Nos. 21-1326, 22-111

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA, ET AL.,
EX REL. TRACY SCHUTTE & MICHAEL YARBERRY
Petitioners,

v.

SUPERVALU, INC., ET AL.,
Respondents.

UNITED STATES, EX REL. THOMAS PROCTOR,
Petitioner,

v.

SAFEWAY, INC.,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Seventh Circuit

RESPONDENTS' BRIEF

ROBERT N. HOCHMAN
TACY F. FLINT
JAIME L.M. JONES
CLAIRE G. LEE
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603

TYLER J. DOMINO
SIDLEY AUSTIN LLP
787 Seventh Ave.
New York, NY 10019

CARTER G. PHILLIPS*
KWAKU A. AKOWUAH
JOSHUA J. FOUGERE
JILLIAN S. STONECIPHER
ADAM KLEVEN
LAKEISHA F. MAYS
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
cphillips@sidley.com

Counsel for SuperValu, Inc., et al. & Safeway, Inc.
* Counsel of Record

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QUESTION PRESENTED

Whether the court of appeals correctly held that a defendant does not "knowingly" submit a false or fraudulent claim, within the meaning of the False Claims Act, when (a) the alleged falsity turns on an alleged legal (not factual) error, (b) the legal standard applicable to the claim was ambiguous, (c) the defendant's conduct was consistent with an objectively reasonable interpretation of that ambiguous legal standard, and (d) at the time of the claim, no authoritative guidance warned the defendant away from its objectively reasonable course of conduct.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, respondents state as follows:

Albertsons Companies, Inc. ("ACI") is the ultimate parent company of the following respondents:

- AB Acquisition LLC
- Acme Markets, Inc.
- Albertson's LLC
- American Drug Stores LLC
- Jewel Food Stores, Inc.
- Jewel Osco Southwest LLC
- New Albertsons L.P. (formerly New Albertson's, Inc.)
- Safeway Inc.
- Shaw's Supermarket, Inc.
- Star Markets Company, Inc.

ACI is a publicly traded company on the New York Stock Exchange trading under the ticker ACI. As of the date hereof, Cerberus Capital Management, L.P has beneficial ownership of at least 10% of ACI's stock.

United Natural Foods, Inc. ("UNFI") is the parent company of respondent Supervalu Inc. UNFI is a publicly traded company on the New York Stock Exchange trading under the ticker UNFI. As of the date hereof, BlackRock, Inc., a publicly traded company on the New York Stock Exchange trading under the ticker BLK, owns 10% or more of UNFI's stock.

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INTRODUCTION

When the government fails to speak clearly, a regulated party cannot "know" what the law requires.

Relators and the government seek to brush away that pivotal feature of this case. This is not a case about a regulated party misrepresenting or ignoring ascertainable facts that it either knows or could know. Instead, at issue here is the narrow category of False Claims Act (FCA) cases in which "falsity turns on a disputed interpretive question." *United States ex rel. Purcell* v. *MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015). In these consolidated cases, both courts below determined that the applicable legal standards, relating to Medicaid and Medicare reimbursement for prescription drug purchases, were unclear and that respondents' conduct was objectively reasonable in light of that ambiguity.

Ambiguity arose because Congress declined to adopt any statutory standard for determining prescription drug reimbursement rates. In the mid-1970s, the predecessor to the Department of Health and Human Services (HHS) issued a regulation that, without further detail, authorized pharmacies to seek reimbursement from the government for the "usual and customary charge to the general public." Despite the patent ambiguity of that phrase, HHS has never authoritatively explained how a pharmacy should determine the "usual and customary charge to the general public" in the very common situation where the pharmacy provides discounts to some but not all drug purchasers. Into the breach stepped a hodgepodge of courts, government agencies, and industry stakeholders, overwhelmingly indicating that whatever "usual and customary" (U&C) meant, it did not mean that

all discounts to any buyer had to be offered to Medicaid and Medicare.

For years, respondents treated the undiscounted retail price as their U&C price. They did so openly. Respondents, like other Medicaid and Medicare participants, are subject to government and government-authorized audits. During the relevant periods, the government, states, and Medicare Part D plans audited respondents literally *thousands* of times without the government once raising any concern about respondents' U&C price reports. Only in 2016, five years after the complaints against respondents were filed, did a single court of appeals adopt the interpretation under which respondents' reimbursement claims were later deemed incorrect, and thus "false."

That is the backdrop of this case. Against it, the court of appeals held that, where the relevant law is unclear and the defendant acts reasonably, regulated parties are not subject to the breathtaking treble damages and per-claim penalties—which could stack well into the billions here—that the FCA prescribes as automatic punishment. That conclusion was correct.

Relators and the government contend otherwise by equating a private party's statements regarding unresolved legal ambiguity with a private party's statements regarding facts that the party can verify.

