Nos. 21-1326 and 22-111

IN THE

Supreme Court of the United States

UNITED STATES, EX REL. TRACY SCHUTTE, ET AL.,

Petitioners,

v.

SUPERVALU INC., ET AL.,

Respondents.

UNITED STATES, EX REL. THOMAS PROCTOR,

Petitioner,

v.

SAFEWAY, INC.,

Respondent.

On Writs of Certiorari To The United States Court of Appeals For The Seventh Circuit

---

BRIEF OF AMERICAN HOSPITAL ASSOCIATION AND AMERICA'S HEALTH INSURANCE PLANS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

Madhu Pocha
O'MELVENY & MYERS LLP
1999 Avenue of the Stars
Los Angeles, CA 90067
(310) 553-6700

Anton Metlitsky
O'MELVENY & MYERS LLP
7 Times Square
New York, N.Y. 10036
(212) 326-2000

Michael R. Dreeben
Counsel of Record
Amanda M. Santella
Jenya Godina
Danielle Siegel
O'MELVENY & MYERS LLP
1625 Eye Street, N.W.
Washington, D.C. 20006
(202) 383-5300
mdreeben@omm.com

Attorneys for Amici Curiae

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

Statutes and Regulations

Other Authorities

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

INTEREST OF *AMICI CURIAE*[1]

Amici the American Hospital Association ("AHA") and America's Health Insurance Plans ("AHIP") have distinct perspectives and infrequently join forces as *amici*. This case presents an important issue on which the interests of AHA and AHIP are aligned.

AHA represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. AHA members are committed to improving the health of the communities they serve and to helping ensure that care is available to and affordable for all Americans. The AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are considered in formulating health policy. One way in which the AHA promotes the interests of its members is by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases arising under the False Claims Act ("FCA").

AHIP is the national trade association representing health insurance providers. AHIP advocates for public policies that expand access to affordable healthcare 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

---

[1] Pursuant to this Court's Rule 37.6, *amici* state that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amici*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. As a result, AHIP's members have intimate familiarity with the complexity of Medicaid, Medicare, and other programs, as well as the importance of public-private collaboration in the provision of healthcare coverage.

Although members of AHA and AHIP represent different interests and thus often have diverging perspectives on policy questions, they face the same uniquely challenging regulatory landscape and share concerns regarding the proper construction of the FCA, which has effectively become a healthcare enforcement statute.[2] Erroneous construction and expansion of the FCA threatens the legitimate business activities of every government contractor, hospital, healthcare provider, health insurance provider, and grant recipient in the nation, and creates tremendous and unnecessary costs and burdens for entities participating in health benefit programs sponsored by the federal government. These costs ultimately divert resources away from the primary missions of AHA's and AHIP's members: caring for patients, reducing the cost of care, and ensuring a healthy citizenry.

---

[2] *See* U.S. Dep't of Justice, Fraud Statistics (Sept. 30, 2022), https://www.justice.gov/opa/press-release/file/1567691/ (nearly 80% of 2022 recoveries—over $1.7 billion—derived from matters for which the Department of Health and Human Services ("HHS") was the primary client agency).

INTRODUCTION AND SUMMARY OF ARGUMENT

Medicare and Medicaid are vital public health programs, but they can operate only with the participation of private parties like *amici*'s members. The Centers for Medicare & Medicaid Services ("CMS") relies on public-private partnerships to deliver high-quality coverage and care through Medicare and Medicaid. The federal government and the public thus have a surpassing interest in encouraging private health insurance providers and hospitals to join these programs. This is also critical to the missions of *amici*'s members. Many are non-profits and accordingly have an obligation to serve patients through such public programs.

But private participation in these programs also demands navigating some of the most complex statutory, regulatory, and sub-regulatory requirements in existence. "[Medicaid] billing parties are often subject to thousands of complex statutory and regulatory provisions," *Univ. Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016), and the Medicare program has been variously described as a "maze," a "legislative and regulatory thicket," a "labyrinth," and "among the most completely impenetrable texts within human experience," *Clarian Health W., LLC v. Burwell*, 206 F. Supp. 3d 393, 397 & n.2 (D.D.C. 2016) (Jackson, J.) (quotation omitted), *rev'd on other grounds sub nom. Clarian Health W., LLC v. Hargan*, 878 F.3d 346 (D.C. Cir. 2017). As a consequence of this regulatory morass, participation in Medicare and Medicaid carries substantial risk of FCA suits, which inevitably result in expensive litigation, reputational harm, and the possibility

of punitive treble damages and statutory penalties. That risk falls heavily on hospitals and health insurance providers, to the ultimate detriment of patients, enrollees, and taxpayers. The FCA defense rooted in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007), is necessary to protect participants in these programs from counterproductive and unjustified suits.

A. This case does not concern FCA allegations of clear-cut factual misrepresentations or noncompliance with unambiguous program requirements. Those types of suits are of course subject to abuse and require courts to rigorously enforce the FCA's statutory elements to weed out non-meritorious claims. *See Escobar*, 579 U.S. at 192. Nevertheless, *amici* recognize that the FCA can be a useful vehicle for punishing fraudulent conduct that violates clear legal requirements and that the statute creates strong incentives for compliance by government contractors with those requirements.

Instead, this case concerns a very different type of FCA suit: one that alleges non-compliance with *ambiguous* regulatory requirements. In such cases, even if a defendant's conduct comports with an objectively reasonable construction of an ambiguous regulatory requirement, the defendant can still face FCA allegations and be exposed to punitive treble damages, statutory penalties, and reputational harm if the government or a court ultimately rejects its reasonable construction.

