No. 21-1140

In the Supreme Court of the United States

UNITEDHEALTHCARE INSURANCE COMPANY, ET AL.,
PETITIONERS

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

Eligible Medicare beneficiaries may elect to receive coverage through a private insurer under Medicare Part C, also known as "Medicare Advantage," rather than directly from the government through traditional Medicare. The Centers for Medicare & Medicaid Services (CMS) pays Medicare Advantage insurers in part based on diagnosis codes submitted by each insurer. In 2010, Congress required Medicare Advantage insurers to return overpayments they receive from CMS within 60 days of identifying them. 42 U.S.C. 1320a-7k(d)(1) and (2). In 2014, CMS promulgated the Overpayment Rule to implement that statutory requirement. Consistent with longstanding Medicare rules, the Overpayment Rule provides that when an insurer discovers that a previously submitted diagnosis is not supported by the beneficiary's medical record, the associated payment is an "overpayment" subject to the 60-day return requirement and other procedural measures.

The questions presented are:

1. Whether the Overpayment Rule violates the Medicare statute's instruction to the Secretary to adjust payment amounts to Medicare Advantage insurers to ensure "actuarial equivalence."

2. Whether the Rule violates the Medicare statute's requirement that the Secretary use the "same methodology" to calculate risk scores that facilitate the Medicare Advantage bidding process as the Secretary uses in paying Medicare Advantage plans.

3. Whether the Rule is arbitrary and capricious because it reflects an unexplained departure from past regulatory policy.

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OPINIONS BELOW

The amended opinion of the court of appeals (Pet. App. 1a-53a) is reported at 16 F.4th 867. The order denying rehearing and amending the opinion of the court of appeals (App. 107a-108a) is not published in the Federal Reporter but is available at 2021 WL 5045254. A prior opinion of the court of appeals is reported at 9 F.4th 868. The order of the district court (Pet. App. 54a-89a) is reported at 330 F. Supp. 3d 173. The opinion of the district court denying reconsideration (Pet. App. 90a-106a) is unreported but is available at 2020 WL 417867.

JURISDICTION

The judgment of the court of appeals was entered on August 13, 2021. A petition for rehearing was denied on

November 1, 2021 (Pet. App. 107a-108a). On January 18, 2022, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including February 14, 2022, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Medicare is a federal health insurance program for the elderly and disabled, see Medicare Act, 42 U.S.C. 1395 *et seq.*, which is administered by the Centers for Medicare & Medicaid Services (CMS). Under Medicare Parts A and B, known as "traditional" Medicare or "fee-for-service," CMS pays medical providers directly for services provided to Medicare beneficiaries. *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Under Medicare Part C, eligible beneficiaries can enroll in Medicare Advantage plans offered by private insurers, which in turn pay medical providers for care provided. See *United States* v. *United Healthcare Ins. Co.*, 848 F.3d 1161, 1167 (9th Cir. 2016). In return for this coverage, CMS pays the private insurers a pre-determined monthly amount for each beneficiary they enroll, without regard to services actually received by the beneficiary. See 42 U.S.C. 1395w-23(a)(1)(A); *United Healthcare Ins. Co.*, 848 F.3d at 1167.

As originally enacted, the per-capita payments to Medicare Advantage insurers did not depend on the health of the enrolled beneficiaries. As a result, Medicare Advantage insurers tended to enroll the healthiest (and least costly) Medicare beneficiaries, thereby increasing costs for the Medicare program as a whole. C.A. App. 487. To address that problem, Congress directed the Secretary to "adjust the payment amount

* * * for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, * * * so as to ensure actuarial equivalence." 42 U.S.C. 1395w-23(a)(1)(C)(i). These adjustments are intended to "ensure[] that [Medicare Advantage] organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees * * * and more for less healthy enrollees)." C.A. App. 95.

b. To determine the amount of these "risk adjustment[s]," CMS uses a model calibrated on data from traditional Medicare. C.A. App. 115-116. Specifically, the model uses regression analysis to determine how beneficiaries' demographic factors and medical conditions in a given year are likely to affect traditional Medicare expenditures on those beneficiaries the following year. *Id.* at 236-327. The model produces "relative factors" that reflect, for each condition or demographic factor, its expected marginal cost relative to traditional Medicare's average per-beneficiary expenditure. *Id.* at 237. For example, the relative factor for diabetes without complications in 2014 was 0.118, which means that a diabetes diagnosis was expected to increase traditional Medicare's expenditures on a beneficiary by 11.8% of its average per capita expenditure. *Id.* at 276.

For each beneficiary, summing the relative factors for that individual's conditions and demographic factors creates a "risk score" that predicts how much traditional Medicare will spend on that beneficiary the following year, relative to the average beneficiary. C.A. App. 532. For example, a beneficiary with a risk score of 1.022 is expected to cost Medicare slightly more than the average traditional Medicare beneficiary, who by

definition has a risk score of 1.0. *Id.* at 276-277. In determining how much a Medicare Advantage plan will be paid for enrolling a particular beneficiary, CMS multiplies this risk score by a base payment rate for the applicable geographic area. See 42 C.F.R. 422.258, 422.304.

To calculate risk scores for beneficiaries under Medicare Advantage, CMS requires the insurers to submit beneficiary data, including diagnosis codes based on diagnoses obtained from provider claims or through review of medical records. 42 C.F.R. 422.310(b), (d), and (e); C.A. App. 410-411. When an insurer reports a relevant diagnosis code, that submission leads directly to increased payment. For example, if an insurer reports a diabetes diagnosis code for a particular beneficiary, the beneficiary's risk score will increase by 0.118, thereby increasing the insurer's monthly payment for that beneficiary by 11.8% of the base rate.

c. Because diagnosis data bear directly on payment, CMS has long required Medicare Advantage insurers to "certif[y] (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness" of diagnosis data. 42 C.F.R. 422.504(*l*). CMS further requires that "[e]ach diagnosis code submitted must be supported by a properly documented medical record." *United Healthcare Ins. Co.*, 848 F.3d at 1168; see, *e.g.*, C.A. App. 66; 42 C.F.R. 422.310(d)(1) (requiring that Medicare Advantage coding conform to national standards); 45 C.F.R. 162.1002(a)(1) (adopting the International Classification of Diseases (ICD-9) as the national standard); C.A. App. 456, 458 (ICD-9 requires medical-record support for all diagnosis codes).