The FCA's text, this Court's precedents, and the common law all reject that approach. The statute defines "knowingly" to encompass mental states from actual knowledge to reckless disregard. In *Safeco Insurance Co. of America* v. *Burr*, this Court confronted the same scienter spectrum and held that a regulated entity cannot be a "knowing or reckless violator" when it conducts itself consistent with an objectively

reasonable interpretation of ambiguous legal obligations. 551 U.S. 47, 70 n.20 (2007). The FCA's text also specifies what must be known: "information." That key term, ignored by relators and the government, points to objectively discernible and falsifiable facts. When the government leaves the law ambiguous, it deprives regulated parties of the "information" needed to "know" one's legal obligations. *Safeco* also describes how "common law" and "history" have drawn indelible lines within which reasonable actors do not knowingly or recklessly violate the law, "whatever their subjective intent may have been." *Id.* at 69-70 & n.20.

All of this authority comports with the foundational due process principle that punishment cannot be imposed on entities who lacked fair notice of the law's requirements. The Solicitor General contends—astonishingly—that fair-notice protection "does not apply to those who request federal funds." U.S. Br. 31. But this Court has already made clear that "strict enforcement" of the FCA's "rigorous" "scienter requirement[]" is critical to provide "fair notice" and protection against "open-ended liability." *Universal Health Servs., Inc.* v. *United States ex rel. Escobar,* 579 U.S. 176, 192 (2016).

Nothing about this case threatens the government's ability to ensure compliance with the law. Regulators can bring enforcement or regulatory proceedings, breach of contract claims, or other actions that allow the government to recoup overpayments. The FCA has nothing to say about any of that; it is *not* an "all-purpose antifraud statute" or "garden-variety" regulatory enforcement tool. *Id.* at 194. Applying *Safeco* helps hold the FCA within its proper bounds. It prevents self-interested relators and the government from converting ordinary, longstanding, openly ob-

served conduct in the face of legal ambiguity into *punitive* liability under the FCA. Their position, not respondents', would "turn[] the law on its head." Pet'r Br. 4. The Court should affirm.

STATEMENT

I. FACTUAL BACKGROUND.

A. Respondents' Prescription Drug Prices.

SuperValu and Safeway are nationwide grocery chains that operate pharmacies. Both companies establish retail prices for prescription drugs which they offer to customers who pay with cash, rather than through insurance. For a number of years, both companies had programs aimed at helping uninsured and underinsured customers afford prescription drugs.

1. One was price matching. If a customer asked a pharmacist, the pharmacy would match prices offered by a local competitor. The customer initiated by identifying a nearby competitor offering a lower price. The pharmacist then contacted the competitor to verify the price, and would match only upon receiving verification. See JA2, 60-65, 203-05.

SuperValu began price matching in the 1980s, and Safeway started two decades later. JA2, 40-41, 203-05. Eventually, competitors began to refuse to verify their prices, and pharmacists could not match them. JA62. Many SuperValu chains ended price matching in 2013, and all ended the practice by December 2016. JA2. Safeway stopped matching prices in July 2015. JA203.

2. The other program involved discounts made available to pharmacy club members. Certain Safeway divisions had membership clubs starting in 2008, which provided discounts to members who opted to

enroll. JA203-04. Qualifying customers could enroll by submitting a form and providing certain personal information. *Proctor* Dkt. 178-3. Enrolled members received various discounts on their prescriptions. JA207. Safeway ended its membership program in 2015.

3. The individualized discounts available at the companies' pharmacies were, by definition, exceptions to the undiscounted retail price offered to cash-paying customers. These discounts made up a small percentage of the companies' overall business. JA65; SJA270-74. From 2006 to 2016, price matches amounted to 1.7% of SuperValu's drug sales, and 26.6% of total cash sales. JA30; *Schutte* Dkt. 164-15 at 8. For SuperValu's top-20 selling drugs, price matches represented less than half of cash sales during the relevant timeframe. *Schutte* Dkt. 164-15 at 8.

Safeway's numbers are similar. Price matches amounted to only 1.4% of its overall sales from 2006 to 2015, and 17.6% of cash transactions in that time. *Proctor* Dkt. 176-21 at 7. Membership club transactions amounted to 2% of overall sales during the relevant period, and 26.9% of cash sales. *Id.* Together, discounts applied to 3.3% of overall sales and less than half of cash sales. *Id.*; JA228, 237.[1]

B. Usual and Customary Prices.

A pharmacy's U&C prices are subject to various definitions and rules under different sources of law.

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[1] Relators assert that "discounted sales constituted a majority of its cash sales," Pet'r Br. 8, but they get there by combining "Club Card Sales" and "override Sales," the latter of which included but was not limited to price matches. Relators' expert did the same for the top 20 generic drugs. *See Proctor* Dkt. 176-21, at 7, 9-10. The government similarly relies on cherry-picked datasets. *See* U.S. Br. 5. The relevant statistics are above.

