No. 21-1145

In The
Supreme Court of the United States

MOLINA HEALTHCARE OF ILLINOIS, INC.
AND MOLINA HEALTHCARE, INC.,

Petitioners,

v.

THOMAS PROSE,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

BRIEF OF AMERICA'S HEALTH INSURANCE PLANS (AHIP) AS *AMICUS CURIAE* SUPPORTING PETITIONERS

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STATEMENT OF INTEREST[1]

America's Health Insurance Plans, Inc. ("AHIP") is the national trade association representing health insurance providers. AHIP advocates for public policies that expand access to affordable health care coverage for all Americans through a competitive marketplace that fosters choice, quality, and innovation. AHIP's members provide health and supplemental benefits to hundreds of millions of Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. As a result, AHIP's members have broad experience working with state and federal governments to ensure that patients have access to needed treatments and medical services that improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. AHIP's members also have intimate familiarity with the complexity of Medicaid, Medicare, and other programs, and the importance of public-private collaboration in the provision of health care coverage.

AHIP has a strong interest in ensuring that the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and similar state laws are interpreted and implemented correctly. When properly construed and applied, these

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[1] Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part, and no person other than *amicus* or its counsel made a monetary contribution to this brief's preparation and submission. Pursuant to Rule 37.2, all parties received timely notice of *amicus's* intent to file this brief, and all parties have consented to this filing.

laws can reduce costly fraud and deter improper business practices. Improper construction and expansion of these laws, however, threatens the legitimate business activities of every government contractor, health insurance provider, and grant recipient in the nation, and creates tremendous and unnecessary costs and burdens for entities participating in government markets like health care. AHIP submits this brief to provide the Court its perspective on why the Seventh Circuit's decision in this case could gravely undermine the public-private partnerships critical to delivering high-quality, cost-effective health care to millions of Americans through Medicaid and Medicare, and thus why this Court's review of both questions presented is warranted.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Seventh Circuit's decision allowing Respondent's insufficiently pled FCA case to proceed beyond a motion to dismiss unduly expands the statute in two ways: it permits lawsuits that do not identify a specific false claim to reach discovery, and it allows for liability based on non-fraudulent breaches of contract or regulatory violations. Allowing the decision below to stand (along with similar decisions from other circuits in the two splits at issue) could be extremely damaging to the Medicaid and Medicare programs, which use managed care organizations ("MCOs") to deliver benefits through public-private partnerships to more than 90

million Americans. This Court's intervention is urgently needed.

In the health care context, the Seventh Circuit's flawed rationale presents significant risks. MCOs that partner with federal and state governments to provide care through Medicaid, Medicare, and other programs are subject to myriad and labyrinthine regulations and contractual requirements, along with robust enforcement mechanisms designed to respond to compliance problems. The possibility of being subject to the FCA's harsh penalties for ordinary regulatory or contractual infractions may impose unnecessary and unreasonable costs on MCOs. Those costs risk undermining the success of the private-public partnerships that in recent decades have been vital to our nation's public health.

This Court should grant the petition to resolve two splits implicated and deepened by the Seventh Circuit's decision: (1) Whether the heightened pleading standards set forth in Rule 9(b) require an FCA plaintiff to plead specific details of at least one "false or fraudulent" claim; and (2) Whether under *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016), a mere request for payment that does not make any specific representations can nonetheless be "false or fraudulent" under the FCA if it fails to disclose non-compliance with a statutory, regulatory, or contractual requirement.

The Seventh Circuit's erroneous answers to these questions—and the implications of its ruling for federal programs that utilize MCOs more broadly—make

clear that courts require guidance on how properly to construe and apply the FCA so as to preserve its important functions without transforming it into "an all-purpose antifraud statute." *Escobar*, 579 U.S. at 194 (quotation marks omitted).

ARGUMENT

By loosening Rule 9(b)'s pleading requirements and transforming ordinary contract and regulatory violations into fraud under the FCA, the Seventh Circuit's decision splits from other circuits and warrants this Court's review. The Seventh Circuit's decision threatens to undermine the carefully calibrated public-private partnerships through which MCOs have for decades delivered high-quality and cost-effective care to millions of Americans. It also fails to account for the reality that these programs are subject to an extraordinary number of complex requirements and existing enforcement mechanisms.

I. The Seventh Circuit's Decision and Those Like It in the Splits at Issue Contravene the False Claims Act's Gatekeeping Protections and Threaten to Undermine Managed Care Organizations' Public-Private Partnerships.

In *Escobar*, this Court made clear that "[t]he False Claims Act is not an all-purpose antifraud statute[ ] or a vehicle for punishing garden-variety breaches of

contract or regulatory violations." 579 U.S. at 194 (quotation marks omitted). The Seventh Circuit's decision cannot be reconciled with this fundamental principle, nor with contrary decisions from other circuits. Certiorari should be granted on both questions presented.