Medicare regulations make clear that diagnosis codes may be audited against the medical record, and

that insurers are required to return payments due to diagnosis codes that are not supported by the medical record. See, *e.g.*, 42 C.F.R. 422.310(e), 422.311(b) and (c). If CMS discovers that a previously submitted diagnosis is unsupported, CMS will recover the associated payment through reconciliation. C.A. App. 128. CMS further requires Medicare Advantage insurers to "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements * * * as well as measures that prevent, detect, and correct fraud, waste, and abuse." 42 C.F.R. 422.503(b)(4)(vi).

If an insurer knowingly withholds errors from CMS—that is, diagnosis codes discovered to be unsupported by the medical record—the insurer is subject to False Claims Act, 31 U.S.C. 3729 *et seq.*, liability. *United Healthcare Ins. Co.*, 848 F.3d at 1175; see C.A. App. 410 ("If upon conducting an internal review of submitted diagnosis codes, the plan sponsor determines that any * * * diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted * * * diagnosis codes as soon as possible.").

2. a. Because Medicare Advantage insurers are paid based on the diagnoses they report, "there is an incentive for [Medicare Advantage] organizations to" report more diagnoses "so that they can increase their payment." C.A. App. 96; see *United Healthcare Ins. Co.*, 848 F.3d at 1168; *United States ex rel. Silingo* v. *WellPoint, Inc.*, 904 F.3d 667, 672 (9th Cir. 2018). Meanwhile, providers who treat traditional Medicare beneficiaries lack that same incentive; although accu-

rate diagnosis coding is required in traditional Medicare, the amount a provider is paid depends more directly on the services rendered (for Part B) or on the diagnosis-related group to which a patient is assigned at discharge (for Part A). Pet. App. 17a.

Medicare Advantage insurers use various methods to identify additional diagnoses. For example, some insurers hire outside vendors to conduct "enrollee risk assessments" in beneficiaries' homes. C.A. App. 290. In many cases, these appear to "primarily serve as a vehicle for collecting diagnoses for payment." *Ibid.* Similarly, the American Medical Association has warned that Medicare Advantage insurers often ask physicians to participate in medical-record reviews whose "purpose * * * [i]s less to assure compliance with MA regulatory requirements and more of a fishing expedition to find data that would support increased risk scores and attendant increased payments to the plan." *Id.* at 390-391.

Congress has repeatedly expressed concern that such methods inflate risk scores and therefore payments to insurers. Given the "differences in [diagnosis] coding patterns between Medicare Advantage plans" and traditional Medicare providers, Congress directed the Secretary to study and "ensure that [risk] adjustment * * * reflects" those differences. See Deficit Reduction Act of 2005 (Deficit Reduction Act), Pub. L. No. 109-171, § 5301(b)(2), 120 Stat. 51. After studying the issue, CMS implemented a "coding pattern * * * adjustment" that reduced all Medicare Advantage risk scores by 3.41% for 2010, which CMS indicated was "conservative." C.A. App. 176; see, *e.g.*, *id.* at 151.

In response, Congress not only codified CMS's adjustment, but also mandated that CMS reduce Medicare

Advantage risk scores by an additional 1.3% for 2014, and by further amounts for later years. Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1102(e)(3)(D), 124 Stat. 1046. Later, finding that reduction likewise insufficient, Congress mandated even larger reductions, requiring that CMS reduce the Medicare Advantage risk scores produced by the risk adjustment model by a minimum of 5.9% in 2019. 42 U.S.C. 1395w-23(a)(1)(C)(ii)(III).

b. For similar reasons, Medicare Advantage insurers also have an incentive to avoid informing CMS that previously reported diagnosis codes lack supporting medical-record documentation. The rate of unsupported diagnoses varies by insurer and the nature of that insurer's practices, but their impact can be significant. The record contains audits by the Department of Health & Human Services's Office of the Inspector General of two UnitedHealth plans, both petitioners before this Court, that found that 43% and 45% of the plans' sampled risk scores were inaccurate due to unsupported diagnoses. C.A. App. 471, 476. The payment impact of just the sampled invalid codes was $183,247, *id.* at 471, and $224,388, *id.* at 477. When extrapolated to the entire contract, the impact was $115 million, *id.* at 471, out of $827 million in contract payments, *id.* at 469, and $423 million, *id.* at 477, out of $2.3 billion in payments, *id.* at 476.

One further method adopted by a few Medicare Advantage insurers is the use of "one-way" chart reviews, which aim to identify new diagnoses while ignoring evidence that previously reported diagnoses are invalid. See C.A. App. 36-37; see also *id.* at 52 (citing *United Healthcare Ins. Co.*, 848 F.3d at 1166). The United States is currently pursuing a False Claims Act suit

that alleges that petitioners UnitedHealth and its subsidiaries engaged in such a one-way chart review program. See *id.* at 614-685. The suit alleges that UnitedHealth reviewed millions of medical records "to mine for diagnoses that the providers themselves did not report." *Id.* at 617-618. UnitedHealth then allegedly "used the results of the chart reviews to only increase government payments (*i.e.*, submit additional codes not reported by the providers)," while "ignoring other information from the chart reviews which would have led to decreased payments" by demonstrating that previously reported diagnoses lacked supporting medical-record documentation. *Id.* at 618. For the payment years 2010 to 2015, this practice allegedly generated over $3 billion in additional risk adjustment payments to UnitedHealth and its affiliates. *Id.* at 648.

