700 Health Care Lane
MN017-E900
Minnetonka, MN 55343;

HEALTH PLAN OF NEVADA, INC.,
2720 N. Tenaya Way
Las Vegas, NV 89128;

MEDICA HEALTHCARE PLANS, INC.,
9100 South Dadeland Boulevard
Suite 1250
Miami, FL 33156;

No. _______________

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

OXFORD HEALTH PLANS (CT), INC.,
4 Research Drive
Shelton, CT 06484;

OXFORD HEALTH PLANS (NJ), INC.,
4 Research Drive
Shelton, CT 06484;

OXFORD HEALTH PLANS (NY), INC.,
4 Research Drive
Shelton, CT 06484;

PACIFICARE LIFE AND HEALTH INSURANCE COMPANY,
5995 Plaza Drive
Cypress, CA 90630;

PACIFICARE OF ARIZONA, INC.,
1 East Washington Street
Suite 1700
Phoenix, AZ 85004;

PACIFICARE OF COLORADO, INC.,
6465 South Greenwood Plaza Boulevard
Centennial, CO 80111;

PACIFICARE OF NEVADA, INC.,
2720 N. Tenaya Way
Las Vegas, NV 89128;

PHYSICIANS HEALTH CHOICE OF TEXAS LLC,
5800 Granite Parkway
Suite 900
Plano, TX 75024-6619;

PREFERRED CARE PARTNERS, INC.,
9100 South Dadeland Boulevard
Suite 1250
Miami, FL 33156;

SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.,
2720 N. Tenaya Way
Las Vegas, NV 89128;

UNITEDHEALTHCARE BENEFITS OF TEXAS, INC. (formerly PacifiCare of Texas, Inc.),
5800 Granite Parkway
Suite 700
Plano, TX 75024-6619;

UNITEDHEALTHCARE COMMUNITY PLAN OF OHIO, INC. (formerly Unison Health Plan of Ohio, Inc.),
9200 Worthington Road
Westerville, OH 43082;

UNITEDHEALTHCARE COMMUNITY PLAN OF TEXAS, LLC (formerly Evercare of Texas, LLC),
14141 SW Freeway
Sugar Land, TX 77478;

UNITEDHEALTHCARE INSURANCE COMPANY OF NEW YORK,
2950 Expressway Drive
Suite 240
Islandia, NY 11749-1412;

UNITEDHEALTHCARE OF ALABAMA, INC.,
33 Inverness Center Parkway
Birmingham, AL 35242;

UNITEDHEALTHCARE OF ARIZONA, INC.,
1 East Washington Street
Suite 1700
Phoenix, AZ 85004;

UNITEDHEALTHCARE OF ARKANSAS, INC.,
Mail Route # AR001-1001
1401 Capitol Avenue
Third Floor, Suite 375
Little Rock, AR 72205;

UHC OF CALIFORNIA (formerly PacifiCare of California, Inc.),
5995 Plaza Drive
Cypress, CA 90630;

UNITEDHEALTHCARE OF FLORIDA, INC.,
495 North Keller Road
Suite 200
Maitland, FL 32751;

UNITEDHEALTHCARE OF GEORGIA, INC.,
3720 Davinci Court
Suite 300
Norcross, GA 30092;

UNITEDHEALTHCARE OF NEW ENGLAND, INC.,
Mail Route #RI010-3400
475 Kilvert Street, Suite 310
Warwick, RI 02886-1392;

UNITEDHEALTHCARE OF NEW YORK, INC.,
77 Water Street
14th/15th Floor
New York, NY 10005;

UNITEDHEALTHCARE OF NORTH CAROLINA, INC.,
3803 North Elm Street
Greensboro, NC 27455;

UNITEDHEALTHCARE OF OHIO, INC.,
9200 Worthington Road
Westerville, OH 43082-8823;

UNITEDHEALTHCARE OF OKLAHOMA, INC. (formerly PacifiCare of Oklahoma, Inc.),
7666 East 61st Street
Suite 500
Tulsa, OK 74133-1112;

UNITEDHEALTHCARE OF OREGON, INC. (formerly PacifiCare of Oregon, Inc.),
Five Centerpointe Dr.
Suite 600
Lake Oswego, OR 97035;

UNITEDHEALTHCARE OF PENNSYLVANIA, INC. (formerly Unison Health Plan of Pennsylvania, Inc.),
1001 Brinton Road
Pittsburgh, PA 15221;

UNITEDHEALTHCARE OF THE MIDLANDS, INC.,
Mail Route # NE010-3700
2717 North 118th Street
Omaha, NE 68164-9672;

UNITEDHEALTHCARE OF THE MIDWEST, INC.,
13655 Riverport Drive
P.O. Box 2560
Maryland Heights, MO 63043-4812;

UNITEDHEALTHCARE OF UTAH, INC.,
2525 Lake Park Blvd
Salt Lake City, UT 84120;

UNITEDHEALTHCARE OF WASHINGTON, INC. (formerly PacifiCare of Washington, Inc.),
7525 SE 24th Street
Suite 200
Mercer Island, WA 98040;

UNITEDHEALTHCARE OF WISCONSIN, INC.,
Mail Route # WI030-1000
10701 West Research Drive
P.O. Box 26649
Wauwatosa, WI 53226-0649;

and

UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.,
1300 River Drive
Suite 200
Moline, IL 61265,

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as Secretary of the Department of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20201;

CENTERS FOR MEDICARE AND MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244;

and

UNITED STATES OF AMERICA,

Defendants.

1. Plaintiffs in this case are Medicare Advantage organizations in the UnitedHealth Group family, the nation's leading provider of Medicare Advantage health benefits products. They bring this action seeking judicial review of a regulation promulgated by the Centers for Medicare & Medicaid Services ("CMS"), an agency of the Department of Health and Human Services ("HHS"), that governs the reporting and returning of "overpayments" from CMS to insurance plans in the Medicare Advantage Program ("Final Rule").

2. Medicare Advantage is part of the federal Medicare program under which private health insurance plans like plaintiffs agree to assume the risk of providing health benefits to Medicare beneficiaries, whose costs of care would otherwise be borne by CMS, in exchange for fixed monthly payments from CMS that vary in amount based, in part, on the relative health status of the plan's beneficiaries as compared to the health status of an average CMS beneficiary.

3. In order to ensure that plans are fairly and appropriately compensated for the risk the Medicare Advantage program enables CMS to shift onto private plans, Congress has directed

CMS to assess the relative health status of a plan's members compared to those of an average beneficiary on "traditional" Medicare in a manner that "ensure[s] actuarial equivalence." Congress mandated that the payments received by plans be calculated by CMS on the basis of a true apples-to-apples comparison of the health status of beneficiaries of traditional Medicare and those of a plan.

4. The Final Rule violated that statutory mandate of actuarial equivalence, and arbitrarily departed from prior CMS pronouncements on the subject. That rule requires plans to report and return "overpayments" the plans have received from CMS based on an assessment of the health status of the plan's members that is wholly inconsistent with (and far more searching than) the manner in which CMS assesses the health status of the average traditional Medicare beneficiary. CMS expressly refused to allow plans to determine the relative health status of its members using the same method that CMS uses when CMS calculates the plan's payment in the first instance or when CMS performs its own audits of Medicare Advantage plans—despite the fact that CMS adopted the latter methodology at the urging of the American Academy of Actuaries precisely to ensure that it abides by Congress's mandate to compensate plans on an "actuarial[ly] equivalen[t]" basis. Because CMS was correct in its earlier determination of what "actuarial equivalence" requires in the context of its own audits, and the Final Rule is an arbitrary and capricious departure from that prior determination, the rule must be vacated.