A. Regarding the First Question Presented, the Seventh Circuit's Decision Erroneously Loosens Rule 9(b)'s Pleading Requirements.

With respect to the first question presented—whether Rule 9(b) requires plaintiffs in FCA cases to plead details of the alleged false claims—the Seventh Circuit held that plaintiffs need not plead *any* details about the actual claims submitted. App-13. But, as Judge Sykes explained in dissent, courts "are not at liberty to loosen pleading standards under circumstances where a specific false statement is hard to identify." App-29. By "loosen[ing] pleading standards," she wrote, the majority enabled "the very fishing expedition that Rule 9(b) is meant to avoid." *Id.* (quotation marks omitted).

Under the Seventh Circuit's ruling, MCOs may be forced to defend against meritless fraud claims that will survive motions to dismiss absent specific allegations of a misrepresentation. This approach is contrary to Rule 9(b) and will add unnecessary costs to the claims and administrative expenses used in

establishing capitated payments through annual rate setting processes.[2]

These costs, combined with the costs associated with the Seventh Circuit's position on the second question presented, ultimately will be borne by states, which cover some of the costs for Medicaid; the federal government, which subsidizes both Medicaid and Medicare; and enrollees, who will receive reduced benefits or pay higher costs. The scope of those impacts could be massive, as states and the federal government successfully partner with MCOs to provide coverage to more than 90 million Americans across both programs. Accordingly, certiorari should be granted on the first question presented.[3]

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[2] A capitation rate is a fixed monthly fee for each person in a given beneficiary group in exchange for a specified set of health services (regardless of which services are used by any particular patient). App-2; *see also* CMS, *2020-2021 Medicaid Managed Care Rate Development Guide* (July 2, 2020), https://www.medicaid.gov/medicaid/managed-care/downloads/2020-2021-medicaid-rate-guide.pdf.

[3] The split on this question is acknowledged and deep—the First, Sixth, Eighth, and Eleventh Circuits have held that Rule 9(b) requires FCA plaintiffs to plead the false claim element with particularity, and the Third, Fifth, Seventh, Ninth, Tenth, and D.C. Circuits allow the submission of a false claim to be inferred. *See* Petition for Writ of Certiorari ("Pet.") at 5. That certiorari is warranted to resolve the split on this important issue is confirmed by the two other cases seeking it, which should be held for this case. *See Johnson v. Bethany Hospice & Palliative Care LLC*, No. 21-462; *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, No. 21-936.

B. Regarding the Second Question Presented, the Seventh Circuit's Decision Threatens to Transform Ordinary Contract and Regulatory Violations into Fraud.

Granting review in this case also will allow the Court to consider the critical second question presented—whether a request for payment that makes no specific representations about the goods or services provided can be actionable under an "implied false certification" theory.[4]

As Judge Sykes stated in dissent, the majority opinion on this issue "establish[es] a new rule that a mere request for payment from the government, coupled with material noncompliance with a contractual condition, is a cognizable FCA violation subject to the full panoply of remedies authorized by the Act, including qui tam suits and treble damages." App-24. The majority's reasoning is contrary to the rationale of *Escobar* and in conflict with other circuits that have faithfully applied the FCA to require an actual false claim—not merely a contractual or regulatory violation existing at the time of a request for payment.

Not only is the Seventh Circuit's expansive reading of the FCA wrong as a legal matter, but it is highly problematic as a practical matter. It threatens to

[4] The circuits are split on this question, too. The Third, Fifth, Ninth, and Eleventh Circuits have held that a mere request for payment absent any specific representations cannot be actionable, and the Fourth, Seventh, and D.C. Circuits have held that it can. *See* Pet. at 7.

transform ordinary contract and regulatory violations into fraud and risks creating costs and harm for Medicaid and Medicare programs and their enrollees. MCOs that partner with government entities to facilitate those highly complex programs are subject to an extraordinary number of requirements, any one of which could give rise to a fraud claim under the Seventh Circuit's decision. It simply cannot be the case that every regulatory or contractual violation can give rise to an FCA case.[5]

The Seventh Circuit's decision also does not advance these critical health care programs. The success of public-private partnerships between government entities and MCOs requires that the partnership not be a venture fraught with intolerable risk. Medicaid and Medicare Advantage MCOs already are subject to government compliance programs that mandate ongoing monitoring and auditing by the MCOs[6] and the

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[5] Under the Seventh Circuit's decision, the FCA's materiality requirement, 31 U.S.C. § 3729(a)(1)(A), provides no meaningful safeguard, because the Seventh Circuit reasoned that an MCO defendant could not mount a materiality defense because it is a "sophisticated player in the medical-services industry" and/or because of the mere existence of a difference in capitation rates between enrollment groups. App-3. As Judge Sykes explained, that approach would mean "that *every* service under a contract with actuarial pricing is material." App-38.