The United States also alleges in the same litigation that UnitedHealth structured payment arrangements with some health care providers to incentivize them to report additional diagnoses on which UnitedHealth could collect payment. See C.A. App. 619-620. UnitedHealth then allegedly ignored evidence indicating that these "incentivized" providers were reporting invalid diagnoses. *Id.* at 620.

3. In 2010, Congress amended the Medicare Act to require a person that "has received an overpayment" to "report and return the overpayment" no later than "60 days after the date on which the overpayment was identified." 42 U.S.C. 1320a-7k(d)(1)(A) and (2)(A). If the person fails to do so, the overpayment becomes an "obligation" for purposes of the False Claims Act, which among other things makes it unlawful to "knowingly conceal[] or knowingly and improperly avoid[] or de-

crease[] an obligation to pay or transmit money or property to the Government." 31 U.S.C. 3729(a)(1)(G); see 42 U.S.C. 1320a-7k(d)(3). The statute defines "'overpayment'" to mean "any funds that a person receives or retains under" the Medicare statute "to which the person, after applicable reconciliation, is not entitled." 42 U.S.C. 1320a-7k(d)(4)(B). And it defines "'person'" to include "a provider of services," which includes Medicare Advantage organizations. 42 U.S.C. 1320a-7k(d)(4)(C)(i).

In 2014, CMS implemented this statutory provision for Medicare Part C by promulgating the Part C Overpayment Rule. 42 C.F.R. 422.326; see C.A. App. 58. Tracking the statute, the Rule similarly defines "overpayment" as "any funds that [a Medicare Advantage insurer] has received or retained under [the Medicare Advantage program] to which the [Medicare Advantage insurer], after applicable reconciliation, is not entitled." 79 Fed. Reg. 29,844, 29,958 (May 23, 2014) (42 C.F.R. 422.326(a)) (capitalization and emphasis omitted). The Rule further provides that "[i]f a[] [Medicare Advantage] organization has identified that it has received an overpayment, the * * * organization must report and return that overpayment." 42 C.F.R. 422.326(b). The preamble to the Rule explains that "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." 79 Fed. Reg. at 29,921. In other words, consistent with longstanding CMS rules, see pp. 4-5, *supra*, if a Medicare Advantage insurer identifies that a previously reported diagnosis is not supported by the medical record, it must return the payment received

based on that diagnosis. This requirement applies, however, only to overpayments that are "identified"; Medicare Advantage insurers "cannot reasonably be expected to know that every piece of data [they submit] is correct." *United Healthcare Ins. Co.*, 848 F.3d at 1169 (quoting 65 Fed. Reg. 40,170, 40,268 (June 29, 2000)).

4. Petitioners UnitedHealthcare and other Medicare Advantage insurers under the umbrella of UnitedHealth Group Incorporated brought suit in the District Court for the District of Columbia, challenging the 2014 Part C Overpayment Rule. Pet. App. 25a.

a. The district court granted summary judgment for petitioners and vacated the Rule on three grounds. Pet. App. 25a-26a.

First, the district court agreed with petitioners that treating payments corresponding to unsupported diagnosis codes as "overpayments" violates the Medicare statute's "actuarial equivalence" provision. Pet. App. 71a-78a. That provision, as noted above, see pp. 2-3, *supra*, directs the Secretary to "adjust the payment amount" that Medicare Advantage insurers receive for each beneficiary for various risk factors "so as to ensure actuarial equivalence." 42 U.S.C. 1395w-23(a)(1)(C). The court reasoned "that payments for care under traditional Medicare and Medicare Advantage are both set annually based on costs from unaudited traditional Medicare records, but that the 2014 Overpayment Rule systemically devalues payments to Medicare Advantage insurers by measuring 'overpayments' based on audited patient records." Pet. App. 72a. In the court's view, "[t]he 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." *Id.* at 78a. And that, the court concluded, would violate the "actuarial equivalence" provision. *Ibid.*

Second, the district court agreed with petitioners that CMS failed to comply with a provision of the Medicare statute that requires CMS, when annually publishing average risk scores for traditional Medicare beneficiaries in each county, to calculate the published scores "us[ing] the same methodology as is expected to be applied in making payments" to Medicare Advantage plans. Pet. App. 78a-79a (quoting 42 U.S.C. 1395w-23(b)(4)(D)). The court reasoned that the Rule violated that "same methodology" provision because, it believed, the Overpayment Rule requires use of "audited diagnosis codes for Medicare Advantage patients, in sharp contrast to unverified diagnosis codes for traditional Medicare patients." *Id.* at 78a (citation omitted).

Third, the district court held the Rule's interpretation of "overpayment" was an arbitrary and capricious departure from prior agency policy. Pet. App. 79a-84a. In 2012, CMS had published a notice of a new Risk Adjustment Data Validation (RADV) methodology for auditing Part C diagnosis codes, which would use sampling to approximate comprehensive auditing of all diagnosis codes for certain selected contracts each year. *Id.* at 80a; C.A. App. 394-398. CMS announced in that notice that it intended to adopt some sort of adjustment to "account[] for the fact that the documentation standard used in RADV audits to determine a contract's payment error * * * is different from the documentation standard" for the traditional Medicare data used to calibrate the risk adjustment model. Pet. App. 80a-81a (ci-

tation and emphasis omitted). The district court reasoned that "[h]aving recognized that actuarial equivalence, mandated by statute, required an [] 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." *Id.* at 84a.[1]

b. After the district court entered its judgment, CMS completed and published a study of whether an adjuster was appropriate in its contract-level RADV audit methodology, together with a notice of proposed rulemaking. See C.A. App. 727-732; 83 Fed. Reg. 54,982, 55,040-55,041 (Nov. 1, 2018). The study concluded, based on empirical analysis, "that errors in [traditional Medicare diagnosis] data do not have any systematic effect on * * * the payments made to MA organizations." 83 Fed. Reg. at 55,040. CMS further stated that, "even if we had found that diagnosis error in [traditional Medicare] claims data led to systematic payment error in the MA program," an adjuster in RADV would still be inappropriate because "it would be inequitable to correct any systematic errors in the payments made to audited plans only," since not all plans