Compared to the majority of FCA suits, this type of FCA action carries substantially less public benefit and substantially more risk for Medicare and

Medicaid contractors. No amount of compliance efforts could independently resolve ambiguity or safeguard a hospital or health insurance provider from adopting a *reasonable* interpretation of an unclear legal obligation. Accordingly, by merely participating in Medicare and Medicaid, *amici*'s members are exposed to substantial FCA risk in the event that a court, CMS or the U.S. Department of Justice ("DOJ") later construes an ambiguous regulatory obligation in a manner contrary to their otherwise reasonable construction.

These types of suits are particularly problematic because the very compliance efforts that defendants undertake to adhere to "the most completely impenetrable texts within human experience," *Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994), can end up being used as evidence of their awareness that other interpretations were available and that their interpretation might be rejected, thereby converting the chosen reasonable interpretation into a "knowing" violation of the regulatory scheme.

B. Allowing liability to be imposed on the basis of a reasonable interpretation of ambiguous program requirements would, among other adverse ramifications, (i) punish regulated entities for engaging in good-faith internal debates and compliance activities; (ii) force entities to choose between waiving their attorney-client privilege to defend themselves at summary judgment or else facing enormous liability and reputational risk at trial; and (iii) expose regulated entities to extreme settlement pressure with respect to non-meritorious claims.

In the meantime, every dollar diverted from *amici*'s members' primary objectives harms patients and raises the costs of healthcare for all Americans. And all these adverse outcomes would be realized simply because the government agency failed to promulgate a clear and unambiguous legal requirement.

C. To date, the harmful effects of such FCA suits have been tempered because federal courts have generally embraced a complete threshold defense based on *Safeco*: where liability hinges on an interpretation of an ambiguous legal obligation, a defendant does not act with the requisite scienter if (i) its conduct comported with an objectively reasonable interpretation of that legal obligation and (ii) it was not warned away from that interpretation by authoritative guidance. *See* 551 U.S. at 69-70. That standard ensures that a defendant who adopts an objectively reasonable (even if ultimately incorrect) construction of an ambiguous regulatory scheme may raise a legal defense either on the pleadings or at summary judgment, and thus avoid the substantial adverse consequences described above. And anytime the government wants to eliminate the *Safeco* defense's availability, it need only issue authoritative guidance that eliminates the ambiguity in question.

Even the government appears to agree that the "administrative complexity" and regulatory ambiguity endemic to Medicare and Medicaid is a problem. Br. for the United States as *Amicus Curiae* ("GB") 31. But the proposed solution offered by the government and Petitioners is untenable. They suggest that the *Safeco* defense is unnecessary because regulated entities can always ask the government to clarify the meaning of an ambiguous legal obligation. In

fact, Petitioners and the United States contend that regulated entities have an *affirmative obligation* to seek such clarification to avoid FCA liability.

As an initial matter, that proposed solution inverts the ordinary relationship between government and citizens with respect to the clarification of legal obligations, raising grave concerns regarding due process and agency accountability. And to the extent the government suggests that its regulations are too voluminous and complex for the government itself to clarify them, that is an argument in favor of *Safeco*, not against it. If even the government cannot follow the complex web of regulations it has established so as to clarify them, the proposition that the regulated parties must do the government's work for it or else face FCA punishment is perverse.

But even if the government's purported "solution" to this problem were not legally dubious, it would be practically implausible. As detailed below, the experience of *amici*'s members shows that the government rarely offers responsive answers to guide regulatory compliance and often deliberately declines to provide clarity to regulated parties. Indeed, certain of *amici*'s members report that the government is so unresponsive to regulated parties' requests for clarifying guidance that they have simply stopped trying.

D. The FCA can function as intended when regulations are clear. When they are not, the *Safeco* defense is necessary in order to give effect to a basic fair-notice principle: the government should regulate clearly, in a manner that regulated parties can understand. If the government satisfied that very basic responsibility, the *Safeco* defense would never be

needed. That the government either cannot or will not do so should not result in potential exposure to massive liability for private entities working cooperatively to ensure that Medicare and Medicaid serve the public as Congress intended.

ARGUMENT

I. HEALTHCARE ENTITIES FACE AN INCREDIBLY COMPLEX STATUTORY AND REGULATORY ENVIRONMENT

This Court has repeatedly acknowledged the exceptionally convoluted nature of the legal obligations imposed by the Medicare and Medicaid statutes. The sheer number of pages of statutory and regulatory provisions governing the programs is staggering. *See, e.g.*, *Escobar*, 579 U.S. at 192 ("[Medicaid] billing parties are often subject to thousands of complex statutory and regulatory provisions"); *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (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"). Healthcare legislation, the Court has observed, is "among the most intricate ever drafted by Congress," with a "Byzantine construction" that is "almost unintelligible to the uninitiated." *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981) (quotation omitted). And time and again, the Court has recognized that the legal obligations of regulated entities participating in these programs are "complex," "technical," and "intricate." *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"); *Ill. Council*, 529 U.S. at 7-8 (referring to "a complex set of statutory provisions" within the Medicare Act); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (calling Medicare "a complex and highly technical regulatory program" (quotation omitted)); *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.").