[6] *See* Medicare Managed Care Manual, *Ch. 21 Compliance Program Guidelines* (Jan. 11, 2013), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf; 42 C.F.R. § 438.608.

government.[7] Rather than resorting to high-stakes litigation or allegations of fraud, the government requires MCOs to have processes for correcting and reporting self-identified potential contractual or regulatory issues, and can work with the MCO to resolve them. In the instant case, for example, "the government continued to contract with Molina after learning that Molina could no longer provide SNF services," including after the relator filed its case alleging fraud. App-18. The government thus did not need an FCA lawsuit to enable it to get the benefit of its bargain with its MCO partner. A host of administrative sanctions and penalties also can be imposed via contractual and/or regulatory provisions.[8] This dual approach of compliance and sanction recognizes the practical balance required in running a complex program. MCOs are expected to have procedures in place to prevent and detect compliance errors, and government partners have tools to audit and respond to problems, but that system cannot be so unreasonable and costly as to make it impossible to operate. The Seventh Circuit's decision essentially overrules these reasonable requirements by suggesting MCOs need to implement programs that attempt to eliminate all compliance

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[7] 42 C.F.R. § 438.66; CMS, *2022 Program Audit Process Overview* (Dec. 2021), https://www.cms.gov/files/document/2022-program-audit-process-overview.pdf.

[8] *See*, *e.g.*, 42 C.F.R. § 422.750 (Medicare MCOs can be subjected to enrollment, payment, and marketing suspensions, as well as civil penalties); *id.* § 438.702 (Medicaid MCOs can be subjected to civil money penalties, enrollment and payment suspensions, and other intermediate sanctions).

risks (an extremely costly and impossible task) or be viewed as committing an FCA violation and subjected to harsh penalties.

Unduly expanding the FCA's reach to encompass even technical violations—as the Seventh Circuit's decision does—opens the door to relators seizing control of public-private partnerships by determining how to address alleged breaches. Such a shift undermines the entire notion of a public-private partnership, including the carefully crafted oversight and monitoring structures implemented through regulation and contract, and the trust and relationships needed for such partnerships to thrive. In particular, the Seventh Circuit's unfounded framework creates greater costs and burdens for participating MCOs—either through far more costly compliance programs that will make it difficult or impossible to operate and are still unlikely to eliminate all errors, or through draconian liability for even minor violations—with corresponding impacts on the governments that use MCOs and the beneficiaries who rely upon these programs. It also significantly changes the risk associated with partnering with governments to deliver public health programs.

These risks are especially acute given the FCA's "bounty" system and "punitive" liability—treble damages, per-claim penalties, and attorney's fees and expenses. *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772, 784 (2000); 31 U.S.C. §§ 3729(a), 3730(d)(1)-(2). In light of that scheme, the Seventh Circuit's decision gives plaintiffs an incentive to litigate irrelevant infractions. It also exposes MCOs

to treble damages based on allegations that they collected capitation payments while in alleged breach of a Medicare or Medicaid contract—absent any allegations that the MCO made any specific representations about the goods or services it was providing. The result may well be that the Medicaid and Medicare programs—which cover some of our country's most vulnerable individuals—are harmed as the added costs of unnecessary litigation reduce the ways in which MCOs are otherwise able to use those resources to offer more effective and efficient approaches to accessing care. Simply put, an MCO should not be exposed to devastating liability for violating a program requirement that is not directly related to payment and which is already subject to monitoring and correction under the laws and regulations governing that program. More importantly, the many millions of Americans who depend upon—and in many instances have selected—MCOs to deliver their Medicaid or Medicare coverage should not suffer the harm from the reduced advancements in access to effective and efficient care as resources are diverted from innovation to inappropriate litigation. Yet that is exactly the scheme contemplated by the Seventh Circuit's decision. Certiorari should be granted on the second question presented.

II. The Seventh Circuit's Decision Upsets the Carefully Calibrated Public-Private Partnerships Through Which MCOs Deliver High-Quality and Cost-Effective Care Under Extraordinary Complex Government Programs.

The public-private partnerships between MCOs and federal and state governments to deliver health care to people enrolled in Medicaid and Medicare serve a significant number of Americans and are critical to improving health care access and quality while also reducing costs. These partnerships are subject to extensive requirements and carefully calibrated enforcement mechanisms which protect government partners while also ensuring that MCOs are not hampered in delivering services because of a risk of expensive litigation and draconian fraud-based penalties resulting from mere contract and regulatory violations. Absent this Court's intervention, this balance is upset. The resources of such partnerships should be directed towards continuing to innovate in providing coverage for effective and efficient care, rather than to inappropriate litigation.