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[1] In an aspect of the judgment the United States did not challenge on appeal, the district court invalidated the Overpayment Rule's interpretation of an "identified overpayment." 42 C.F.R. 422.326(c). The district court held that, by including overpayments that should have been identified through "reasonable diligence," the rule unlawfully imposed a scienter standard more stringent than that in the False Claims Act, which provides the enforcement mechanism for violations of the 2010 overpayment provision. Pet. App. 85a-87a (citation omitted). The court also held that the interpretation violated the Administrative Procedure Act's, 5 U.S.C. 701 *et seq.*, notice-and-comment requirement because it was not a "logical outgrowth" of the proposed rule. Pet. App. 88a (citation omitted).

are audited each payment year. *Id.* at 55,041. CMS accordingly proposed "not [to] include an * * * Adjuster" in its RADV audit methodology. *Ibid.* CMS has not yet implemented the contemplated methodology.

Citing the study, the government filed a motion under Federal Rule of Civil Procedure 60(b) asking the district court to reconsider its first and second holdings. D. Ct. Doc. 76 (Nov. 5, 2018). The court denied the motion. Pet. App. 90a.

5. The court of appeals reversed and remanded.

The court of appeals first held that the actuarial-equivalence provision does not limit the Secretary's ability to recover payments for diagnoses that a Medicare Advantage insurer identifies as unsupported by medical-record documentation. Pet. App. 3a-4a, 29a-48a. The court reasoned that "[a]ctuarial equivalence is a directive to CMS" that "describes the goal of the risk-adjustment model Congress directed CMS to develop." *Id.* at 4a; see *id.* at 31a-38a. "It does not separately apply to the requirement that Medicare Advantage insurers avoid known error in their payment requests," and "assuredly does not unambiguously demand that, before CMS can collect known overpayments from Medicare Advantage insurers, it must engage in unprecedented self-auditing to eliminate an imagined bias in the body of traditional Medicare data CMS used in its regressions." *Id.* at 4a-5a; see *id.* at 38a-40a.

The court of appeals further held that, even if the "actuarial equivalence" provision were implicated here, petitioners failed to meet their "burden to show the systematically skewed inaccuracies on which [their] theory depends." Pet. App. 5a; see *id.* at 40a-49a. The court also concluded that petitioners' claim failed because they "never challenged the values CMS assigned to the

risk factors it identified or the level of the capitation payments resulting from CMS's risk-adjustment model," and petitioners "cannot belatedly do so in the guise of a challenge to the Overpayment Rule." *Id.* at 5a; see *id.* at 40a-41a.

The court of appeals likewise rejected petitioners' "'same methodology'" claim, explaining that that statutory provision concerning data publication was "[m]eant to facilitate Medicare Advantage insurers' bidding for contracts with CMS" and "merely clarifies that, in computing the data it publishes, CMS must use the same risk-adjustment model that it already uses to set monthly payments to Medicare Advantage insurers." Pet. App. 5a-6a; see *id.* at 49a-50a. But, as the court explained, it "says nothing about what constitutes an 'overpayment.'" *Id.* at 6a; see *id.* at 50a.

Finally, the court of appeals rejected petitioners' arbitrary-and-capricious claim. Pet. App. 50a-52a. The court held that the Overpayment Rule and contract-level RADV audits "are plainly distinguishable" error-correction mechanisms, and CMS's one-time intention to apply an adjustment in one context but not the other was reasonable and did not require further explanation. *Id.* at 6a; see *id.* at 50a-52a. The court also held in the alternative that the contemplated adjuster "came in direct response to concerns about actuarial equivalence," and "the actuarial-equivalence requirement" does not pertain to the statutory overpayment-refund obligation or the Overpayment Rule challenged here. *Id.* at 6a; see *id.* at 51a.

On petitioners' petition for panel rehearing, the court of appeals amended its judgment to clarify that the reversal of the district court's judgment applied

only to the portion of the judgment challenged by the government on appeal. Pet. App. 107a-108a.

ARGUMENT

The court of appeals correctly rejected petitioners' challenges to the Overpayment Rule. Nothing in the Medicare Act suggests that before CMS can collect known overpayments from a Medicare Advantage insurer—mistaken payments that the insurer *knows* were not supported by medical-record documentation—CMS must engage in unprecedented auditing or make use of an adjuster to eliminate a supposed bias in traditional Medicare data. The decision below does not conflict with any decision of this Court or any other court of appeals, and petitioners' claims about the consequences for the Part C program are without merit. Further review is not warranted.

1. The court of appeals correctly held that the Overpayment Rule does not violate the Medicare Act's "actuarial equivalence" provision. Pet. App. 29a-48a. As the court explained, the actuarial-equivalence provision governs the Secretary's design of the risk adjustment model that establishes the beneficiary-specific monthly payment amount to which a Medicare Advantage insurer is entitled; it does not limit an insurer's "obligation to refund any individual, known overpayment." *Id.* at 34a. Moreover, petitioners' claim independently fails because petitioners failed to establish the premise on which its theory depends: that the Overpayment Rule will lead to Medicare Advantage insurers' systemic underpayment. *Id.* at 46a-47a. Those independent and alternative holdings do not warrant this Court's review.

a. The court of appeals correctly held that the actuarial-equivalence provision does not preclude CMS

from requiring Medicare Advantage insurers to return individual overpayments. Pet. App. 31a-40a.

i. As the court of appeals explained, the actuarial-equivalence provision is an instruction to the Secretary regarding "CMS's calculation and disbursement of monthly payments in the first instance." Pet. App. 35a. As originally enacted, the per-capita payment amount did not depend on the health of the enrolled beneficiaries, so Medicare Advantage insurers tended to enroll the healthiest (and least costly) Medicare beneficiaries. See pp. 2-3, *supra*. To eliminate the incentive to skew Medicare Advantage beneficiary populations, Congress provided:

> [T]he Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) 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). The cross-referenced subparagraphs identify the per-capita "payment" amounts CMS is to use in making "monthly payments under this section in advance to each [Medicare Advantage] organization" for coverage of each enrolled beneficiary. 42 U.S.C. 1395w-23(a)(1)(A). Congress further directed the Secretary to "provide for implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors." 42 U.S.C. 1395w-23(a)(3)(C)(i).