Other courts agree. *See Clarian Health*, 206 F. Supp. 3d at 397 (observing that "the obtuse text of the Medicare statute has produced much inspired grappling among judges" and collecting cases). Courts have deemed the legal provisions governing Medicare to be a "maze," *Hall v. Sebelius*, 667 F.3d 1293, 1301 n.9 (D.C. Cir. 2012); a "legislative and regulatory thicket[,]" *Adirondack Med. Ctr. v. Sebelius*, 29 F. Supp. 3d 25, 28 (D.D.C. 2014), *aff'd sub nom. Adirondack Med. Ctr. v. Burwell*, 782 F.3d 707 (D.C. Cir. 2015), a "labyrinth[,]" *Biloxi Reg'l Med. Ctr. v. Bowen*, 835 F.2d 345, 349 (D.C. Cir. 1987), an "intricate tangle," *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 17 (D.C. Cir. 2011), and "among the most completely impenetrable texts within human experience," *Rehab. Ass'n*, 42 F.3d at 1450. As one judge vividly put it, the Medicare statute is akin to "a law written by James Joyce and edited by E.E. Cummings." *Cath. Health Initiatives-Iowa, Corp. v. Sebelius*, 841 F. Supp. 2d 270, 271 (D.D.C. 2012*), rev'd on other grounds*, 718 F.3d 914 (D.C. Cir. 2013).

The complexity does not stop there. Regulated healthcare entities must keep track of not only statutes and regulations, but also an elaborate and ever-evolving thicket of sub-regulatory guidance. CMS "estimates that it issues literally thousands of new or revised guidance documents (not pages) every single year, guidance providers must follow exactingly if they wish to provide healthcare services to the elderly and disabled under Medicare's umbrella." *Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (Gorsuch, J.). These documents often lack sufficient clarity and detail. Indeed, the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS-OIG") has on occasion reprimanded CMS for its failure to provide clear sub-regulatory guidance. *See, e.g.*, HHS-OIG, *Some MAO Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care*, OEI-09-18-00260, at 1, 20 (Apr. 2022) (rebuking CMS for providing guidance that was "not sufficiently detailed" with respect to the appropriate use of certain clinical criteria in medical necessity reviews and calling for CMS to clarify "what the Medicare Managed Care Manual means" on this point, including by providing "specific examples of criteria that would be considered allowable and unallowable"). The enormity of keeping up with this web of legal obligations is such that, in 2017, "[a]n average-sized community hospital … spen[t] nearly $7.6 million annually" to comply with federal regulations. AHA, *Regulatory Overload: Assessing The Regulatory Burden On Health Systems, Hospitals, And Post-Acute Care Providers*, at 4 (Oct. 2017). Yet even those extensive ef-

forts do not preclude *qui tam* relators and the DOJ from bringing FCA suits.[3]

Regulated entities may be ensnared in FCA litigation based on any one of their countless obligations under the various regulatory proclamations described above. And a predicate to such an FCA claim could come in any number of forms—a regulated entity could, for example, be accused of violating an obligation supposedly established by a manual later incorporated into a contract. *See, e.g.*, *United States ex rel. Osinek v. Permanente Med. Grp., Inc.*, No. 13-CV-03891-EMC, 2022 WL 16925963, at *11-13 (N.D. Cal. Nov. 14, 2022) (denying motion to dismiss FCA claim premised on purported violation of diagnosis coding guidelines incorporated by reference in a sub-regulatory manual that was in turn incorporated into a contract via a parenthetical clause, and also holding in the alternative that regulations compelled the same outcome).

Further complicating matters, agency guidance can often be contradictory, inconsistent, and ever-evolving, making reliance on governmental pronouncements perilous. *Cf. Bittner v. United States*, 143 S. Ct. 713, 722 (2023) (noting that "the government ha[d] repeatedly issued guidance to the public at odds with the interpretation it now asks us to

[3] Such suits may arise many years after a regulated entity confronting an ambiguous legal obligation has chosen one reasonable interpretation within a range of alternative interpretations. Later authoritative interpretations may resolve the ambiguity by undercutting that reasonable choice—not only requiring a change in practices, often at great cost and operational difficulty, but also catalyzing follow-on FCA litigation that threatens enormous liability and reputational harm.

adopt"). Examples of suits stemming from shifting guidance are abundant. One health equipment supplier, for instance, was subjected to an FCA suit despite "substantial confusion created by contradictory instructions and guidance" by an authority responsible for advising as to Medicare diagnosis coding systems. *United States v. Medica Rents Co.*, 2008 WL 3876307, at *3 (5th Cir. Aug. 19, 2008). And in the case that later roiled the Fourth Circuit with respect to the applicability of the *Safeco* defense, the defendant drug company faced FCA claims based on regulations that lacked "clear or consistent language" and as to which CMS had "encourage[d] [regulated entities] to make 'reasonable assumptions.'" *United States ex rel. Sheldon v. Forest Lab'ys, LLC*, 499 F. Supp. 3d 184, 210, 212 (D. Md. 2020), *aff'd sub nom. United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. 2022), *vacated on reh'g en banc*, 49 F.4th 873 (4th Cir. 2022).

Regulated entities must not only navigate a web of regulations and guidance, but also must maintain effective compliance programs and make operationally necessary choices between alternative reasonable interpretations in the face of unstable or unclear agency pronouncements. That is a herculean task—even for organizations like *amici*'s members that devote significant time and resources to rigorous compliance programs.

II. REQUIRING REGULATED ENTITIES TO SEEK CLARIFICATIONS OF AMBIGUOUS REGULATIONS FROM THE AGENCY OR ELSE FACE FCA EXPOSURE IS NOT A VIABLE SOLUTION TO THAT COMPLEXITY

The government and Petitioners contend that the solution to this immense regulatory complexity is to place the onus on regulated entities to obtain clarity from agencies in order to avoid FCA exposure. The government acknowledges the "administrative complexity of many federal funding programs" but contends that, in light of the government's "limited resources," it is the regulated entity's responsibility to "seek[] clarification" of legal obligations in order to avoid punitive liability under the FCA. *See* GB31-32. Petitioners likewise insist that FCA liability based on conduct consistent with a reasonable construction of an unclear legal obligation is appropriate because "the law places the burden on claimants seeking public funds to ensure that their claims are not false" and to "know the law" notwithstanding legal ambiguity, including agency-created ambiguity. Pet. Br. 44-45.