A. MCOs Serve Significant Numbers of Medicaid and Medicare Enrollees Nationwide through Public-Private Partnerships.

Federal and state governments largely rely on private entities to deliver high-quality, affordable health care services to the public. Over the last several

decades, states and consumers have increasingly selected MCOs as the way to provide and receive those services.

As of July 1, 2019, nearly 66 million Medicaid beneficiaries—83.5% of all people enrolled in Medicaid—were enrolled in a managed care plan, and 55 million Medicaid beneficiaries—70% of all people enrolled in Medicaid—were enrolled in a comprehensive managed care plan.[9] Those numbers are even higher today, as Medicaid enrollment steadily increased during the COVID-19 pandemic, rising by 13.3 million people—20.6%—between February 2020 and September 2021.[10] Managed care is now "the dominant delivery system" for Medicaid nationwide.[11]

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[9] CMS, *2019 Share of Medicaid Enrollees in Managed Care*, https://data.medicaid.gov/dataset/79692ea5-21e1-56bf-8149-97d437120c4b/data?conditions[0][resource]=t&conditions[0][property]=year&conditions[0][value]=2019&conditions[0][operator]==.

[10] Bradley Corallo & Sophia Moreno, *Analysis of Recent National Trends in Medicaid and CHIP Enrollment*, Kaiser Family Foundation (Mar. 3, 2022), https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/.

[11] CMS, *CMS Informational Bulletin Re: Medicaid and CHIP Managed Care Monitoring and Oversight Tools* (June 28, 2021), https://www.medicaid.gov/federal-policy-guidance/downloads/cib06282021.pdf; Elizabeth Hinton et al., *10 Things to Know about Medicaid Managed Care*, Kaiser Family Foundation (Oct. 29, 2020), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care/ ("As of July 2021, 41 states (including DC) contract with comprehensive, risk-based managed care plans to provide care to at least some of their Medicaid beneficiaries.").

The Medicare Advantage program serves nearly 29 million Medicare beneficiaries (45% of all people eligible to receive Medicare) through private health plans.[12] And nearly 50 million people are enrolled in Medicare Part D coverage, a voluntary prescription drug benefit for Medicare beneficiaries that is provided through private health insurance plans approved by the federal government.[13] Of those, over 23 million people are enrolled in stand-alone prescription drug plans and nearly 26 million people are enrolled in drug benefit coverage through a Medicare Advantage plan.[14]

B. MCOs are Designed, and Relied upon by States, to Deliver High-Quality, Cost-Effective Care.

MCOs are structured to deliver higher-quality and more cost-effective health care than fee-for-service models.[15] They have been proven to achieve both those goals through their partnerships with federal and state governments.

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[12] *See* CMS, *Monthly Contract Summary Report—February 2022*, https://www.cms.gov/research-statistics-data-and-systems-statistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2022-02.

[13] *Id.*

[14] *Id.*

[15] Under fee-for-service arrangements, "states pay providers directly and are solely responsible for monitoring access." MACPAC, *Monitoring Managed Care Access*, https://www.macpac.gov/subtopic/monitoring-managed-care-access/.

MCOs typically deliver services to Medicaid enrollees through a capitated managed care model. Under that model, the state government and MCO enter a contract pursuant to which the government agrees to pay the MCO a capitation rate. This model advances multiple goals, "including improving care coordination and quality of care, ensuring provider access for enrollees, improving program accountability, and making state budgets more predictable and potentially achieving administrative savings."[16]

1. MCOs Improve Health Services Delivery.

MCOs provide care coordination and prioritize value and quality in the services delivered to beneficiaries. Research has shown that shifting from fee-for-service arrangements to MCOs improved both access to care and quality of care for Medicaid beneficiaries across multiple states. For example:

- "New Mexico saw hospital admissions reduced by 19%, nursing facility use reduced by 17%, and emergency department visits reduced by 8% after implementing a managed long-term services and supports program for adults with disabilities and older adults."[17]

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[16] Lisa R. Shugarman et al., *White Paper: The Value of Medicaid Managed Care* 22 (Nov. 12, 2015), https://www.healthmanagement.com/wp-content/uploads/HMA-Value-of-MMC-White-Paper-FINAL-111215.pdf.

[17] AHIP, *The Value of Medicaid: 3 Questions & Answers About Managed Care* (Sept. 24, 2018), https://www.ahip.org/news/

- In South Carolina, 63% of adults with diabetes covered by a Medicaid MCO health plan monitored their blood sugar levels compared to 33% of adults covered by Medicaid fee-for-service.[18]
- In California, people continually enrolled in managed health plans are more likely to report a usual source of care and to have visited a doctor in the past year than those covered by Medicaid fee-for-service.[19]

MCOs also play a leading role in developing strategies in coordination with government partners to combat health disparities and promote health equity.[20]

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articles/the-value-of-medicaid-3-questions-answers-about-managed-care.