The actuarial-equivalence provision thus governs "the design of the risk adjustment model as a whole,"

describing the "'payment amount[s]'" that "the risk adjustment model should [aim to] produce." Pet. App. 37a (citation omitted; brackets in original). Specifically, it directs the Secretary to ensure "that the lump-sum monthly payments to Medicare Advantage insurers be set as if an insurer's beneficiary pool were actuarially equivalent to traditional Medicare's population," *id.* at 36a, by "accounting for the distinct profiles of each insurer's beneficiary population," including "'age, disability status, gender, institutional status, * * * health status,'" and "'such other factors as the Secretary determines to be appropriate,'" *id.* at 38a, 58a (quoting 42 U.S.C. 1395w-23(a)(1)(C)(i)).

But nothing in the actuarial-equivalence provision addresses how CMS should evaluate the validity of diagnoses or speaks to an insurer's obligation to substantiate its entitlement to payment for a particular beneficiary—including by complying with program rules governing data formatting and submission, medical-record documentation, and so forth. And as particularly relevant here, nothing in the actuarial-equivalence provision purports to restrict CMS from requiring insurers to refund known overpayments they erroneously elicited from CMS. An insurer's obligation to refund payments that the insurer knows were not supported by the beneficiary's medical records is not affected by the separate and "earlier-in-time requirement" that the per-beneficiary payments to Medicare Advantage insurers be calculated to ensure "actuarial equivalence" between beneficiary pools. Pet. App. 36a.

As the court of appeals explained, "[t]he actuarial-equivalence requirement and the overpayment-refund obligation apply to different actors, target distinct issues arising at different times, and work at different

levels of generality." Pet. App. 37a. The court thus correctly concluded that "[t]he statute's actuarial-equivalence requirement does not apply to the separate statutory obligation on insurers to refund overpayments they erroneously elicit from CMS; nor, by the same token, does actuarial equivalence apply to the Overpayment Rule that implements that statutory obligation." *Id.* at 33a.

ii. Petitioners' contrary arguments lack merit.

Petitioners principally emphasize (Pet. 20-21) that the statutory overpayment provision applies to "funds that a person receives or retains under subchapter XVIII * * * to which the person * * * is not entitled under such subchapter." 42 U.S.C. 1320a-7k(d)(4)(B). "[S]ubchapter XVIII" in turn, contains the entire Medicare program, including the actuarial-equivalence provision. In petitioners' view, this cross-reference means that the actuarial-equivalence provision directly limits application of the overpayment provision.

The text cannot bear that weight. A cross-reference to the Medicare Act as a whole obviously does not mean that every provision within that statute—even those that address different aspects of the statutory scheme—directly governs the payment to which an insurer is "entitled." Said otherwise, Section 1320a-7k(d)(4)(B)'s cross-reference to Subchapter XVIII does not convert the actuarial-equivalence provision from an instruction regarding model design into an entitlement to retain a mistaken or fraudulent payment that the insurer never should have received in the first place.

Petitioners further argue that because the statutory definition of "'overpayment'" "consists of funds 'under subchapter XVIII' to which a person is 'not *entitled un-*

der [subchapter XVIII],'" CMS or a court, in determining whether there is an overpayment, "must first determine the payment to which an insurer was 'entitled'"—and the payments to which Medicare Advantage insurers are entitled are then assertedly governed by the actuarial-equivalence provision and other provisions of subchapter XVIII. Pet. 21 (quoting 42 U.S.C. 1320a-7k(d)(4)(B)). But, as already explained, the actuarial-equivalence provision describes the "'payment amount[s]'" that "the risk adjustment model should [aim to] produce" for beneficiaries with particular characteristics, including their medical diagnoses. Pet. App. 37a (citation omitted; brackets in original); see pp. 16-17, *supra*. An insurer is not, and has never been, "entitled" to a payment that corresponds to a diagnosis that should never have been coded in the first instance because it lacks support in the medical record. *Ibid.*

The history of both the actuarial-equivalence provision and the overpayment-return obligation further refute petitioners' contention. Since the inception of the current risk adjustment model, CMS has taken a similar approach to diagnosis data—measuring the validity of reported diagnosis codes based on medical-record support and incorporating limited mechanisms for identifying and correcting unsupported diagnoses—in both traditional Medicare and Medicare Advantage. But because of practical differences in how the programs operate, the error-correction mechanisms in the two programs have never been identical. See Pet. App. 40a. During that time, Congress has repeatedly tinkered with the risk-adjustment model, yet never suggested that this approach violates the actuarial-equivalence provision. See, *e.g.*, American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 639, 126 Stat. 2357; Health

Care and Education Reconciliation Act § 1102(e), 124 Stat. 1046; Deficit Reduction Act § 5301, 120 Stat. 48-51.

Likewise, CMS has long required that diagnosis codes be supported by the medical record and that insurers return payments due to unsupported diagnoses. See pp. 4-5, *supra*. In the 2010 overpayment provision, Congress strengthened those pre-existing obligations by requiring insurers to report and return overpayments within sixty days of their discovery, and making specific provision for False Claims Act liability for those that do not. 42 U.S.C. 1320a-7k(d). In so doing, Congress made no reference to the Medicare statute's long-standing actuarial-equivalence provision, let alone any suggestion that it could be interposed as a defense. See *ibid.*

Indeed, as the court of appeals recognized, applying actuarial equivalence to the Medicare statute's separate obligation to refund particular, known overpayments would seriously undermine that obligation. Petitioners' theory (Pet. 27)—that CMS cannot recover for even the most obviously mistaken or fraudulent diagnosis until it accounts for unsupported codes in the traditional Medicare data that it uses to calculate Medicare Advantage payment rates—would require costly changes to Medicare programs and significantly impede CMS's efforts to prevent waste, fraud, and abuse.