That proposed solution—requiring regulated entities to affirmatively seek clarification, rather than requiring the government to make legal obligations clear before seeking to impose punitive FCA liability on private entities for "knowingly" violating them—conflicts with the practical realities experienced by *amici*'s members; with foundational principles of due process and agency accountability; and with the sole precedent on which Petitioners and the government rely to justify their inversion of the ordinary relationship between the government and its citizenry with respect to clarifying legal obligations.

A. The Experience Of *Amici*'s Members Makes Clear That Placing The Burden On Regulated Entities To Seek Clarification Of Ambiguous Regulations From The Agency Would, In Practice, Be Unworkable

The experiences of *amici*'s members in attempting to obtain guidance from CMS regarding ambiguous legal obligations vividly illustrate how impracticable it is for a regulated entity to seek clarification from the relevant agency in every instance of regulatory uncertainty, and how such efforts are routinely rebuffed. Examples abound.[4]

1. *Providing non-substantive responses to inquiries regarding ambiguous obligations.* In September 2017, a health insurance provider sent a letter to CMS seeking guidance regarding a regulatory obligation that it believed CMS was enforcing without having first lawfully promulgated. CMS responded in January 2018 in a manner that failed to acknowledge the health insurance provider's quandary, instead stating generically that "CMS cannot advise [the health insurance provider] of its legal obligations under the various laws and regulations that apply to requests for payments from the Medicare Program."

CMS used similar language to deflect another health insurance provider that had sought for years to obtain clarification of ambiguous rules by providing CMS with detailed information about its compli-

[4] The underlying documents from which these examples are sourced are on file with *amici*'s counsel and will be provided upon request, accompanied where necessary by a motion to seal.

ance efforts. Rather than respond substantively or engage as to the propriety of the organization's response, CMS stated in a June 2016 email that it "cannot provide legal advice to [the health insurance provider] about whether its current or proposed courses of actions are compliant with [the] laws and obligations" to which it was subject; reiterated in a June 2020 letter that, "[t]o the extent that your communication seeks 'advice' regarding [your] legal obligations, it is not CMS's practice to modify the established legal and contractual obligations of [Medicare Advantage] organizations through informal 'advice'"; and ultimately, in lieu of providing guidance, simply directed the organization to review government briefs filed in an omnibus response in pending Medicare litigation.

2. *Failing to provide needed clarity about new rules.* In 2013, CMS promulgated a final rule changing the criteria governing when inpatient hospital admissions are appropriate for payment. AHA contacted CMS to express concerns that hospitals would not be able to operationalize elements of the new policy without significant further guidance from the agency. In a comprehensive, twenty-page letter to CMS, AHA identified and described in detail its specific concerns about the rule, set forth numerous scenarios causing concern and confusion for AHA's members, and urged the agency to issue "clear, detailed and precisely written guidance" to provide necessary clarity. *See* Letter from Linda E. Fishman, Senior Vice President, Pub. Pol'y Analysis & Dev., AHA to Jonathan Blum, Deputy Adm'r and Dir. for the Ctr. of Medicare, CMS 1 (Sept. 18, 2013), https://www.aha.org/system/files/media/file/2023/03/

aha-urges-cms-to-issue-subregulatory-guidance-on-the-inpatient-admissions-and-review-criteria-finalized-in-fy-2014-hospital-inpatient-pps-final-rule-9-18-13.pdf. AHA further offered to begin discussions with CMS to develop a long-term workable solution. *Id.* at 3.

CMS responded to AHA's inquiry with a document providing three sparse answers to "frequently asked questions," but did not address any of its specific concerns, engage with the numerous scenarios laid out in AHA's submission, or provide further guidance regarding how AHA's members could appropriately operationalize ambiguous elements of the rule. *See* Letter from Marilyn Tavenner, CMS Adm'r to Rich Umbdenstock, President and CEO, AHA (Sept. 26, 2013), https://www.aha.org/system/files/media/file/2023/03/cms-to-aha-regarding-issuing-a-clarification-modification-to-cms-inpatient-hospital-policy-letter-9-26-2013.pdf. Nor did CMS accept AHA's offer to discuss long-term solutions. *See id.* The agency merely suggested that it would provide additional guidance to providers in the future. *Id.* at 1.

Several years later, AHA faced similar challenges in seeking clarity from CMS regarding a new rule governing Medicare payment disbursement. In 2017, after failing to obtain a response from CMS to many phone calls and emails requesting guidance regarding hospitals' eligibility for an exception to the rule, AHA wrote a letter to CMS expressing its concern that many hospitals were unsure of their eligibility and had tried to obtain further clarity on the issue to no avail. AHA asked CMS to provide clarity by notifying hospitals via Medicare Administrative

Contractors as to whether they qualified. Yet CMS never provided the requested clarity or even responded to AHA's letter. In fact, CMS took until 2021 to release results of an audit of hospitals' eligibility for the exception, with a staggering percentage failing to qualify. CMS ultimately implemented a reconsideration process, all while failing to engage with AHA's renewed requests for clarity and guidance on the issue. *See* AHA, *Special Bulletin: CMS to Review Mid-Build Exception Audit Determinations for Hospitals that Failed to Qualify* (Sept. 10, 2021).