[18] *Id.*

[19] *See* CALIFORNIA HEALTH CARE FOUNDATION, ACCESS TO PHYSICIANS IN CALIFORNIA'S PUBLIC INSURANCE PROGRAMS 7 & Table 2 (May 2004), https://www.chcf.org/wp-content/uploads/2017/12/PDF-AccessToPhysiciansInCAPublicProgramsIB.pdf; *see also The Value of Medicaid Managed Care in Quality Improvement: A Comparison of Quality Outcomes Across State Medicaid Program Delivery Models*, Health Management Associates (Nov. 2021), https://www.healthmanagement.com/wp-content/uploads/HMA-Value-of-Managed-Care.pdf (finding that MCOs outperformed other models on care continuum metrics due to their "structured care coordination and specialized programs," and that "the growth of Medicaid managed care plans has led to higher quality scores in several core areas of adult and child measures").

[20] *See*, *e.g.*, *Medicaid Managed Care Contract Language: Health Disparities and Health Equity*, State Health & Value Strategies, Princeton Univ. (Jan. 2022), https://www.shvs.org/wp-content/uploads/2021/08/SHVS-MCO-Contract-Language-Health-Equity-and-Disparities_January-2022.pdf (managed care documents illustrating how states are leveraging managed care to promote

And they have been critical players in responding to health care delivery challenges posed by COVID-19.[21]

2. MCOs Promote Cost Effectiveness.

By design, MCOs promote cost effectiveness in care delivery. Because they receive a fixed amount per patient under the capitation model, and so "assume[] financial risk for the cost of covered services and plan administration," they have a strong incentive "to coordinate care so that needed services are provided in the most cost-effective manner."[22] MCOs do so by using proven techniques to ensure that the federal government and states receive maximum value for the dollars they spend while improving quality of care. These techniques include encouraging more preventive health

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health equity and address health disparities); *Medicaid Managed Care: Strategies to Address Social Determinants of Health & Health Equity*, Together for Better Medicaid (Dec. 2021), https://assets.togetherforbettermedicaid.org/media/tbm_hma_strategies-for-addressing-sdoh-and-health-equity-brief_december-2021.pdf (explaining that managed care provides greater flexibility than fee-for-service to address health equity and detailing ways that MCOs are addressing social determinants of health).

[21] *See* Michael Nardone & Susan C. Reinhard, *The Role of Medicaid Managed Long-Term Services and Supports During the COVID-19 Pandemic*, AARP Public Policy Institute (Oct. 2021), https://www.aarp.org/content/dam/aarp/ppi/2021/10/role-medicaid-managed-long-term-services-and-supports.doi.10.26419-2Fppi.00152.001.pdf.

[22] MACPAC, *Report to the Congress on Medicaid and CHIP* 155 (Mar. 2013), https://www.macpac.gov/wp-content/uploads/2013/03/March-2013-Report-to-the-Congress-on-Medicaid-and-CHIP.pdf.

care, managing prescription drug benefits, and providing disease management services that improve quality of life in a cost-effective manner. The Seventh Circuit's ruling hampers this result.

The cost savings achieved by partnering with MCOs are well documented. For example:

- Between 2011 and 2018, Medicaid MCOs managed a significantly higher percentage of prescriptions at meaningfully lower average cost than did fee-for-service prescription drug programs. Had all Medicaid prescription drugs been subject to fee-for-service arrangements instead of MCO-managed arrangements in 2018, Medicaid program costs would have been $6.5 billion higher.[23]
- States that began including prescription drugs in their Medicaid MCO administered benefits between 2011 and 2013 realized aggregate program savings of $1.2 billion in 2014 as compared with states that continued administering their drugs through fee-for-service programs through 2014.[24]

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[23] AHIP, *The Value of Medicaid Managed Care: Making Prescription Drugs More Affordable for States and Taxpayers* 2 (Feb. 2020), https://www.ahip.org/documents/AHIP-MMCResearch_RxDrugs.pdf.

[24] *See* Joel Menges et al., *Comparison of Medicaid Pharmacy Costs and Usage in Carve-In Versus Carve-Out States* 1-2, 5, 11-12 (Apr. 2015), https://www.themengesgroup.com/upload_file/medicaid_pharmacy_carve-in_final_paper_the_menges_group_april_2015.pdf.

- Ohio Medicaid MCOs saved taxpayers up to $4.4 billion in 2016 and 2017 compared to the costs of a traditional fee-for-service program, and approximately $2.4 million per month through the state's managed long-term services and supports program.[25]

Similarly, Medicare Advantage and Part D MCO plans offer high-quality and cost-effective solutions to the benefit of consumers and the government. MCOs have driven the success and growth of the Medicare Advantage program, providing benefit and care management not otherwise available in the fee-for-service program.