5. The Final Rule also should be vacated because it constitutes an unlawful and unreasonable interpretation of the statute in an additional way. Congress mandated that plans return to CMS any overpayments that a plan has "identified"—an actual knowledge standard. In the Final Rule, by contrast, CMS required plans to instead return any overpayment that the plan not only has identified, but also any overpayment that the plan "*should* have identified through

the exercise of reasonable diligence"—a negligence standard. CMS's interpretation violates the plain meaning of the statute, or at a minimum is an unreasonable interpretation of any statutory ambiguity, and is therefore contrary to law.

PRELIMINARY STATEMENT

6. The Medicare Advantage program gives Medicare beneficiaries the option to receive their health benefits from a private health plan, such as those run by plaintiffs, instead of from CMS. Private health insurance plans that choose to participate in the Medicare Advantage program agree to assume the risk of providing health benefits to Medicare beneficiaries, whose costs of care would otherwise be borne by CMS, in exchange for fixed monthly payments from CMS. The payment amounts are established based, in part, on the relative health status of the plan's beneficiaries as compared to the health status of an average CMS beneficiary. In order to ensure that plans are fairly and appropriately compensated for the risks that the Medicare Advantage program enables CMS to shift onto private plans, and at the same time ensure that plans do not have an incentive to "cherry pick" healthier-than-average members, Congress mandated that CMS assess the relative health status of a plan's members as compared to those of an average beneficiary on "traditional" Medicare in a manner that "*ensure[s] actuarial equivalence*."

7. The process by which CMS adjusts a plan's payments to account for the relative health status of its beneficiaries is known as "risk adjustment." CMS calculates the average health status of its own beneficiaries on the basis of diagnostic codes that providers (*e.g.*, physicians) submit to Medicare on claims forms. Diagnostic codes are numerical codes used by the healthcare industry on claims and other forms to designate a particular medical diagnosis (the diagnostic code for diabetes with renal manifestations, for example, is 250.40). As part of this

process, CMS does not obtain the underlying medical charts of its beneficiaries, nor does it otherwise seek to determine whether any of the diagnosis codes on which it relies in assessing the health status of its beneficiaries are in fact supported by those charts. Instead, it treats the diagnosis codes submitted to it on claims forms as valid representations of its beneficiaries' medical conditions.

8. CMS likewise relies on diagnostic codes submitted to it by Medicare Advantage plans to calculate the comparative health status of a plan's beneficiaries. As with CMS, and pursuant to CMS guidance, Medicare Advantage plans generally gather those diagnostic codes from data submitted to the plan by providers on claims or encounter forms in a process that, again like CMS, does not involve review of a patient's underlying medical chart. This process achieves actuarial equivalence—CMS assesses the health status of its members as well as those of a Medicare Advantage plan utilizing the same types of information: diagnostic codes obtained from claims data that are not compared to the beneficiaries' medical charts.

9. In the Final Rule, however, CMS violated the statutory mandate of actuarial equivalence, and arbitrarily departed from prior CMS pronouncements. That rule, which has been in effect since July 2014, imposes obligations on plans that result in a retroactive adjustment of the payments owed to a plan after the contract year has ended and CMS has calculated the plan's payment for that year. Specifically, the rule requires plans to withdraw previously submitted diagnostic codes when a plan has determined, or should have determined through the exercise of reasonable diligence, that a diagnostic code is not adequately documented in the *underlying medical chart*, concluding that each such "erroneous" diagnostic code is an "overpayment." CMS imposed this retrospective corroboration requirement on plans notwithstanding the fact that CMS had calculated the plan's payment for the contract year in the

first place on the basis of a calculation of the average health status of a CMS beneficiary that was derived entirely from diagnosis codes obtained from *claims data* that CMS conclusively treated as "valid" and which it made no effort at all to confirm were adequately documented in its beneficiaries' medical charts.

10. This violation of the statutory actuarial equivalence mandate harms Medicare Advantage plans and Medicare beneficiaries alike. Although physicians and their staff are on the whole excellent at diagnosing and treating disease, they are less proficient (and less well trained) in coding and documentation. It is well known in the industry that providers submit diagnostic codes that are not adequately documented in the corresponding medical charts—both when seeing traditional Medicare patients and when seeing those covered by private Medicare Advantage plans.[1] By requiring plans to withdraw diagnostic codes that the plan did or should have determined through the exercise of reasonable diligence were not supported by underlying medical charts—a requirement that CMS did not impose on itself when it set the corresponding payment amounts for that contract year—the Final Rule creates the false impression that an MA plan's patients in general *had fewer medical conditions*, and were thus less costly to insure, than CMS's identically situated traditional beneficiaries, and thus causes systemic unlawful and unfair underpayment of Medicare Advantage plans in contravention of the statutory requirement of actuarial equivalence. The rule is all the more troubling because the plans that undertake the most thorough and scrupulous review of the codes submitted to them by providers will be the most severely underpaid.

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[1] That does not mean that any wrongdoing has taken place; nor does it establish that the patient does not actually have the coded condition. It simply means that, in the judgment of subsequent coders conducting retrospective reviews of medical charts, the applicable coding guidelines (which are not always black and white) are not always satisfied.

11. The unlawful and arbitrary nature of the Final Rule can be demonstrated by an example. Consider a pair of identical twins who are Medicare beneficiaries, each with the identical medical history and health conditions, and thus each with the exact same expected level of annual medical expenditures. One of those beneficiaries is a traditional Medicare beneficiary and the other has chosen to enroll in a private Medicare Advantage plan. Assume further that both beneficiaries have been assigned a diagnostic code of complex diabetes by their respective providers, but that neither provider adequately documented the existence of that diagnosis in their patient's respective medical chart. When CMS determines the health status of its member (as well as the corresponding actual expenditures it incurred for that member), it treats the diagnosis code of complex diabetes as conclusively correct and does not check whether the code was supported by adequate medical record documentation. Under the Final Rule, however, if the Medicare Advantage plan determines that the complex diabetes code for its beneficiary was not supported by adequate medical record documentation, it is required to withdraw that diagnosis code from its data submission and return any funds it received as a result of submitting it.

12. The result of the rule will thus be that the plan's *identical* beneficiary will—artificially and contrary to fact—be determined to have a less severe health status (a lower "risk score") than his identical twin CMS beneficiary, and the plan's payment will be retroactively reduced, simply because CMS imposed on plans a validation criterion it did not impose on its own corresponding data. The magnitude of this inequity and payment disparity will be amplified if the disparate validation criteria are applied across the plan's entire beneficiary population. Such a result is fundamentally inconsistent with the statutorily mandated requirement of actuarial equivalence.

13. The Final Rule is also an arbitrary and unreasoned departure from CMS's previously adopted methodology—still in effect—for auditing the same Medicare Advantage plans. CMS annually conducts retrospective annual audits, known as Risk Adjustment Data Validation (or "RADV") audits, on a subset of Medicare Advantage plans. CMS initially proposed conducting these RADV audits by comparing a sample of the diagnostic codes submitted by a plan to its members' underlying medical charts, and extrapolating any observed "payment error rate" over the plan's entire population to calculate a contract-level "payment recovery" by CMS. The American Academy of Actuaries, however, pointed out that the proposed methodology would not be consistent with the requirement of actuarial equivalence because it would subject a plan's diagnostic codes to a documentation standard (medical records) that was different from the documentation standard used by Medicare in developing its risk adjustment model (claims data). And CMS agreed.