Petitioners' suggestions for how to implement their theory illustrate the difficulty. According to petitioners (Pet. 26), for CMS to recover for even a single unsupported diagnosis code, CMS must either systematically audit traditional Medicare data and then generate a new risk adjustment model that eliminates any effect from unsupported diagnosis codes in those data, or else

broadly audit data from traditional Medicare—which receives a massive volume of claims—to determine the error rate, then afford Medicare Advantage insurers an adjustment for some theoretically equivalent number of errors. The scale of these endeavors would substantially limit CMS's ability to enforce data integrity standards.[2]

Yet according to petitioners, absent such measures, CMS cannot recover a single known overpayment. For example, even if CMS discovered that an insurer was paid twice for the same beneficiaries, on petitioners' reading, CMS would first have to prove the insurer received an actuarially equivalent amount—through some combination of systematic auditing and a free pass for some overpayments—before it could recover the double payment.

Petitioners' position also ignores the substantial discretion Congress afforded the Secretary in establishing the risk-adjustment model. Specifically, the statute provides that "the Secretary shall adjust the payment amount * * * 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) (emphasis added). The next sentence further emphasizes the Secretary's substantial discretion

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[2] Petitioners suggest that CMS could more readily ascertain the error rate through sampling, Pet. 26, but creating a reliable sampling model for traditional Medicare data would itself be an extensive undertaking. Among other considerations, CMS would presumably need to account for varying beneficiary characteristics, geographic factors, treatment sites, and error rates across different conditions.

over model design: "The Secretary *may* add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence." *Ibid.* (emphasis added). Congress thus gave the Secretary broad discretion to determine what adjustments are appropriate. See *ibid.*

Finally, petitioners incorrectly suggest (Pet. 21-22) that the government failed to raise this argument below. To the contrary, the government has consistently argued that the actuarial-equivalence provision is an instruction to the Secretary regarding the design of the risk-adjustment model, and that Congress never intended it to require changes to how the Secretary handles invalid diagnoses in either Medicare Part C or traditional Medicare. See, *e.g.*, D. Ct. Doc. 57-1, at 30, 40 (Dec. 4, 2017); Gov't C.A. Br. 41-43; Gov't C.A. Reply Br. 5-7; C.A. Oral Arg. at 12:49-13:09, https://www.cadc.uscourts.gov/recordings/recordings2020.nsf/69CAC5288163BCEC85258615005BE6BA/$file/18-5326.mp3 (government counsel agreeing with the court that "the actuarial-equivalence requirement simply doesn't apply to the Overpayment Rule," because "actuarial equivalence is an instruction to the Secretary as to how to design the risk-adjustment model").

b. The court of appeals also correctly rejected petitioners' actuarial-equivalence argument on the alternative ground that, even if that provision could theoretically govern insurers' obligation to return payments based on false or unsupported diagnoses, petitioners failed to establish that the Overpayment Rule would in fact cause Medicare Advantage insurers to be underpaid. Pet. App. 46a-47a. Petitioners contend (Pet. 24-25) that the Overpayment Rule will inevitably cause insurers to be underpaid because CMS measures health

in the traditional Medicare population based on both supported and unsupported diagnosis codes, but measures health in Part C based only on supported codes. Petitioners' argument rests on both incorrect factual premises and faulty empirical predictions.

i. Petitioners' contention that CMS takes a fundamentally different approach to unsupported diagnoses in traditional Medicare is incorrect. CMS measures the validity of diagnoses in both traditional Medicare and Part C by their support in the medical record, so an unsupported diagnosis does not justify payment in either program. See Gov't C.A. Br. 27-29, 33-35. Both programs incorporate limited mechanisms for identifying and correcting unsupported diagnoses for specific individual beneficiaries. See *id.* at 16-17, 35-37.

And as particularly relevant here, both programs also include an Overpayment Rule. Traditional Medicare is governed by the Part A and Part B Overpayment Rule, which requires providers who identify an unsupported diagnosis to return any resulting overpayment, 42 C.F.R. 401.303, 401.305(a)(1) and (b)(1), as the Part C Overpayment Rule does for Medicare Advantage insurers, see pp. 8-9, *supra*. Neither Overpayment Rule requires comprehensive error correction or that providers or insurers identify every unsupported diagnosis; rather, both rules require payments for unsupported diagnoses to be returned when identified.

To be sure, the particular mechanisms for identifying and correcting unsupported diagnoses vary in some particulars, given the different structures and incentives of the two programs. Pet. App. 41a-42a; Gov't C.A. Br. 33-40. It therefore is reasonable for CMS to use distinct tools to respond to different problems. And as explained above, Congress has long been aware of

CMS's use of particular measures tailored to the different programs; indeed, Congress, too, has spelled out distinct obligations for traditional Medicare and Medicare Advantage, such as the coding pattern adjustment that applies to the latter program but not the former. See pp. 6-7, *supra*.

ii. Even assuming *arguendo* that no error correction mechanism existed in traditional Medicare, petitioners' predictive empirical contention—that requiring Medicare Advantage insurers to return payments for unsupported diagnoses will inevitably lead to underpayment—is unsubstantiated.

First, petitioners identify no reason why the traditional Medicare data that goes into the risk-adjustment model would suffer systematically from unsupported codes like those the Part C Overpayment Rule targets, *i.e.*, codes lacking substantiation in medical records. Petitioners' principal concern (Pet. 9) is with unsupported diagnoses in Part B. But as the court of appeals explained, "if anything, the fact that providers for [Part B] beneficiaries are generally paid based on services, not diagnoses, would seem to tend toward underreporting, not overreporting, of diagnoses within traditional Medicare." Pet. App. 42a.