The substantial improvements to access and quality of care and cost savings are why states are increasingly choosing to partner with MCOs to provide Medicaid services, which deliver care more effectively and less expensively than the traditional fee-for-service health insurance model. Similarly, the substantial improvements to access and quality of care and cost savings are why nearly 29 million Americans eligible for Medicare have chosen to have their care delivered by Medicare Advantage plans instead of through the traditional fee-for-service program.

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[25] *See Managed Care Saved Ohio Taxpayers $4.4B*, The Business Journal (Mar. 1, 2019), https://businessjournaldaily.com/managed-care-saved-ohio-taxpayers-4-4b/.

C. The Complexity of the Medicaid and Medicare Programs Make the Seventh Circuit's Expansion of FCA Liability Particularly Problematic for MCOs.

Partnering with governments to deliver Medicaid and Medicare services to millions of Americans is no easy task for MCOs. Medicare and Medicaid are extremely complex programs with labyrinthine statutory, regulatory, and programmatic requirements. Transforming violations of these requirements into FCA violations would be unwise, unworkable, and untenable. This is why it is so critical that the Court take up the second question presented: whether a request for payment that makes no specific representations about the goods or services provided can be actionable as fraud (with concomitant damages) under an "implied false certification" theory.

Robust audit programs, enforcement, and penalty mechanisms already exist to prevent and detect violations and address situations if a MCO falls short of compliance—loosening the FCA's pleading standards and requirements for implied certification therefore is not necessary. These mechanisms include a full spectrum of remedies specifically authorized by Congress and the agencies, ranging from repayment of amounts improperly received to termination from the programs. *See*, *e.g.*, 42 C.F.R. § 456 Subparts K, O; *id.* § 438 Subpart I. Treating such violations as fraud ignores this complexity, undermines these programs, and ultimately harms the many individuals and governments that have benefited from the quality, efficiency,

and innovations in access to care that MCOs have delivered. The complexity of the programs described below, as well as the remedies already available for federal and state governments to deploy in the event of noncompliance with the requirements, make an expansion of FCA liability here unnecessary and unwise.

This Court has repeatedly acknowledged the complexity of the Medicare and Medicaid programs. *See*, *e.g.*, *Wis. Dep't of Health & Fam. Servs. v. Blumer*, 534 U.S. 473, 477 (2002) (interpreting "a complex set of instructions made part of the federal Medicaid statute" concerning spousal impoverishment); *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 7-8 (2000) (noting that the scheme governing review of Medicare denials involves "a complex set of statutory provisions"); *id.* at 13 (calling Medicare "a massive, complex health and safety program . . . embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts"); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (calling Medicare "a complex and highly technical regulatory program"); *Bowen v. Massachusetts*, 487 U.S. 879, 900 n.31 (1988) (explaining that "the Medicaid Act" is "a complex scheme . . . that governs a set of intricate, ongoing relationships between the States and the Federal Government"); *Schweiker v. Hogan*, 457 U.S. 569, 571 (1982) ("The statutory provisions governing the Medicaid program are complex."); *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981) (explaining that "the provisions setting

requirements for state Medicaid plans" fall within legislation "among the most intricate ever drafted by Congress," with "Byzantine construction" and great "complexity").

This complexity manifests in an extremely numerous and complicated web of provisions with which MCOs must comply. *See*, *e.g.*, *Escobar*, 579 U.S. at 192 ("[Medicaid] billing parties are often subject to thousands of complex statutory and regulatory provisions").

1. Medicare's Extensive Requirements.

Medicare's complex web of regulations and requirements for Medicare Advantage plans cover a multitude of areas, including: enrollment and disenrollment; marketing; enrollee notices; claims and appeals; benefit design; bidding and payments; reporting; monitoring; network adequacy and provider contracting; medical management; care management; coordination of benefits with other payers; Star Ratings and other quality measures; licensure; and solvency.

The sheer volume of sources embodying these requirements is staggering. For example, there are 225 pages of regulations governing Medicare Advantage,[26] and CMS's manual on Medicare managed care contains 21 chapters, with a 54-page chapter on

[26] 42 C.F.R. Part 422, https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-part422.pdf.

compliance program guidelines.[27] Medicare Advantage Plans also must keep track of CMS's weekly sub-regulatory memos[28]and the annual rate notice.[29] There are also a significant number of guidelines governing marketing and communications by Medicare Advantage plans.[30] Medicare Part D is similarly complicated. There are 232 pages of governing regulations,[31] plus a manual from CMS[32] and formulary guidance[33] and reporting requirements. Even the CMS application for organizations seeking to provide Medicare Advantage Services is 120 pages, and the Medicare Part D application is 140 pages.[34]

Medicare Advantage MCOs and Part D plans are subject to government compliance programs that, for

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[27] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.