14. Accordingly, to ensure actuarial equivalence, CMS's final RADV methodology—which CMS continues to apply when it conducts its own audits of Medicare Advantage plans—requires CMS first to audit a sample of its own claims data by comparison to its members' underlying medical charts, utilizing the same criteria to which it subjects plans' data. CMS's final RADV methodology then determines whether the plan has been overpaid, and thus whether there will be any contract-level payment recovery, by determining whether the plan's "payment error rate" (determined in part by the percentage of codes not adequately supported by underlying medical charts) exceeds CMS's own corresponding error rate (determined in the same way), and if so, by how much.

15. By contrast, in adopting the Final Rule, without any reasoned explanation for the departure, CMS concluded that *any* codes that a plan determines to be unsupported by a medical

chart constitute an overpayment that must be returned, regardless of how low the plan's overall "error" rate or whether it in fact exceeds CMS's corresponding rate. Again, an example may help illustrate the arbitrary and unlawful inconsistency between the Final Rule and CMS's RADV methodology. Suppose, hypothetically, that there exists an industry-wide coding error rate that impacts CMS's data and a plan's data equally, and that both CMS's and a plan's resulting payment error rate is 10%. Under the RADV methodology, if CMS were to select the plan for an audit today, it would conclude that no contract-level payment recovery was due because the plan's error rate did not exceed that of CMS. In that situation, the plan's diagnostic codes appropriately measure the health of its members and it has *not been overpaid*. Indeed, even if the plan had an error rate of 11%, the resulting payment recovery amount if CMS were to audit the plan would be 1% (the difference between the plan's error rate of 11% and CMS's rate of 10%).

16. By contrast, under the Final Rule, assuming again the same 10% industry-wide error rate, if a plan were to audit *itself* today and undertake to compare all of its diagnostic codes to underlying medical charts, CMS would require the plan to return fully 10% of its payment to CMS. In promulgating the Final Rule, CMS provided no reasoned explanation of how it could possibly make sense that the determination of whether, and if so by how much, a plan has been overpaid would vary so dramatically based on nothing more than whether it was CMS or the Medicare Advantage plan that conducted the audit.

17. Finally, the Final Rule is unlawful and unreasonable for yet another, independent, reason. The Final Rule interprets and implements a statutory provision enacted by Congress in 2010. *See* Pub. L. No. 111-148, § 6402, 124 Stat. 119, 755-56 (2010). That statutory provision requires any person "who has received an overpayment" to report and return it within 60 days of

the date on which the overpayment was "identified." Dictionaries define to "identify" as to "establish" or "determine" the identity of something. The plain meaning of the word "identified" limits the reach of Congress's mandate to overpayments that a plan affirmatively *knows* it has received. In the Final Rule, however, CMS expanded the definition of the term "identified" beyond all recognition by defining it to mean "determined, *or should have determined by the exercise of reasonable diligence*"—a negligence standard. CMS's construction of the term "identified" is inconsistent with the plain meaning of the term, and, in the alternative, is an unreasonable interpretation of an ambiguous provision. There is no indication whatsoever that Congress intended to impose an obligation on plans to ferret out overpayments that the plans "should" have—but did not in fact—identify.

18. For all these reasons and others described below, the Final Rule is "arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law," and it must be set aside.

PARTIES

19. Plaintiffs are each Medicare Advantage organizations in the UnitedHealth Group family that offer the full spectrum of health benefit plans for individuals, employers, and Medicare and Medicaid beneficiaries, and contract directly with more than 850,000 physicians and healthcare professionals and 6,000 hospitals and other facilities nationwide. Collectively, plaintiffs serve approximately one-in-five Medicare Advantage beneficiaries—roughly 3.5 million individuals—across all major senior health benefits product categories.

20. Defendant Sylvia M. Burwell is the Secretary of the United States Department of Health and Human Services. She is sued in her official capacity. Through the Centers for Medicare & Medicaid Services, the Secretary administers the Medicare Advantage program.

21. The Secretary maintains the headquarters of HHS in Washington, D.C.

JURISDICTION AND VENUE

22. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331. This action arises under the Medicare Act, 42 U.S.C. § 1395 *et seq.*; the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702 and 706; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

23. Venue is proper under 28 U.S.C. § 1391(e).

FACTUAL ALLEGATIONS

The Medicare Advantage Program

24. The Medicare Advantage program originated with the Balanced Budget Act of 1997, which added Part C (section 1851 through 1859) to the Medicare Act.[2] Initially referred to as Medicare + Choice, the program enables most individuals eligible for traditional Medicare (Parts A and B) to receive healthcare benefits through private insurance plans that contract with CMS instead of through the federal government. In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act further amended the Medicare Act, giving the program its current name.[3]

25. Under traditional Medicare, CMS offers eligible individuals benefits from its network of Medicare-enrolled healthcare providers—*e.g.*, doctors, hospitals, and medical groups. The government sets rates for the care, and reimburses providers for each service rendered or procedure performed. For this reason, traditional Medicare beneficiaries are often referred to as fee-for-service (or "FFS") beneficiaries.

26. Under Medicare Advantage, a private insurer contracts with CMS to serve the role of intermediary between the beneficiaries and the healthcare providers in CMS's place. The insurer is responsible for providing at least the same level of benefits that traditional Medicare

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[2] *See* Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275-327 (1997).

[3] *See* Pub. L. No. 108-173, § 201, 117 Stat. 2066, 2176 (2003).

offers, and for ensuring that providers are paid for their services. In return, the federal government pays the insurer set (or "capitated") per-member-per-month payments calculated to reflect the average amount the government would otherwise spend providing those benefits to a beneficiary of similar demographic and health status.

27. By design and effect, Medicare Advantage plans assume the risk of providing healthcare to their enrollees that CMS would otherwise bear. Healthcare needs are inherently unpredictable on an individual basis. The needs of two individuals, even with similar characteristics and health history, can vary significantly in any given year. A perfectly healthy individual can contract a debilitating disease, or require no serious care. An individual managing a chronic illness like diabetes may suffer a series of unexpected complications, or none at all.

28. Medicare Advantage plans agree to make available a predetermined set of benefits in exchange for predetermined compensation from CMS. CMS shifts the risk of insuring these individuals—exchanging unpredictable, variable public expenditures for a set monthly payment—and Medicare beneficiaries are afforded an impressive array of healthcare options to fit their personal circumstances and needs.[4]

29. The results are impressive. Over 90% of seniors enrolled in Medicare Advantage plans report being "satisfied" with their insurance coverage (in fact, nearly 70% are "highly

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[4] *See* Medicare.gov, Different Types of Medicare Advantage Plans (last visited Dec. 22, 2015), http://www.medicare.gov/sign-up-change-plans/medicare-health-plans/medicare-advantage-plans/types-of-medicare-advantage-plans.html; Bob Herman, *Medicare Advantage membership nears 18 million ahead of annual enrollment*, Modern Healthcare (Sept. 16, 2015), http://www.modernhealthcare.com/article/20150916/NEWS/150919908 (noting the continual shift of patients from traditional to Medicare Advantage plans "due to their low premiums and extra perks").

satisfied") and 58% of those who switched from traditional Medicare prefer the new plan.[5] Medicare Advantage plans cover certain additional benefits, or have lower co-pays, than traditional Medicare. Moreover, because the government furnishes Medicare Advantage plans the same monthly payment regardless of their actual expenditures, those plans have a strong financial incentive to provide this excellent care in the most efficient and cost-effective manner.