Second, as noted above, diagnosis data can reflect both underreporting (failure to report valid diagnoses) and overreporting (reporting unsupported diagnoses), which will tend to have opposite effects on the risk adjustment model. Medicare Advantage insurers, who design their own compliance programs, have strong incentives to systematically identify underreporting, whereas CMS does not do so in traditional Medicare. Thus, petitioners have not demonstrated that requiring Med-

icare Advantage insurers to *also* account for overreporting, when discovered, will lead to improper underpayment.

Suppose, for example, an insurer has been paid for all reported diagnoses under the current risk adjustment model and has not returned any payments for unsupported diagnoses. On petitioners' theory, this insurer would have received an actuarially equivalent payment. Now suppose the insurer starts a medical-record review program to find additional diagnoses to report for payment and, in doing so, also identifies that some previously reported diagnoses are unsupported by the medical record. Absent a requirement to report these unsupported diagnoses, the program would be skewed in one direction. Requiring insurers to report both types of errors, rather than ignoring overpayments, only limits insurers' ability to inflate payments through a one-way ratchet; it does not lead inevitably to underpayment.

Third, petitioners ignore that unsupported diagnoses in traditional Medicare can cause some payment rates or relative factors to increase and others to decrease, compared to a hypothetical model with no errors, making the net effect on a Medicare Advantage insurer's payment uncertain. If, for example, the payment rate for diabetes is improperly deflated from $2500 to $2000 due to the presence of unsupported diabetes codes in traditional Medicare, that means the risk adjustment model may *overestimate* the cost of other conditions. That result could occur because, for beneficiaries who actually have diabetes, the model would underestimate the portion of their treatment costs attributable to diabetes and instead allocate those costs to other conditions. Whether any particular insurer's

overall payments would increase or decrease would depend on its mix of beneficiaries.

Fourth, petitioners ignore that if CMS audited traditional Medicare to remove all unsupported diagnosis codes, CMS would also avoid costs incurred due to those codes. Thus, if CMS discovered that it paid a provider $2000 to treat a patient for diabetes when the patient did not have that condition, it would claw back that money, reducing its total diabetes expenditure. Petitioners thus have not established that CMS's corresponding payment to Medicare Advantage insurers for a diabetes diagnosis code would increase if their auditing proposal were adopted.

Notably, CMS's October 2018 study concerning an adjuster in the context of contract-level RADV audits suggests that "errors in [traditional Medicare] claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to [Medicare Advantage] organizations." C.A. App. 731. In fact, CMS determined that the impact of errors in traditional Medicare data "is less than one percent on average and in favor of the [Medicare Advantage] plans." *Ibid.*

Finally, as the court of appeals noted, petitioners have "never taken the opportunity that arises annually to challenge the accuracy of the risk-adjustment model or pricing when CMS announces the relative factors and base payment rates that it will use for the upcoming year." Pet. App. 40a-41a. Rather than relying on the actuarial-equivalence provision to challenge the application of the payment rates to which that provision actually pertains, petitioners seek to leverage that provision to preclude the enforcement of longstanding rules

regarding medical-record documentation and the return of individual overpayments. The court correctly rejected that argument.

c. In any event, these independent and alternative holdings do not warrant this Court's review.

i. Petitioners fail to identify a conflict among the courts of appeals. To the contrary, the decision below is consistent with that of the only other court of appeals to have considered a similar question. See *United States* v. *United Healthcare Ins. Co.*, 848 F.3d 1161, 1175 (9th Cir. 2016) (holding that insurers may be liable under the False Claims Act for designing medical-record reviews to "avoid identifying erroneously submitted diagnosis codes" that would require return of corresponding payments).

Nor is there any reason to believe that the decision below will prevent further percolation. A district court in the Ninth Circuit, for example, recently rejected the argument that the actuarial-equivalence provision allows participants in the Medicare Advantage program to avoid returning payments for diagnosis codes identified as invalid. *United States ex rel. Ormsby* v. *Sutter Health*, 444 F. Supp. 3d 1010, 1067 (N.D. Cal. 2020). In addition, some petitioners have themselves asserted actuarial equivalence as a defense in False Claims Act litigation. See, *e.g.*, *United States ex rel. Poehling* v. *UnitedHealth Grp., Inc.*, No. 16-8697, 2019 WL 2353125, at *1 (C.D. Cal. Mar. 28, 2019). There is no sound reason for the Court to grant review unless and until a conflict in authority emerges.

ii. Petitioners' assertions regarding the effects of the decision below on the Medicare Advantage program are without merit. As explained above, see pp. 4-5, *su-*

pra, CMS has long required that, if a submitted diagnosis is discovered to be invalid, insurers must return any resulting payment. As relevant here, the Overpayment Rule merely clarifies that such payments are subject to the procedural requirements of the 2010 statutory overpayment provision. See 42 U.S.C. 1320a-7k(d)(2)(A) and (3). There is accordingly no reason to expect that the Overpayment Rule will have a significant effect on the operation of Medicare Part C.

The record in this case further demonstrates that prior industry practice was consistent with the Overpayment Rule. For example, one petitioner in this case—a UnitedHealth plan—stated well before promulgation of the Rule that it conducts medical-record reviews to validate diagnoses and that "[c]odes found to be inaccurate or incomplete through chart validations are deleted." C.A. App. 485-486; see, *e.g.*, *id.* at 47 (comment by America's Health Insurance Plans—one of petitioners' amici—explaining that Medicare Advantage plans conduct "targeted reviews" to "ensure data integrity by confirming the diagnosis data submitted to the agency"; "[i]n the course of these reviews, MA organizations may also find that previously submitted codes should be deleted as well as identify additional codes that are appropriate for submission"). The fact that no other insurer brought a timely Administrative Procedure Act, 5 U.S.C. 701 *et seq.*, challenge to the Overpayment Rule besides UnitedHealth and its affiliates only further demonstrates that the Overpayment Rule does not significantly change the operation of the Medicare Advantage program.[3]

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[3] Petitioners' assertion that any reduction in payment to Medicare Advantage insurers will have a substantial adverse impact on the

2. The court of appeals also correctly rejected petitioners' claim that the Overpayment Rule violates the "same methodology" requirement in Section 1395w-23(b)(4)(D) of the Medicare Act. That provision has a specific function: it governs data relevant to the process by which Medicare Advantage insurers bid for contracts with CMS; like the actuarial-equivalence provision, however, it does not bear on the separate overpayment-refund obligation.