[28] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly.

[29] Advance Notice of Methodological Changes for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies (Feb. 2, 2022), https://www.cms.gov/files/document/2023-advance-notice.pdf.

[30] https://www.cms.gov/files/document/medicare-communications-marketing-guidelines-2-9-2022.pdf.

[31] 42 C.F.R. Part 423, https://www.govinfo.gov/content/pkg/CFR-2020-title42-vol3/pdf/CFR-2020-title42-vol3-part423.pdf.

[32] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.

[33] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.

[34] https://www.cms.gov/files/document/cy-2023-medicare-advantage-part-c-application.pdf; https://www.cms.gov/files/document/2023-part-d-application-final.pdf.

example, require them to "establish and implement policies and procedures to conduct a formal baseline assessment of the [MCO's] major compliance and [fraud, waste, and abuse] risk areas."[35] An MCO also "must have a system of ongoing monitoring and auditing that is reflective of its size, organization, risks and resources to assess performance in, at a minimum, areas identified as being at risk."[36]

Additionally, both Medicare Advantage and Plan D plans are subject to extensive reporting requirements. These plans must have an effective procedure to develop, compile, evaluate, and report information to CMS in the time and manner that CMS requires. Medicare Advantage plans must submit data annually from which their performance is measured and compared on approximately 40 quality, patient experience, and administrative measures. The program areas covered by the reporting requirements include grievances, denials and appeals data, enrollment and disenrollment data, and special needs plans care management requirements.[37] CMS can terminate a Medicare contract for low performance in the quality ratings program for three consecutive years.[38] The Part D reporting requirements also cover multiple, similar

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[35] Medicare Managed Care Manual § 50.6.2, *supra* note 6.

[36] *Id.* § 50.6.1. States are required to impose similar compliance program obligations on Medicaid MCOs.

[37] CMS, *Part C Reporting Requirements*, https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/ReportingRequirements.

[38] https://www.cms.gov/files/document/2022-star-ratings-fact-sheet1082021.pdf; 42 C.F.R. §§ 422.510(a)(4)(xi), 423.509(a)(4)(x).

program areas.[39] Data that plans submit pursuant to the Medicare Advantage and Plan D reporting requirements are subject to CMS's data validation process, which is conducted annually by an independent, external entity to ensure the data is reliable, valid, complete, comparable, and timely.[40]

Likewise, Medicare Advantage and Part D plans are subject to a rigorous audit program.[41] During each audit cycle, CMS audits plans that represent about 95% of the enrollment under the Medicare Advantage and Plan D programs.[42] The audit covers a plan's compliance program effectiveness policies and protocols; Part D formulary and benefit administration program; and handling of Medicare Advantage and Part D coverage determinations, appeals, and grievances.[43] CMS can impose various sanctions for violations discovered during audits and other monitoring activities, including civil monetary penalties; intermediate sanctions such as suspension of marketing, enrollment, and

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[39] https://www.cms.gov/files/document/cy2022part-d-reporting-requirements012022.pdf; https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.

[40] CMS, *Part C and Part D Data Validation*, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDataValidation.

[41] CMS, *2020 Part C and Part D Program Audit and Enforcement Report* (May 14, 2021), https://www.cms.gov/files/document/2020-program-audit-enforcement-report.pdf.

[42] *Id.* at 5.

[43] CMS, *2022 Program Audit Process Overview* 4 (Dec. 2021), https://www.cms.gov/files/document/2022-program-audit-process-overview.pdf.

payment; and terminations. *See* 42 C.F.R. § 422.750. CMS also publicly discloses audit results and enforcement actions taken against plans.[44] In addition, it conducts annual plan performance reviews, and may deny a Medicare Advantage or Plan D plan's application either to offer benefits under a new contract or in an expanded service area due to compliance issues or actions.[45]

2. Medicaid's Extensive Requirements.

Like Medicare, Medicaid has extensive statutory, regulatory, and programmatic requirements. Moreover, in the Medicaid context, states can promulgate their own rules on top of the baseline requirements established by CMS. For example, states can establish more stringent requirements via plan contracts or seek waivers from CMS to relax standards, resulting in a web of requirements that can differ state to state. Thus, for Medicaid, MCOs must comply with the federal rules plus regulations, guidance, and contractual

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[44] CMS, *Part C and Part D Enforcement Actions*, https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.