3. *Failing to provide diagnosis coding guidance.* CMS routinely brushes aside requests from regulated entities to clarify ambiguous diagnosis coding requirements in connection with the Medicare program.[5]

In a July 2019 email exchange, for instance, a health insurance provider and AHIP member reached out to CMS to obtain Medicare coding guidance. CMS responded by stating that "CMS is unable to respond to individual requests for interpretation of coding guidance" and is "unable to provide guidance on the coding practices of providers." It instead referred the health insurance provider to generic coding resources.

Similarly, in a November 2015 email exchange, a coding consultant contacted CMS multiple times regarding industry confusion about the Medicare standards for diagnosis coding of chronic medical conditions. A CMS official eventually responded by

---

[5] These diagnosis coding requirements have repeatedly served as the basis for FCA actions. *See, e.g.*, *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1166 (9th Cir. 2016).

refusing to provide an interpretation, stating that CMS "cannot provide any additional guidance," and instead referred the consultant to generic "CMS coding resources." The consultant, in turn, emphasized that insurance providers "want[] to do the right thing" and that the lack of "concrete directions" makes that difficult, particularly when "the industry and the professional organizations cannot get on the same page."

In yet another example, in a 2011 email exchange, a healthcare company repeatedly contacted CMS auditors requesting guidance on interpretation of a diagnosis coding guideline. After months of failing to respond, CMS ultimately refused to provide any guidance, instead stating "CMS is unable to respond to individual requests for interpretation of … coding guidelines."

4. *Forcing regulated entities to take extraordinary steps to obtain pathways for guidance.* A high-profile FCA settlement reached in February 2023 included, as part of the agreement between DOJ, HHS-OIG, and healthcare and health insurance provider UPMC, a procedure for UPMC to seek clarification regarding the billing regulations at issue. That provision was necessary, one of the defendant's lawyers explained, because "[m]edical schools and their hospitals ha[d] sought clarity about the billing regulation … for years, and the United States has never provided it." John Commins, *UPMC Will Pay $8.5M to Settle False Claims Allegations*, HealthLeaders (Feb. 27, 2023). Accordingly, one of the purposes of the settlement was to "provide[] a mechanism" that could "lead to authoritative guidance" on the issue. *Id.* Absent these extraordinary measures—including

agreeing to settle an FCA action for millions of dollars—obtaining clarification of the requirement directly from CMS would not have been possible. *See id.*

* * *

Published decisions further illustrate the real-world impracticality of placing an affirmative duty on regulated entities to seek clarity from CMS. In *Sheldon*, for example, the Fourth Circuit emphasized that prescription drug manufacturers were not "taking advantage of CMS's silence"; on the contrary, in an HHS-OIG report, "almost two thirds reported a desire for additional guidance" on the regulatory ambiguity in question. 24 F.4th at 355. "Facing these requests," however, "CMS demurs," and in fact "specifically instructs manufacturers not to submit their assumptions to the agency, and states that if a manufacturer does so, CMS will not review the assumptions." *Id.*; *see id.* at 356 (emphasizing that CMS had "resist[ed] attempts to get it to clarify its view"); *see also, e.g.*, *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518 (6th Cir. 2012) (outside counsel for regulated entity asked CMS to confirm its interpretation of legal obligation, but received no response; in the course of ensuing FCA litigation, the government initially denied receiving the request for clarification before ultimately producing the document in question).

These are not isolated examples; to the contrary, the government's inability or unwillingness to clarify deep ambiguities in its own Medicare and Medicaid regulations is commonplace and longstanding. Indeed, certain of *amici*'s members report that the pre-

vailing view for at least a decade, after years of failed attempts to request clarity or guidance from CMS regarding ambiguous legal obligations, is that any such effort is now essentially futile. The fact that these members have simply given up after years of trying illustrates the complete implausibility of the government's proposed solution in this case.

B. Not Only Is Such An "Affirmative Duty" For Regulated Entities Profoundly Impractical, But It Also Inverts Due Process Principles Without Legal Foundation

1. It is the quintessential promise of the Due Process Clause that "a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed." *McBoyle v. United States*, 283 U.S. 25, 27 (1931). When "innocent mistakes made in the absence of binding interpretive guidance are … converted into FCA liability," "potential due process problems" result because such liability would "penaliz[e] a private party for violating a rule without first providing adequate notice of the substance of the rule." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) (quotation omitted).

Closely intertwined with this problem is the fact that, "[w]hether purposeful or not, the agency's failure to write a clear regulation winds up increasing its power." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2440-41 (2019) (Gorsuch, J., concurring in the judgment). It is thus a critical principle of agency accountability that regulators are obliged to issue clear guidance defining the legal requirements imposed on regulated parties—and to affirmatively provide additional guidance when necessary—before subjecting regu-

lated entities to punitive liability for violations of those requirements. A contrary rule would allow the agency to exploit ambiguity to expand regulatory power, with significant implications for the separation of powers and individual liberty. *See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 499 (2010) ("The growth of the Executive Branch, which now wields vast power and touches almost every aspect of daily life, heightens the concern that it may slip from the Executive's control, and thus from that of the people.").

2. The sole authority proffered by the government and Petitioners for contravening those foundational principles of fair notice and agency accountability is this Court's decision in *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51 (1984), which they argue supports a reversal of the ordinary allocation of the burden of establishing the clarity of legal obligations whenever an entity seeks money from the government. *See* GB31-32; Pet. Br. 44-45. That case cannot bear the weight that the government and Petitioners place on it.