As the court of appeals explained, Pet. App. 49a, each year, Medicare Advantage insurers bid for contracts after CMS announces the county-specific benchmarks for the coming year. 42 U.S.C. 1395w-23(b)(1)(B). The base rate for a given county is then determined by the benchmark derived from traditional Medicare's per-capita expenditures in the county and the accepted bid submitted by a Medicare Advantage insurer. Pet. App. 49a. An insurer covering a beneficiary with a risk score of 1.0 can expect to receive the base rate for the beneficiary's home county, whereas beneficiaries with risk scores higher or lower than 1.0 will draw prorated payments above or below the base rate, respectively. *Ibid.*

The "'same methodology'" requirement in Section 1395w-23(b)(4) "plays a specific role" in this bidding process. Pet. App. 50a. In the section titled "Annual announcement of payment rates," the Medicare Act directs CMS to compute and publish annually the "average risk factor" for traditional Medicare beneficiaries

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Part C program is also inconsistent with Congress's repeated judgment that Medicare Advantage insurers have been *over*paid; indeed, Congress on a number of occasions has required CMS to apply larger reductions to Part C risk scores and payments. See pp. 6-7, *supra*.

on a county-by-county basis, "using the same methodology as is expected to be applied in making payments" to Medicare Advantage insurers. 42 U.S.C. 1395w-23(b)(4)(D) (emphasis omitted). In other words, the statute directs that the information CMS publishes for Medicare Advantage insurers to use in determining their bids must be calculated using the same methodology that will be used in actually making payments to those insurers. CMS complies with this provision each year by calculating and publishing risk scores using its current risk adjustment model, based on data gathered through traditional Medicare processes.

Petitioners' argument (Pet. 29-30) that this data-publication provision requires CMS to substantially alter the administration of Part C—either by permitting insurers to retain payment for known unsupported diagnoses, or by instead conducting systematic auditing to remove any effect of erroneous diagnoses—thus finds no basis in the text. And it would unmoor the "same methodology" language from its surrounding text, context, and role in the statutory scheme.

In any event, the court of appeals' holding does not conflict with that of any other court of appeals. Nor does the decision below preclude further percolation. Indeed, petitioner UnitedHealth has made the "same methodology" argument in district court litigation in the Ninth Circuit. See *Poehling*, 2019 WL 2353125, at *5. Review of this question at this juncture is thus unwarranted.

3. The court of appeals also correctly rejected petitioners' argument that the Overpayment Rule is an arbitrary and capricious departure from prior agency policy. As explained, see pp. 4-5, *supra*, CMS has long re-

quired that Medicare Advantage insurers return payments for diagnoses that are discovered to be unsupported by medical-record documentation. The Overpayment Rule accordingly clarified the applicable procedures but did not alter the underlying obligation.

Petitioners argue, however, that the absence of an adjuster in the Overpayment Rule represents a reversal from CMS's policy with respect to a different program for reviewing Part C claims. Pet. 30-32. Specifically, petitioners point to the new contract-level methodology for RADV audits that CMS announced in 2012, under which the agency would determine a payment error rate for a sample of enrollees covered under the contract with a particular Medicare Advantage insurer and then extrapolate that error rate to the entire contract. C.A. App. 394-398. Petitioners emphasize that in CMS's 2012 notice, the agency stated that it intended to adopt a "Fee-for-Service [FFS] Adjuster" to "account[] for the fact that the documentation standard used in [the contract-level] RADV audits to determine a contract's payment error * * * is different from the documentation standard" in the traditional Medicare data used to calibrate the risk adjustment model. *Id.* at 397-398.

But as the court of appeals explained, "[c]ontract-level RADV audits, which would effectively eliminate—and require repayment for—all unsupported codes in a Medicare Advantage insurer's data" are a "materially distinct" error-correction mechanism "from the Overpayment Rule challenged here, which requires only that an insurer report and return to CMS known errors in its beneficiaries' diagnoses that it submitted as grounds for upward adjustment of its monthly capitation payments." Pet. App. 52a. CMS's decision not to implement an adjustment under the Overpayment Rule thus

does not reverse any prior policy. To the contrary, as the agency explained in the final Overpayment Rule, the proposed contract-level RADV audit methodology "does not change" the grounds on which CMS had long required that individual identified errors be corrected and that payment requests be supported by medical-record documentation. C.A. App. 64-65.

Notably, moreover, since publishing its 2012 notice, CMS has preliminarily explained that it does not intend to use an FFS Adjuster for contract-level RADV audits because it would be inequitable to adjust payments only to audited plans and because "errors in [traditional Medicare] claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model." Pet. App. 51a-52a (quoting C.A. App. 731) (brackets in original); p. 12 *supra*.

Petitioners also briefly contend that the Overpayment Rule "departed from CMS's past statements about the coding intensity adjuster," where CMS stated that Medicare Advantage "'plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid,'" and that "'to pay plans accurately'" requires "'establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings.'" Pet. 31 (quoting C.A. App. 177-178). Even assuming departure from a prior "statement" were a valid APA claim, continuing to require Medicare Advantage insurers to return payments that are based on *unsupported* diagnoses does not conflict with CMS's statement about coding and risk adjustment consistency in the context of diagnoses that may well be supported. As explained above, any obligation to ensure that payment amounts and coding practices for various diagnoses are consistent across Medicare does not preclude CMS from recovering payments based on

diagnosis codes that were never supported by medical-record documentation in the first instance. See pp. 15-22, *supra*.

Again, petitioners fail to identify a conflict between the holding of the court of appeals and that of any other circuit. The Overpayment Rule is consistent with insurers' longstanding obligation to refund payments for diagnoses discovered to be unsupported by medical-record documentation. See pp. 27-28, *supra*.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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