Risk Adjusted Monthly Payments

30. Per-member, per-month payments to Medicare Advantage plans begin with the government's average monthly expenditures for the average FFS beneficiary. But they cannot and do not end there. Not every Medicare beneficiary is the average beneficiary. Some are sicker, and present an increased risk of higher-than-average healthcare expenditures. Some are healthier, and are generally expected to have lower-than-average healthcare costs. As noted above, Medicare Advantage plans assume the risk of covering each patient's actual expenditures when they agree to participate in the program. But Congress long ago decided it would be inappropriate and unsustainable to ignore these varying levels of risk and expected costs that come with providing care to different types of beneficiaries.[6]

31. Indeed, Congress decided that without adjustment to ensure fair and accurate compensation for all beneficiaries, Medicare Advantage plans would have an incentive not to enroll sicker-than-average Medicare beneficiaries. In the absence of some sort of risk adjustment, the plans would receive from CMS a payment based on the average expenditures for the average beneficiary, but would be responsible for paying for the actual services of these

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[5] *See* Mellman Group & Winston Group, *Seniors Highly Satisfied With Medicare Advantage*, Better Medicare Alliance (Nov. 18, 2015), http://bettermedicarealliance.org/press-releases/seniors-highly-satisfied-medicare-advantage.

[6] *See* Medicare Program; Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588, 4657 (Jan. 28, 2005).

sicker-than-average patients. And, in the end, Medicare's sickest beneficiaries would be deprived of the choice of insurance plans that Congress intended under the Medicare Advantage program.

32. Congress therefore requires CMS to adjust its monthly payments to Medicare Advantage plans to account for various risk factors that affect expected healthcare expenditures, such as age or health status, "to ensure actuarial equivalence" between traditional Medicare and Medicare Advantage plans.[7] These "risk adjustments" are designed to account for the relative health of each Medicare Advantage plan's enrollees as compared to the average FFS beneficiary.[8] As CMS has explained, the purpose of risk adjustment is to make sure that Medicare Advantage plans are "paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees)."[9] CMS's written contract with MA plans likewise states that "CMS agrees to pay the MA Organization under this contract in accordance with the provisions of § 1853 of the [Social Security] Act." Section 1853 has been codified at 42 U.S.C. § 1395w-23 and is the statutory section that includes the "actuarial equivalence" mandate.

33. Under the program CMS has devised to meet this statutory and contractual requirement, monthly payments are adjusted based on a beneficiary's demographics (*e.g.*, age, gender, geography, etc.) and health history. CMS generally gathers demographic data from

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[7] *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i).

[8] *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i); 42 C.F.R. § 422.308(c)(1).

[9] 70 Fed. Reg. at 4657.

information it already has on file for eligible beneficiaries.[10] It relies primarily on "risk adjustment data" submitted by Medicare Advantage plans for enrollees' health history.[11]

34. With every claim or encounter a healthcare provider submits to a Medicare Advantage plan regarding a service provided to a member, the provider generally includes at least one "diagnostic code" from the more 60,000 codes cataloged in the International Classification of Disease, Tenth Revision, Clinical Modification (or "ICD-10-CM") Guidelines for Coding and Reporting that justifies the particular service for which the doctor is seeking payment.[12] Medicare Advantage plans compile these codes for each enrollee, filter out codes from certain provider types or derived from certain encounters (as instructed by CMS), and submit the remainder to CMS as the plan's "risk adjustment data."[13]

35. At the same time, CMS collects the same diagnostic codes directly from healthcare providers serving FFS beneficiaries through the traditional Medicare claims submitted by those providers. Upon information and belief, CMS filters out the same provider types and encounters, and compiles its codes to determine the health status for every FFS beneficiary.

36. CMS uses these data and the actual expenditures for FFS beneficiaries to create a "risk score" for every Medicare Advantage enrollee relative to the average FFS beneficiary.[14]

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[10] *See* Paulette C. Morgan, Congressional Research Service, *Medicare Advantage Risk Adjustment and Risk Adjustment Data Validation Audits* 3 (2012) ("CRS Medicare Advantage Risk Adjustment").

[11] *See* 42 C.F.R. § 422.310.

[12] *See generally* Centers for Disease Control & Prevention, International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) (last updated October 29, 2015), http://www.cdc.gov/nchs/icd/icd10cm.htm.

[13] *See* 42 C.F.R. § 422.310(b); Centers for Medicare & Medicaid Services, *2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide* § 7.1.5 (2008) ("*Medicare Advantage Participation Guide*").

[14] *See generally* CRS Medicare Advantage Risk Adjustment, *supra* n.10.

For example, a Medicare Advantage enrollee whose annual individual expenditures under traditional Medicare would be expected to equal the average FFS beneficiary's annual expenditures is assigned a risk score of 1.0, while a Medicare Advantage enrollee whose annual individual expenditures would be expected to be 20% higher than the average FFS beneficiary's is assigned a risk score of 1.2.[15]

37. The monthly payment to the Medicare Advantage plan for each enrollee is adjusted accordingly.

Coding "Errors" By Physicians And Other Providers

38. Despite the pivotal role that diagnosis codes play in ensuring fair and accurate compensation to Medicare Advantage plans, it is common knowledge that such data are subject to significant "errors."[16] Many diagnosis codes submitted both to CMS and to plans by providers are not adequately documented in the patient's underlying medical charts. Indeed, on information and belief, this industry wide "error" rate is higher than 20%. To understand why, one needs to understand how those codes are assigned, and their significance to other actors in the healthcare system.

39. As noted above, beneficiary diagnoses originate with the doctors and other healthcare professionals who care for those beneficiaries. But medical schools teach aspiring doctors how to treat patients, not how to memorize or apply an ever-changing catalog of 60,000 diagnostic codes. Except in certain practices, doctors do not generally assign the diagnostic codes that make up risk adjustment data. Instead, doctors record their observations of the patient and the corresponding services they provide on the patients' medical charts in words.

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[15] *See id.* at 7.

[16] *See, e.g.*, MedPAC, *Report to Congress: Medicare and the Health Care Delivery System* 96 (2012), *available at* http://www.medpac.gov/documents/reports/jun12_entirereport.pdf (finding providers do not consistently code conditions from year to year).

Diagnostics coders in back offices are then responsible for assigning codes based on the doctors' notes before submitting a claim or encounter to traditional Medicare or a Medicare Advantage plan.

40. At least one diagnostic code is typically required to receive payment for claims. But doctors are actually compensated under traditional Medicare and most Medicare Advantage plans based on the *services* they provide (such as for an office visit or a procedure), not the patient's diagnosis (let alone the provider's diagnosis *coding*). And neither CMS nor Medicare Advantage plans categorically review the diagnostic codes assigned by these professionals or attempt to validate such codes against the patients' medical charts; nor would it be feasible to do so. UnitedHealth Group alone has over 3.5 million beneficiaries, many of whom see multiple providers every year. Indeed, in determining the relative health status of FFS beneficiaries for risk adjustment purposes, CMS makes *no* effort to pull medical charts and assess whether the diagnosis codes in its data are adequately documented in those charts. Instead, CMS treats a code submitted to it through its claims process as conclusively valid, and assumes that diagnosis code to be accurate when it calculates the average health status of its beneficiaries.