[45] CMS, *2019 Application Cycle Past Performance Review Methodology Final* (Feb. 7, 2018), https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019ApplicationCyclePastPerformanceFinalMethodology.pdf.

provisions imposed by the fifty states, the District of Columbia, and Puerto Rico and other territories.[46]

The breadth and scope of Medicaid requirements are massive. Statutory provisions require that MCOs prove to the state and the Secretary of the U.S. Department of Health and Human Services "that they have the capacity to serve the expected number of enrollees and provide evidence that the plan offers an appropriate range of services, including access to preventive and primary care services, and maintains a sufficient number, mix, and geographic distribution of providers."[47] MCOs also must "have procedures in place for monitoring and evaluating the quality and appropriateness of care and services to beneficiaries and" must prove "that these services reflect the full spectrum of the needs of the populations enrolled under the contract."[48] Further, "Medicaid MCOs must document standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care, adequate primary care, and specialized services capacity."[49]

Federal rules additionally require that state contracts with MCOs incorporate dozens of specific provisions addressing areas including payment,

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[46] *See* MACPAC, *Medicaid 101*, https://www.macpac.gov/medicaid-101/; MACPAC, *Waivers*, https://www.macpac.gov/medicaid-101/waivers/.

[47] MACPAC, *Monitoring Managed Care Access*, https://www.macpac.gov/subtopic/monitoring-managed-care-access/.

[48] *Id.*

[49] *Id.*

information disclosure requirements, anti-discrimination, enrollment and disenrollment, network adequacy standards, marketing activities, cost sharing, services availability, coordination of services and continuity of care, confidentiality, grievance and appeal systems, subcontractual relationships and delegation, health information systems, fraud and abuse detection and mitigation programs, and quality assessment and performance improvement efforts.[50]

MCOs and states also must track the federal policy guidance documents,[51] guidance regarding setting managed care capitation rates,[52] guidance regarding calculating and reporting a medical loss ratio,[53] and guidance regarding collecting, validating, and reporting Medicaid managed care encounter data.[54]

As with Medicare, Medicaid MCOs and states are subject to extensive reporting requirements. "Over the last decade, CMS has engaged in numerous monitoring and oversight activities for Medicaid and CHIP managed care programs. . . . The May 2016 Medicaid and

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[50] 42 C.F.R. § 438; MACPAC, *Features of Federal Medicaid Managed Care Authorities*, https://www.macpac.gov/features-of-federal-medicaid-managed-care-authorities/.

[51] https://www.medicaid.gov/federal-policy-guidance/index.html.

[52] https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html.

[53] https://www.medicaid.gov/medicaid/managed-care/guidance/medical-loss-ratio/index.html.

[54] https://www.medicaid.gov/medicaid/managed-care/guidance/encounter-data/index.html.

CHIP managed care final rule . . . create[d] new reporting requirements for states on their managed care programs and operations."[55] The Annual Managed Care Program Report to CMS—an annual report on each managed care program administered by a state, *see* 42 C.F.R. § 438.66(e)—must include information about program enrollment and service area expansions; financial performance; encounter data reporting; grievances, appeals, and state fair hearings; availability, accessibility, and network adequacy; delegated entities; quality and performance measures; sanctions and corrective action plans; beneficiary support system; and program integrity.[56] Reporting requirements also include a Medical Loss Ratio summary report, 42 C.F.R. § 438.74(a), and an Access Standards Report, 42 C.F.R. § 438.207(d), (e).

Further, states must have a formal monitoring system for all managed care programs that addresses administration and management; appeal and grievance systems; claims management; enrollee materials and customer services; finance, including medical loss ratio reporting; information systems, including encounter data reporting; marketing; medical management, including utilization management; program integrity; provider network management including provider directories; quality improvement; the delivery of long-term services and supports; and other contract items as appropriate. 42 C.F.R. § 438.66. In conducting

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[55] *CMS Informational Bulletin*, *supra* note 7.

[56] *Id.*

these monitoring activities, states must collect and review a variety of program data, including enrollment and disenrollment data, grievance and appeal logs, external quality review organization findings, surveys, qualify measures, MCO annual quality improvement plans, financial reports, and medical loss ratio summary reports.[57]

* * *

In sum, MCOs subject themselves to myriad and complex requirements when partnering with governments to deliver care to people enrolled in Medicaid, Medicare, and other government health programs. By lowering the bar to pleading FCA lawsuits and significantly amplifying the prospect of being subject to the statute's severe penalties for ordinary regulatory or contractual infractions, the Seventh Circuit's decision risks adding significant, unnecessary, and unreasonable costs and burdens on the MCOs in these public-private partnerships, and thus the partnerships themselves, diverting resources from MCOs' ongoing efforts to offer high-quality, cost-effective solutions that have made these plans so beneficial for consumers and governments to the costs of litigating matters for which appropriate remedies already exist.

[57] MACPAC, *Monitoring Managed Care Access*, https://www.macpac.gov/subtopic/monitoring-managed-care-access/.

CONCLUSION

For these reasons, and those advanced by Petitioners, the Court should grant the petition for a writ of certiorari.

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