Heckler was not a False Claims Act case. It instead concerned the circumstances under which the government could be estopped from recouping erroneously disbursed funds obtained by a Medicare contractor, a home healthcare services provider, in reliance on representations made by the government's agent as to the proper interpretation of regulations governing its entitlement to the funds. In *that* context, *Heckler* emphasized that public interest concerns militated against permitting estoppel to run against the government and then reasoned that—in order to render the provider's reliance on the errone-

ous interpretation so reasonable as to estop the government from reclaiming the funds—the provider would have had to "obtain[] an interpretation of the applicable regulations" from an authoritative source. 467 U.S. at 60-61, 64.[6]

Heckler's reasoning arose in the estoppel context: where a private party hoped to leverage estoppel against the government to prevent the recoupment of funds to which the government was otherwise entitled, the Court found it logical to place the burden of seeking clarification of ambiguous legal obligations on that party. But the opposite is true where, instead, the government seeks to impose FCA liability, which is "essentially punitive in nature." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000); *accord Escobar*, 579 U.S. at 182 (referencing FCA's "essentially punitive … nature" (quoting *Stevens*, 529 U.S. at 784)); *cf. Wooden v. United States*, 142 S. Ct. 1063, 1082, 1086 n.5 (2022) (Gorsuch, J., concurring) ("The 'rule of lenity," which "counsels that 'penal laws should be construed strictly,'" "[h]istorically" applied to all "laws inflicting any form of punishment, including ones we might now consider 'civil' forfeitures or fines." (citations omitted)). Instead, "[w]here the imposition of penal sanctions is at issue," due process "prevents … the application of a regulation that fails to give fair warning of the conduct it prohibits or requires." *Gates & Fox Co. v. Occupational Safety & Health Rev. Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986)

[6] The Court even acknowledged that it may not have actually been possible for the provider to do so, *see id.* at 65 n.22, and concluded only that, absent such a definitive interpretation, estoppel could not run against the government.

(Scalia, J.); *see also United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 955 (10th Cir. 2008) (distinguishing *Heckler* as arising "in the context of a contractor's assertion of an equitable estoppel claim against the government").

Beyond that narrow holding in the estoppel context, *Heckler* refers only to a generalized obligation to "turn square corners" when dealing with the government and a broad "duty to familiarize" oneself "with the [applicable] legal requirements" to participate in Medicare. 467 U.S. at 63-64 (quotation omitted). Those unremarkable propositions—that Medicare contractors should act with propriety and should not seek government funds in total ignorance of their obligations under the program—are a far cry from the imposition of an affirmative duty to obtain definitive interpretations of legal obligations that courts have concluded were ambiguous in order to avoid punitive liability under the FCA.

Heckler thus imposes no "affirmative duty" on regulated entities of the type the government and Petitioners envision here. While the government and other *amici* repeatedly emphasize that the complexity of federal programs is such that the burden of clarifying them is too "onerous" and resource-intensive for the government to bear, *see Amicus* Brief of Sen. Charles E. Grassley ("Grassley Br.") 17; GB31-32, those protestations only underscore the inequity of shifting that burden onto a regulated entity as a prerequisite for avoiding penal sanctions, particularly in light of the practical difficulties detailed above.

III. ELIMINATING OR WEAKENING THE *SAFECO* DEFENSE TO FCA ACTIONS WOULD RESULT IN UNTENABLE CONSEQUENCES

Given this background of regulatory complexity—which, contrary to the suggestion of the government and Petitioners, cannot be readily resolved by requiring the regulated party to seek clarity from the agency—the *Safeco* defense is essential in the FCA context. Eliminating or weakening that defense would have severe ramifications for *amici*'s members and, in turn, for the beneficiaries of government benefit programs that depend on their participation.

1. Without a *Safeco* defense, *amici*'s members will be unfairly penalized for engaging in good-faith compliance efforts and internal discussions about the meaning of ambiguous requirements, which are inevitably necessary to navigate the complex regulatory environment in which they operate. Absent *Safeco*, evidence stemming from such internal debate could be later leveraged against the regulated entity in an FCA suit. *See, e.g.*, *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1156 (11th Cir. 2017) (scrutinizing internal emails regarding compliance issues in an effort to identify evidence that defendants' "employees believed or had reason to believe they were violating Medicare regulations" or that a reasonable interpretation had been "manufactured post hoc"); *United States ex rel. Walker v. R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1358 (11th Cir. 2005) (holding that a company's internal communications, including notes of conversations between an employee and a Medicare billing consultant in which the employee sought advice about an ambiguous legal obligation, were relevant to the

meaning of the Medicare regulation at issue and defendant's understanding of that meaning).

But *amici*'s members cannot decline to engage in efforts to interpret ambiguous regulations through reasoned deliberation: if regulated entities were to refrain from engaging in these debates and compliance initiatives, they would risk being deemed "willfully blind" or acting in "deliberate ignorance" in violation of the FCA, 31 U.S.C. § 3729(b)(1)(A). *See* Grassley Br. 10 ("A person can be deliberately ignorant … if that person might have uncovered an interpretation that was 'reasonable' if she had looked. Proof that a defendant consciously chose to avert her gaze, without more, establishes deliberate ignorance."). It strains credulity to imagine that Congress, in drafting the FCA's scienter provision, intended to place regulated entities in that untenable, "Catch-22"-style quandary.