41. CMS regulations require that Medicare Advantage plans certify "based on best knowledge, information, and belief" that their various submissions to CMS, including risk adjustment data, are "accurate, complete, and truthful."[17] Fairly read, these certifications certify to the accuracy of the data plans submit using the same criteria of accuracy that CMS itself uses: these certifications attest that the diagnosis codes submitted by plans are codes that providers actually submitted to the plans for the particular beneficiary and date of service, and that the

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[17] 42 C.F.R. § 422.504(*l*)(2).

codes were submitted by qualifying providers based on what appear to be face-to-face patient encounters.

42. Neither this certification, nor anything else in the plan's contract with CMS, nor any statute or regulation, has ever required Medical Advantage plans to independently validate the work of their enrollees' treating physicians or their back-office staff—just as CMS does not independently validate that work when gathering and filtering its data. On the contrary, CMS's regulations require plans to submit data to CMS that "conform to CMS' requirements for data *equivalent to Medicare fee-for-service data,*" 42 C.F.R. § 422.310(d)(1) (emphasis added)—data drawn from claims that have not been audited against medical charts.

43. Under these circumstances, it is no surprise that even through the good faith efforts of everyone involved, coding discrepancies occur. Because the same doctors generally treat patients with all sorts of insurance coverage, however, there is no apparent reason to believe that those discrepancies disproportionately affect the risk adjustment data of Medicare Advantage plans. To the contrary, the coding issues described above presumably affect both traditional Medicare and Medicare Advantage plans. In a single hour, the same doctor might treat (and diagnose) a Medicare Advantage enrollee, a traditional Medicare beneficiary, and a patient with private commercial insurance. There is no reason why the doctor would document medical charts differently, or her billing office staff would code the medical charts any differently, based on whether the patient is a traditional Medicare beneficiary or a member of a private Medicare Advantage plan. For this reason, both a plan's risk adjustment data and CMS's corresponding data are presumably equally affected by the prevalent industry wide coding error rate.

Risk Adjustment Data Validation Audits

44. CMS previously confronted the significance of the existence of prevalent industry wide coding and documentation errors in assessing whether Medicare Advantage plans have been or have not been overpaid in the context of an auditing program CMS created to identify and collect, through CMS's own efforts, overpayments attributable to inaccurate risk adjustment data.

45. Every year, CMS subjects a subset of Medicare Advantage plans to such Risk Adjustment Data Validation (or "RADV") audits.[18]

46. For each Medicare Advantage plan chosen for such an audit, CMS selects a sample of the plan's enrollees from the audited payment year and requires the plan to submit medical records supporting the risk score for each selected enrollee.[19]

47. CMS then decides if each diagnostic code that factored into the enrollees' risk scores is adequately documented in the submitted medical records, looks to see whether there were additional diagnoses documented in certain of the charts that the providers failed to code, calculates a corrected risk score based on the validated codes, and determines, if necessary, a corrected monthly payment for each sampled enrollee.[20] Starting with 2011 payments, CMS announced that the results of this sampling will then be mathematically extrapolated to all of a

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[18] *See* 42 C.F.R. § 422.311; Center for Medicare and Medicaid Services, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012), *available at* http://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/radvmethodology.zip ("RADV Methodology").

[19] RADV Methodology, *supra* n.18, at 2-3.

[20] *Id.* at 3.

Medicare Advantage plans' enrollees to calculate an estimated payment error for the plan's entire contract with CMS for the audited payment year.[21]

48. If the estimated payment error is negative—*i.e.*, the audit reveals that the Medicare Advantage plan was likely underpaid vis-a-vis the documented health status of its enrollees—no further action is taken.[22] If the estimated payment error is positive, the plan may be required to return a portion of CMS funds received for that payment year.[23]

49. When CMS first proposed a methodology for this auditing process, it suggested that CMS would recover a payment from the audited Medicare Advantage plan calculated on the basis of the plan's absolute extrapolated estimated error rate.[24]

50. In its comments on that proposal, however, the American Academy of Actuaries expressed concern that the methodology would "create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially resulting in payment inequities."[25] The risk-adjustment system, the Academy explained, was "developed with FFS data that, to the best of [its] knowledge, were not validated or audited for accuracy" by comparing the codes to the underlying medical charts.[26] By contrast, the proposed RADV audit process "effectively would

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[21] *Id.* at 3-4.

[22] *Id.* at 4.

[23] *Id.*

[24] *See* Centers for Medicare & Medicaid Services, *Medicare Advantage Risk Adjustment Data Validation (RADV), Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits—Request for Comments* (Dec. 20, 2010), *available at* https://www.cms.gov/HealthPlansGenInfo/Downloads/RADVSamplingPaymentErrorDescription.pdf.

[25] Letter from Thomas F. Wildsmith, Vice President, Health Practice Council, American Academy of Actuaries, to Cheri Rice, Acting Director, Medicare Plan Payment Group, at 2 (Jan. 21, 2011), *available at* http://www.actuary.org/pdf/health/RADV_comment_letter_012111_final.pdf.

[26] *Id.* at 1.

apply those factors only to [Medicare Advantage] data that are validated."[27] In other words, the American Academy of Actuaries explained that it would be inconsistent with the statutory requirement of actuarial equivalence to engage in an apples-to-oranges comparison of claims data (when computing CMS's traditional beneficiaries' risk scores) and medical charts (to validate the risk score of a plan's beneficiaries).

51. In the final methodology, CMS responded to that concern by adding a "FFS Adjuster" that is applied to the estimated contract-level payment error before calculating any final 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 Part C 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."[28]

52. Stated differently, CMS acknowledged in its promulgation of the RADV methodology that without a significant corrective adjustment, it would violate the requirement of actuarial equivalence—to say nothing of being highly unfair—to subject a plan's diagnostic codes to a validation standard (documentation in medical charts) that CMS did not itself use when calculating the health status and corresponding costs of its own beneficiaries. As the American Academy of Actuaries urged, and CMS accepted, application of such inconsistent validation criteria would lead to systemic underpayment and potentially significant payment inequities.

53. Accordingly, when CMS audits a plan utilizing the final RADV methodology today, CMS seeks to recover a contract-level payment from the plan only if the plan's error rate

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[27] *Id.* at 1-2.

[28] RADV Methodology, *supra* n.18, at 4.

exceeds CMS's own error rate—calculated using the same medical documentation and other standards that CMS applies to plans. And even if a plan's error rate exceeds CMS's own rate, the Medicare Advantage plan will be found to have been overpaid only by the amount that the plan's error rate exceeds that of CMS.

Public Law No. 111-148 and the Final Rule

54. Congress has imposed an obligation on all entities that receive payments from Medicare and Medicaid to report and return overpayments that such plans identify on their own. It is the agency's implementation of this obligation that is subject of this lawsuit.

55. Section 6402 of Public Law No. 111-148, 124 Stat. 119, 755-56 (2010), added Section 1128J(d) of the Social Security Act, 42 U.S.C. § 1320a-7k(d).[29] That section requires

[29] Section 6402 of Pub. L. No. 111-148, 124 Stat. 119, 755-56 (2010), provides in full:

> (d) Reporting and Returning of Overpayments.—
>
> (1) In general.—If a person has received an overpayment, the person shall—
>
> (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
>
> (B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
>
> (2) Deadline for reporting and returning overpayments.—An overpayment must be reported and returned under paragraph (1) by the later of—
>
> (A) the date which is 60 days after the date on which the overpayment was identified; or
>
> (B) the date any corresponding cost report is due, if applicable.
>
> (3) Enforcement.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.
>
> (4) Definitions.—In this subsection:

any person, including a Medicare Advantage plan, who has "received an overpayment" to report and return that overpayment to the Secretary of HHS, the State, intermediary, carrier, or contractor, "as appropriate," and to notify in writing the entity to whom the overpayment was returned of the reason for that overpayment.[30]

56. The Act defines "overpayment" as "any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled."[31] And it requires that any "overpayment . . . be reported and returned . . . by the later of . . . the date which is 60 days after the date on which the overpayment was identified; or . . . the date any corresponding cost report is due, if applicable."[32]

57. The Act does not define what the term "identified" means, which triggers the start of the 60-day clock. It does state that "[i]n this subsection" "the terms 'knowing' and 'knowingly' have the meaning given those terms in [the False Claims Act ('FCA'), 31 U.S.C.] section 3729(b)"—*i.e.*, "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth

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> (A) Knowing and knowingly.—The terms "knowing" and "knowingly" have the meaning given those terms in section 3729(b) of title 31, United States Code.
>
> (B) Overpayment.—The term "overpayment" means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.
>
> (C) Person.—
>
> (i) In general.—The term "person" means a provider of services, supplier, medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)).
>
> (ii) Exclusion.—Such term does not include a beneficiary.

[30] 42 U.S.C. § 1320a-7k(d)(1).

[31] *Id.* § 1320a-7k(d)(4)(B).

[32] *Id.* § 1320a-7k(d)(2).

or falsity of the information," 31 U.S.C. § 3729(b)—although neither "knowing" or "knowingly" appears anywhere in the pertinent subsection.[33]

58. To enforce this new obligation, the new Act provides that the continued retention of an overpayment beyond the 60-day deadline after the overpayment is "identified" "is an obligation . . . for purposes of [the FCA, 31 U.S.C.] section 3729."[34] The FCA, in turn, authorizes the United States (through the Department of Justice), or a private citizen acting on its behalf, to bring suit against "any person who . . . knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[35] The FCA is a fraud statute that permits the recovery of treble damages and imposes a civil penalty between $5,500 and $11,000 per obligation avoided or decreased.[36] In addition to these highly punitive damages, a defendant who is found liable under the False Claims Act, or who settles an alleged liability, is subject to potential exclusion from participation in federal healthcare programs such as Medicare.

Proposed Rules

59. In January 2014, CMS issued a notice of proposed rulemaking to implement these new statutory provisions.[37] With respect to Medicare Advantage plans, CMS proposed a new

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[33] *Id.* § 1320a-7k(d)(4)(A). This discrepancy likely arose from an incomplete revision of the bill as it worked its way through Congress. It appears that earlier versions of the bill required persons to report and return overpayments within 60 days after the date the person "knows" of the overpayment. *See* H.R. 3200, 111th Cong. § 1641 (2009); S. Comm. on Finance, *Chairman's Mark: America's Healthy Future Act of 2009* 191 (2009).

[34] *Id.* § 1320a-7k(d)(3).

[35] 31 U.S.C. § 3729(a)(1)(G).

[36] *Id.*

[37] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918 (Jan. 10, 2014).

regulation, 42 C.F.R. § 422.326, entitled "Reporting and Returning of Overpayments" intended purportedly to "clarify the statutory definition of overpayment."[38]

60. Among other things, CMS proposed to define "funds" as any payment that a Medicare Advantage plan has received "based on data that these organizations submitted to CMS for payment purposes for which they have responsibility for the accuracy, completeness, and truthfulness of such data under existing [regulations]," including risk adjustment data.[39]

61. CMS proposed that a Medicare Advantage plan has "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."[40] CMS explained that this definition was drawn from the definition of "knowing" and "knowingly" in the False Claims Act,[41] which as noted above the Medicare Act incorporated despite the fact that those terms do not appear in the relevant section of the Medicare Act.

62. CMS also proposed to amend its regulations to address for the first time the obligation of plans to examine medical charts to assess whether diagnostic codes previously submitted by providers were adequately documented in the corresponding charts.

63. In order to ensure the completeness of their risk adjustment data, some Medicare Advantage plans, including plaintiffs', review the underlying medical charts for some of their beneficiaries to identify any diagnoses adequately documented in those medical charts but not reflected in the plans' claims data. When such diagnoses are found, CMS regulations permit plans to supplement their risk adjustment data submission with additional diagnostic codes until

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[38] *Id.* at 2055-56, 1996.

[39] *Id.* at 1996.

[40] *Id.* at 1997.

[41] 31 U.S.C. § 3729(b).

thirteen months after the close of a payment year. By submitting additional diagnostic codes, Medicare Advantage plans make their risk adjustment data more accurately reflect their beneficiaries' health status, and help ensure that the plans are fully compensated for the risk they assume.[42]

64. Historically, no CMS regulation required plans who conduct such voluntary chart reviews to review the charts also to assess the accuracy of codes that providers had previously submitted in their claims. In the 2014 notice of proposed rulemaking, CMS proposed changing that. Specifically, CMS proposed to "strengthen existing regulations related to the accuracy of risk adjustment data by amending [42 C.F.R.] § 422.310"[43] Under the proposed amendment, so-called "medical record reviews" voluntarily conducted by a Medicare Advantage plans would have to be "designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payments adjustments."[44]

Comments on the Proposed Rules

65. In response to both rules, commenters asked CMS to provide further clarification of what CMS would consider to be an "overpayment" based on inaccurate risk adjustment data.

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[42] CMS does not perform the same review of traditional beneficiaries' medical charts. Accordingly, to maintain actuarial equivalence between traditional Medicare and Medicare Advantage plans, Congress has required CMS to ensure that its risk adjusted payments to Medicare Advantage plans "reflect[] differences in coding patterns between Medicare Advantage plans and [traditional Medicare providers]." 42 U.S.C. § 1395w-23(a)(1)(C)(ii)(I). CMS has implemented this requirement by adjusting Medicare Advantage risk scores to reflect those differences. *See* CMS, *Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 3 (Apr. 7, 2014), https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2015.pdf.

[43] 79 Fed. Reg. at 2000.

[44] *Id.*

66. One commenter, for example, suggested that the agency clarify that "an overpayment cannot exist for an MA organization's particular contract unless CMS's payments to the contract as a whole are inaccurate in light of an appropriate Fee-for-Service Adjuster that is applied to the entire contract."[45] The agency had already acknowledged in the RADV context that a Medicare Advantage plan has not been overpaid—that no payment recovery will be due—until such an adjustment is made "to account for differences between the manner in which CMS develops MA organization premium payments (based on diagnoses in Medicare FFS claims) and the manner in which CMS determines RADV payment errors (based on diagnoses documented in medical records)."[46] Applying the same principle here "means that an overpayment cannot exist for a particular contract unless CMS's payments as a whole to the MA organization pursuant to the contract are inaccurate in light of an appropriate FFS Adjuster applied to the entire contract."[47]

67. Other commenters expressed similar concerns. One insisted that "[a]ny rule or policy regarding . . . any overpayment obligations (§ 422.326) must account for this differential in documentation standards in the same way that CMS does in the RADV context."[48] And UnitedHealth Group stressed "the statutory mandate that [Medicare Advantage plans] be paid appropriately for the health status of their members relative to costs incurred in Fee-For-Service

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[45] Comments of Humana, Inc. at 43, Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Prescription Drug Benefit Programs (CMS-4159-P), Docket ID CMS-2014-0007 ("CMS-4159-P") (Mar. 7, 2014).