2. Stripping *amici*'s members of the *Safeco* defense would create the further problem of forcing them to choose between facing enormous liability and reputational risk at trial or else waiving their attorney-client privilege to introduce evidence in their defense at summary judgment. While not all compliance decisions involve privileged attorney-client communications or work product, this problem would nevertheless frequently arise. For example, in order to counter false allegations that their reasonable interpretations of ambiguous legal obligations were merely bad-faith, post-hoc rationalizations that were not contemporaneously held at the time of the conduct in question, defendants in many cases would have little choice but to introduce privileged communications documenting the development of their in-

terpretations. And that is especially so in the all-too-common situation where one or more *non*-privileged communications, taken in isolation, could plausibly be construed by a jury as signaling bad faith. The lost context is most likely to be provided in privileged communications—after all, most analysis of regulatory ambiguity will be in the form of legal advice sought or given—so if defendants are required to provide that crucial context to defend against FCA suits, privilege waiver will often be the most likely solution.

This Court should not countenance that forced incursion on the attorney-client relationship. *See Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 108 (2009) (emphasizing "the importance of the attorney-client privilege" and its "assur[ance] [of] confidentiality," which "encourages clients to make full and frank disclosures to their attorneys" (quotation omitted)). As this Court has noted, "[i]n light of the vast and complicated array of regulatory legislation confronting the modern corporation," the necessity for ongoing legal advice is a paramount concern of regulated entities, "particularly since compliance with the law in this area is hardly an instinctive matter." *Upjohn Co. v. United States*, 449 U.S. 383, 392 (1981) (citation omitted). The privilege exists to encourage those efforts at legal compliance; a regime in which confidentiality and candor must be sacrificed because of concerns about unjustified exposure of privileged communications will help no one.

3. Furthermore, disallowing the *Safeco* defense—by eliminating a key pleadings and summary judgment stage defense that is capable of consistent application by courts—would expose regulated entities

to significant settlement pressure, even for non-meritorious FCA claims. That pressure mounts because of the enormous exposure inherent in FCA trials, where damages are trebled, civil penalties can be awarded for each allegedly false claim for payment, and reputational harm is all but inevitable. Steep defense costs and the possibility of an adverse decision resulting in collateral consequences such as debarment or exclusion from participation in federal healthcare programs further raise the stakes and contribute to the inexorable drive toward settlement. *See, e.g.*, 42 U.S.C. § 1320a-7 (authorizing HHS-OIG to impose exclusion from federal healthcare programs); *see also* David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen,"* 30 J. Legal Stud. 531, 552 (2001) (noting that healthcare "[p]roviders who believe they are blameless" are nevertheless "under tremendous pressure to settle," including due to "the high probability of bankruptcy and professional disgrace if the jury does not see things the same way the provider does.").[7]

---

[7] Settlement pressure and litigation costs are exacerbated not only by the FCA suits in which the government chooses to participate, but also by the many frivolous lawsuits in which the government declines to intervene—suits brought by *qui tam* relators unburdened by the obligation to exercise prudent judgment. *See Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("[R]elators are … less likely than is the Government to forgo an action arguably based on a mere technical noncompliance with reporting requirements that involved no harm to the public fisc."). Such cases, though often baseless, are nevertheless expensive and burdensome to defend, frequently producing settlements irrespective of their merit.

Coerced settlements, in turn, deplete funds that would otherwise have been devoted to providing Americans with high-quality and affordable patient care. *See, e.g.*, Joan H. Krause, "*Promises to Keep": Health Care Providers and the Civil False Claims Act*, 23 Cardozo L. Rev. 1363, 1368 (2002) (excessive use of the FCA "divert[s] resources away from the goal of providing high-quality medical care to program beneficiaries"). These costs—which provide no value to the public, while enriching *qui tam* relators—thus ultimately harm consumers, as do the enormous administrative and litigation expenses that inevitably accompany FCA litigation.

Settlement pressure can be especially acute for hospitals, many of which operate on such thin margins that defending against an FCA suit could be potentially ruinous. That precarious situation has been compounded by the additional financial strain caused by the COVID-19 pandemic. *See National Hospital Flash Report: January 2023*, Kaufman Hall (Jan. 30, 2023) (reporting that 2022 was "the worst financial year for hospitals and health systems since the start of the COVID-19 pandemic," with approximately half of all U.S. hospitals finishing 2022 with a negative operating margin).

4. These harmful consequences are especially problematic because many regulated entities participate in government benefit programs as part of their obligations as tax exempt entities. While "hospital participation in Medicare and Medicaid is voluntary, … as a condition for receiving federal tax exemption for providing healthcare to the community, not-for-profit hospitals are required to care for Medicare and Medicaid beneficiaries." AHA, *Fact Sheet:*

Underpayment by Medicare and Medicaid (Feb. 2022). Nearly half of all U.S. hospitals fall into this non-for-profit category and thus must participate in Medicare and Medicaid to retain their federal tax exempt status. *See* AHA, *Fast Facts on U.S. Hospitals* (2022). Moreover, "Medicare and Medicaid account for more than 60 percent of all care provided by hospitals." AHA Fact Sheet, *supra.* Accordingly, even if they could, very few hospitals would elect not to participate in these programs. The government's suggestion that the troubling consequences detailed above are simply part of the cost that comes with freely choosing to do business with the government, *see* GB31-32, cannot be squared with the realities of regulated entities' experiences with federal programs, which in any event could not function without robust private party participation.

* * *

Eliminating the *Safeco* defense to FCA actions would unfairly burden *amici*'s members, undermine the trust necessary for effective public-private partnerships, and impose excessive and unnecessary expenses on healthcare organizations and health insurance providers alike. Undercutting these public-private partnerships would, in turn, hinder the public's access to high-quality care that has consistently produced favorable consumer satisfaction and cost-effectiveness metrics. *See, e.g.*, AHIP, *Americans Agree: Protect Medicare Advantage* (Feb. 2023), https://ahiporg-production.s3.amazonaws.com/documents/020923-MA-Cuts-By-The-Numbers.pdf (reporting 93% satisfaction and an average value of $2,000 in extra benefits for Medicare Advantage enrollees). The ultimate cost of hindering the im-

portant missions of *amici*'s members would be borne by patients and the American public as a whole.