[46] *Id.*

[47] *Id.* at 44.

[48] Comments of InnovaCare, Inc./MMM Healthcare, Inc./PMC Medicare Choice at 4, CMS-4159-P (Mar. 7, 2014).

('FFS') for similar beneficiaries."[49] United explained that, far from retaining overpayments, Medicare Advantage plans "w[ould] be *undercompensated* for the relative risk of their membership if they delete diagnosis codes from claims that are unsupported in a medical record and CMS does not simultaneously account for the equivalent diagnoses in FFS data."[50]

68. With respect to when an overpayment would become due, commenters argued that CMS's definition of "identified" was too broad for a statute that could potentially trigger punitive damages under the False Claims Act. As United explained, "it is unreasonable to require Plans to report and return an overpayment based on the broad definition proposed."[51] Another commenter pointed out that the term "knowing," from which CMS had drawn its willful blindness and reckless disregard standard, was "*not actually used* in the overpayment standard . . . , so the mere existence of an errant reference to the False Claims Act definition of 'knowing' does not give CMS sufficient basis to apply the expansive False Claims Act knowledge standard."[52] Instead, United and others suggested that "an identified overpayment should be limited to actual knowledge of an overpayment."[53]

Final Rules

69. On May 23, 2014, CMS published its finalized rules.[54]

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[49] Comments of UnitedHealth Group at 33, CMS-4159-P (Mar. 7, 2014).

[50] *Id.* (emphasis added).

[51] *Id.* at 32.

[52] Comments of Blue Cross Blue Shield Association at 47, CMS-4159-P (Mar. 7, 2014).

[53] Comments of UnitedHealth Group, *supra* n.49, at 32; *see also, e.g.*, Comments of Blue Cross Blue Shield, *supra* n.52, at 41.

[54] *See* Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844 (May 23, 2014).

70. With respect to the proposed rule regarding "medical record reviews," CMS "thank[ed] the commenters for their input," but explained it was "not finalizing the proposed amendment to [42 C.F.R.] § 410.322(e)."[55]

71. CMS did finalize the proposed rule regarding overpayments. Despite the commenters' requests, however, it did not clarify that a Medicare Advantage plan has not received an overpayment unless CMS's payments are inaccurate in light of an appropriate adjustment to account for the corresponding error rate in FFS claim data. To the contrary, in the preamble to the Final Rule, CMS asserted that *any* inadequately documented diagnostic code would result in an overpayment to a Medicare Advantage plan: "For example, a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation *would result* in an overpayment."[56]

72. In response to the claims of inconsistency between the Final Rule and the RADV methodology, CMS simply "disagree[d]."[57] It pointed to the requirement that Medicare Advantage plans "certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS" and it asserted that the agency had a "long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation."[58]

73. The agency did not cite to any statute, regulation, or provision of the Medicare Advantage contract that provided this purported "long-standing" requirement, nor point to any

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[55] *Id.* at 29,926.

[56] *See id.* at 29,921 (emphasis added).

[57] *Id.*

[58] *See id.* at 29,921-22.

prior formal interpretation of the certification that would require Medical Advantage plans to independently validate the work of their enrollees' treating physicians, or their back-office staff, by verifying that every diagnostic code is adequately documented in a patient's medical charts.

74. In any event, the agency provided no explanation for how either purported requirement could conceivably justify one definition of overpayment if identified by CMS during a RADV audit and another if identified by a Medicare Advantage plan on its own. Instead, to avoid the contradiction of applying these inconsistent definitions at the same time, CMS simply stated that plans would be prohibited from reporting and returning self-identified overpayments for contracts that were subject to a RADV audit during the pendency of the audit.[59]

75. Nor did CMS explain how either purported requirement could excuse the agency from fulfilling its statutory mandate to calculate risk adjustment payments so as to "ensure actuarial equivalence" between traditional Medicare and Medicare Advantage plans. And it provided no account of how it could do so by requiring the return of such self-identified overpayments, so defined, without "account[ing] for the fact that the documentation standard used in [the Final Rule] to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims)."[60]

76. Indeed, in promulgating its rule, CMS neither denied that its rule would systemically underpay plans and lead to payment inequity, nor attempted to justify such skewing as consistent with the statute or its prior RADV methodology.

77. Finally, CMS adopted an expansive and clearly erroneous standard for when an overpayment, as defined in the rule, has purportedly been "identified" by a Medicare Advantage

[59] *See id.* at 29,922.

[60] RADV Methodology, *supra* n.18, at 4.

plan. CMS not only refused to narrow its overly broad proposed definition of the term, it made it *broader*. With little explanation, CMS stated it was "revising [its] definition of an identified overpayment to state that an MA organization . . . has 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."[61] The agency refused to specify what reasonable diligence would require in "all factual scenarios," but it indicated that "at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments."[62]

78. CMS thus transformed its proposed rule for creating an obligation that could lead to penalties under the FCA from a recklessness standard (that many commenters feared was itself too harsh) to a negligence standard, without any notice to commenters that it was considering such a standard or any meaningful explanation why, and without a word on how such a standard could be squared with the language of the Act.

Impact of the Final Rule

79. CMS's Final Rule impacts Medicare Advantage plans.

80. By imposing on plans the obligation to delete diagnostic codes that the plans have determined, or should have determined through reasonable diligence, are not adequately documented in the underlying medical charts, even though CMS calculated the health status of its own beneficiaries based on unverified claims data (and not medical charts), the Final Rule artificially makes a plan's beneficiaries appear to have fewer conditions than the identical CMS beneficiaries. This result flows simply from the imposition on plans of a validation criterion that CMS did not utilize itself when calculating the risk scores of its own beneficiaries and will occur

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[61] 79 Fed. Reg. at 29,923 (emphasis added).

[62] *Id.*

even if a plan's beneficiaries have the identical health characteristics as CMS's traditional beneficiaries.

81. As a result, the Final Rule leads to *underpayment* of Medicare Advantage plans. That is because when CMS calculates the relative annual cost impact of insuring a beneficiary for a particular condition, it bases this calculation on the number of its beneficiaries who have the diagnostic code for that condition in its claims data. By requiring plans to delete diagnostic codes that are not supported by medical records, however, CMS allows plans to retain this calculated payment amount only for the smaller set of beneficiaries who have the condition adequately documented in their medical charts.

82. Once again, an example will help make this clear. Assume that the population of traditional Medicare beneficiaries is comprised of five beneficiaries with a diabetes diagnostic code, but that only four of those beneficiaries have the condition documented in their medical charts. Assume further that the annual expected healthcare expenditures for a beneficiary that actually has a documented case of diabetes is $2,500.

83. When CMS runs its risk adjustment model to calculate the relative cost impact of insuring a patient with diabetes, it will observe in its population a total of $10,000 in diabetes-related expenditures for the year ($2,500 times the four beneficiaries who have diabetes).[63] It will then calculate the per-beneficiary cost of diabetes by dividing that $10,000 total in diabetes care by five (the number of its beneficiaries with a diabetes diagnostic code), rather than by four, as CMS's risk adjustment model is based on unverified claims data, not medical charts. In other words, CMS's risk adjustment model, on which Medicare Advantage plan payments are based, calculates the incremental cost impact of insuring a beneficiary with a diagnostic code on a

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[63] For purposes of this example only, we assume that a patient who does not have diabetes documented in the chart in actuality does not have the condition at all.

claims form (in this example, the code for diabetes). The model does not attempt to calculate the incremental cost impact of insuring a beneficiary with a particular code adequately documented on a medical chart.

84. Having built its risk model on unverified claims data, CMS would achieve actuarial equivalence, and would compensate plans appropriately, if it likewise based its risk scores for plans on unverified claims data. This would be an apples-to-apples comparison. If a Medicare Advantage plan likewise had five beneficiaries with a diabetes diagnostic code, but only four of those beneficiaries have the condition adequately documented in their medical charts and CMS paid the plan a risk adjustment payment equivalent to $2,000 for each of the five plan beneficiaries with a diagnostic code of diabetes, its total contract-wide payment of $10,000 would accurately compensate the plan for the total expected costs it would incur in insuring these patients (2,500 times four beneficiaries).

85. Under the Final Rule, however, if the plan determined, or "should have determined based on reasonable diligence," that one of its five beneficiaries with a diabetes diagnostic code did not have diabetes adequately documented in the beneficiary's medical chart after it has submitted its final risk adjustment data for the year, CMS would require the plan to delete that code and return the portion of the plan's annual payment attributed to it—in the example, $2,000. This would result in a total risk adjustment payment to the plan for diabetes of only $8,000 (four times $2,000), which *underpays* the plan by $2,000—or 20%—for the costs the plan agreed to incur in insuring its population. And the same result would hold for every other unsupported code that the plan either actually or "should have" identified throughout its risk adjustment data.

86. There are ways that CMS could satisfy its obligation to ensure actuarial equivalence in its risk adjustment calculations. Having built its risk adjustment model with unverified claims data and calculated the expected annual cost of insuring a beneficiary with a diagnostic code on a claims form (stated differently, the cost per diagnostic code), CMS could pay plans this per-code amount for each plan beneficiary who likewise has a diagnostic code on a claims form.

87. Alternatively, CMS could prospectively modify its risk adjustment model so as to calculate the health status and costs of care for its beneficiaries based on medical charts and not diagnostic codes. Using the same example above, that process would result in a calculation of $2,500 for each beneficiary with diabetes documented on a medical chart. Having built a risk adjustment model based on medical chart data, it would be appropriate—and consistent with actuarial equivalence—for CMS to likewise base a plan's risk adjustment scores only on diagnostic codes that are adequately documented in medical charts.

88. CMS could also have adopted yet another solution, akin to the FFS adjuster it adopted when conducting RADV audits. Even though CMS built is risk adjustment model, and calculated its risk adjustment payments for prior contract years, using unverified claims data, if CMS wishes prospectively to require plans to delete diagnostic codes that the plans have determined to be unsupported by medical charts, there are steps CMS could take prospectively to implement such a requirement while adhering to the statutory mandate of actuarial equivalence. Specifically, CMS could first audit its own claims data to determine what percentage of its own diagnostic code data for prior payment years was not adequately documented in medical charts, utilizing the same coding and documentation standards it would impose on plans. CMS would then have to publish that error rate and provide a feasible method for plans to sample their own

data (because it would be obviously unreasonable to expect plans to obtain the full medical records for each of their millions of beneficiaries); compare the rate at which their codes are not supported by medical charts to CMS's corresponding "error" rate; and to identify whether in light of that comparison they have received an overpayment that has to be returned.

89. CMS chose none of these actuarially equivalent routes. Instead, having built its risk adjustment model to calculate the size of risk adjustment payments based on unverified claims data, under the Final Rule, CMS effectively pays those diluted per-diagnostic-code payment amounts only for the smaller set of beneficiaries who have those codes adequately documented in medical charts, and without implementing any mechanism to account for the difference in documentation standards. This mismatched methodology is a stark violation of the actuarial equivalence mandate and is otherwise arbitrary and capricious.

CAUSE OF ACTION
(Violation of the Medicare Act and the APA)

90. Plaintiffs re-allege and incorporate by reference the allegations contained in all preceding paragraphs.

91. The Final Rule violates the plain language of the Medicare Act, 42 U.S.C. § 1395 *et seq.*; exceeds CMS's statutory authority, *see* 5 U.S.C. § 706(2)(C); and is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, *id.* § 706(2)(A).

92. *First,* by defining as an "overpayment" the retention of any funds based on inaccurate risk adjustment data without accounting for the fact that the FFS claims data on which those payments are based are not subject to the same validation criteria, the Final Rule violates

the Medicare Act's mandate for CMS to set Medicare Advantage plans' monthly payments so as "to ensure actuarial equivalence" between traditional Medicare and Medicare Advantage plans.[64]

93. *Second*, by defining "overpayment" differently when identified by CMS during a RADV audit than when identified by Medicare Advantage plans on their own, without any principled basis for such distinction, the Final Rule is arbitrary and capricious in violation of the APA, 5 U.S.C. § 706(2)(A).

94. *Third*, by failing to meaningfully respond to comments identifying these concerns, CMS failed to abide by the APA procedural requirements for informal rulemaking, 5 U.S.C. § 553(c), and abused its discretion, *id.* § 706(2)(A).

95. *Fourth*, by defining "identified" in a manner that is inconsistent with the plain text of the Medicare Act and, in any event, in a manner that is not a reasonable definition of the term, the Final Rule is arbitrary, capricious, not in accordance with law, and in excess of CMS's statutory authority, 5 U.S.C. § 706(2)(A), (C).

96. *Fifth*, by defining "identified" in a manner that was not a logical outgrowth of the proposed rule, CMS failed to abide by the APA procedural requirements for informal rulemaking, 5 U.S.C. § 553(c), and abused its discretion, *id.* § 706(2)(A).

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray that this Court:

A. Declare that the Final Rule violates the plain language of the Medicare Act, 42 U.S.C. § 1395 *et seq.*; exceeds CMS's statutory authority, 5 U.S.C. § 706(2)(C); and is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, *id.* § 706(2)(A).

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[64] 42 U.S.C. § 1395w-23(a)(1)(C)(i).

B. Declare that CMS may not lawfully require plans to delete diagnostic codes that are not supported by medical charts without first either (1) prospectively changing its risk adjustment model so as to base its calculations of Medicare's population based on medical charts and not unverified claims data, or (2) prospectively creating some reasonable mechanism to both account for the fact that the existing risk adjustment model was based on unverified claims data and not medical charts and providing plans with the information necessary to enable them to calculate the adjustment and know whether they have been overpaid;

C. Set aside the Final Rule as exceeding CMS's statutory authority, 5 U.S.C. § 706(2)(C); and arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, *id.* § 706(2)(A); and

D. Provide such further relief as the Court may deem just and proper.

January 29, 2016

Respectfully submitted,

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