IV. LIMITING THE ESSENTIAL *SAFECO* DEFENSE IS UNNECESSARY GIVEN ITS ALREADY-RESTRICTED DOMAIN

The only way to avoid these adverse consequences in the context of ambiguous legal requirements is the *Safeco* defense to FCA liability. Adopting a moderated form of the *Safeco* defense instead of the version endorsed by the Seventh Circuit would be both ineffective and unnecessary.

A. Adopting The *Safeco* Defense For The FCA In The Form Embraced By The Seventh Circuit Is The Only Way To Avoid Adverse Consequences

Petitioners and the dissenting judge below, in their efforts to discredit the Seventh Circuit's formulation of the *Safeco* defense, have emphasized the supposedly incendiary evidence that could be excluded from the scienter inquiry under that approach. *See, e.g.*, Pet. Br. 53 (decrying the exclusion of potential evidence indicating that a defendant "was actually on notice" that its reasonable interpretation was incorrect (emphasis omitted)); *United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649, 665, 667, 670 (7th Cir. 2022) (Hamilton, J., dissenting) (criticizing majority for rendering irrelevant supposedly "egregious" evidence of "*post hoc* rationalizations"). This Court should not be swayed by that misguided emphasis on so-called "bombshell evidence," even assuming the existence of a case that, once all evidence was placed in proper context, involved a true "smoking gun."

Any attempt to carve out an exception to the *Safeco* rule making evidence of subjective intent categorically irrelevant in the narrow circumstances just described would be unworkable—and would ultimately result in the same adverse consequences as if *Safeco* were eliminated entirely. For one thing, crafting a coherent exception to *Safeco* would be effectively impossible. The evidence of subjective intent in cases like this is simply that the defendant considered but ultimately rejected one reasonable interpretation of a regulation in favor of another. If the defendant's subjective intent is relevant, then it is difficult to craft a rule that would deem some such evidence relevant but other such evidence irrelevant. And even if the Court could craft a limited exception permitting certain categories of supposedly highly probative evidence of subjective intent, such a carve-out would open the floodgates to meritless FCA litigation and force courts into a line-drawing exercise that no court could effectively administer. In that scenario, *Safeco*'s effectiveness would be gutted, since it would become in practice impossible to adjudicate the defense on the pleadings or at the summary judgment stage.

B. *Safeco*'s Reach Is Already Limited, So It Does Not Need To Be Cabined Further

1. For the reasons described above, the *Safeco* defense is essential—but only in the particular segment of FCA cases at issue here: those that involve (i) a claim of legal falsity that (ii) stems from an ambiguous legal obligation, for which (iii) the defendant adopted an objectively reasonable obligation and (iv) was not warned away from that obligation by authoritative guidance. *Safeco* has no role to play

when the basis of FCA liability turns on a factual misrepresentation; when the legal obligation is clear; where the defendant's interpretation is not objectively reasonable; or when authoritative guidance existed to steer the entity in the right direction. Those broad limitations confine the *Safeco* defense to its proper role as a threshold legal screen so that FCA litigation does not needlessly proceed down complicated factual pathways in cases that involve genuine quandaries for the regulated party.

Further tempering *Safeco*'s reach is the government's ability to eliminate the availability of the defense simply by issuing clear and unambiguous program guidance. Even if it has not initially done so, the government can at any time take the affirmative step of "warning away" government contractors from their otherwise reasonable but ultimately erroneous interpretations by issuing further authoritative guidance.

2. *Safeco*'s impact is also cabined by the government's ample alternative mechanisms for recouping improperly remitted funds and punishing negligence or wrongdoing. The government does not need to rely on the blunt tool of the FCA in every case to accomplish the goal of combatting improper government payments, breaches of contract, or even fraud.

Robust audit programs and enforcement and penalty mechanisms already exist to prevent and detect violations of federal program requirements. 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 U.S.C. § 1395gg (recovery of overpayment); 42 C.F.R. § 405.371 (recoupment); 42 U.S.C. § 1320a-7 (program exclusion); 42 C.F.R. § 488.430 (civil monetary penalties).

Finally, the FCA has diminished importance as a spur to compliance efforts in the category of cases at issue here. While the risk of FCA exposure can in some cases create strong compliance incentives in light of the draconian penalties at stake, compliance procedures cannot by themselves resolve an inherent ambiguity in a regulatory regime or preclude adoption of an objectively *reasonable* construction. Given the alternative tools available to the government and the reduced functionality of the FCA with respect to the sole category of cases to which the *Safeco* defense is applicable, the notion that recognizing the *Safeco* defense would meaningfully detract from the government's ability to recoup funds and fight fraud rests on a false premise.

CONCLUSION

For the foregoing reasons, the judgments of the court of appeals should be affirmed.

Respectfully submitted,

Madhu Pocha
O'MELVENY & MYERS LLP
1999 Avenue of the Stars
Los Angeles, CA 90067
(310) 553-6700

Anton Metlitsky
O'MELVENY & MYERS LLP
7 Times Square
New York, N.Y. 10036
(212) 326-2000

Michael R. Dreeben
Counsel of Record
Amanda M. Santella
Jenya Godina
Danielle Siegel
O'MELVENY & MYERS LLP
1625 Eye Street, N.W.
Washington, D.C. 20006
(202) 383-5300
mdreeben@omm.com

Attorneys for Amici Curiae

March 2023