1. U&C Charges Under Medicaid.

Medicaid offers healthcare coverage to low-income individuals. Each state administers its own Medicaid program. Provided the state's program meets the Medicaid Act's requirements, the federal government pays the state back a portion of the total amount the state expended under its Medicaid plan. See *Ark. Dep't of Health & Hum. Servs.* v. *Ahlborn*, 547 U.S. 268, 275 (2006).

a. Federal law allows states to offer outpatient prescription-drug coverage through Medicaid plans. 42 U.S.C. § 1396d(a)(12). Congress did not establish a payment structure, instead authorizing HHS to issue regulations regarding state Medicaid agencies' payments for prescription drugs. *Id.* §§ 1302 and 1396r-8.

HHS's predecessor adopted the current version of its regulation in 1975. Pharmacies may charge "the lower of the cost of the drug … plus a dispensing fee established by the State, or the provider's usual and customary charge to the general public." 40 Fed. Reg. 34,516, 34,519 (Aug. 15, 1975). The "usual and customary" language has remained virtually unchanged for nearly 50 years. 42 C.F.R. § 447.512(b)(2).

Throughout that time, HHS has kept mum about the meaning of operative terms. HHS did not comment on the adoption of "usual and customary" in 1975 and has not commented on or defined it in subsequent Medicaid regulations. *E.g.*, 43 Fed. Reg. 45,176 (Sept. 29, 1978); 72 Fed. Reg. 39,142 (July 17, 2007). HHS also has not defined "the general public," and has actually refused requests to do so in related contexts. 72 Fed. Reg. at 39,164 (discussing 42 C.F.R. § 447.504).

b. States, on the other hand, sometimes do address the meaning of U&C through state Medicaid plans

submitted to and approved by the Centers for Medicare & Medicaid Services (CMS), 42 U.S.C. § 1396-1; 42 C.F.R. § 447.518 (a)(1), as well as statutes, regulations, and subregulatory guidance. These layers of authority often result in complex and sometimes internally inconsistent U&C schemes.

Illinois is a good example. Four different sources identify four different standards for determining the U&C price. See App. A. 10a-14a. One says to look to the price charged to a "non-third-party payor," *id.* 10a; another, the "general public"—without defining that term, *id.* 11a; another, a "special discount group," *id.* 10a; and another, "cash customers," *id.* 12a. These sources are all over the place, and yet none of them addresses how pharmacies should treat individualized price-match or membership club discounts.

Other states define U&C differently, and definitions have evolved over time. For example, Massachusetts—a state not at issue—defined U&C in a way that plainly excluded discounts extended to *cash*-paying customers through price matching and membership clubs until 2009. JA42-44. It defined U&C as "the lowest price that a pharmacy charges or accepts *from any health insurer or PBM* … on the same date of service." JA42 (emphasis added). Then, in 2009, Massachusetts deleted the above definition from its state plan and adopted a new one: "[t]he lowest price that a provider charges or accepts from *any payer* … on the same date of service." *Id.* "[A]ny payer" would presumably capture cash-paying customers.

c. This case concerns claims submitted to Medicaid programs in California, Delaware, Hawai'i, Illinois, Montana, New Jersey, New Mexico, Nevada, Utah, Virginia, Washington, and the District of Columbia. Several of these states had no definition of U&C

price. See App. A (detailing state statutes and regulations). Others had varying definitions of "usual and customary" in various sources. See *id.* Some addressed "discounts" in one way or another, but none addressed discounts available to cash-paying customers through price matching or membership programs during the relevant period. See *id.*

2. U&C Charges Under Medicare Part D.

Medicare Part D provides optional coverage for prescription drugs to Medicare-eligible individuals. To do so, CMS contracts with private insurers who serve as Medicare Part D plan sponsors. Minority Staff of the U.S. Sen. Comm. on Fin., *A Tangled Web: An Examination of the Drug Supply and Payment Chains* vii, 35 (June 2018) ("*Tangled Web*"). Sponsors typically contract with private pharmacy benefit managers (PBMs) to administer Medicare Part D. *Id.* at vii. PBMs then negotiate contracts with individual pharmacies that set prescription drug reimbursement rates. *Id.*

a. If a pharmacy does not have a contract with a sponsor (directly or through a PBM), the pharmacy is "out-of-network." In that case, the sponsor or PBM unilaterally decides what to pay the pharmacy, and federal Medicare regulations limit the beneficiary's out-of-pocket cost in part based on "the out-of-network pharmacy's … usual and customary price." 42 C.F.R. § 423.124(b).

In 2005, CMS adopted a regulation defining U&C in this narrow context as "the price that an out-of-network pharmacy … charges a customer who does not have any form of prescription drug coverage for a covered Part D drug." 42 C.F.R. § 423.100. CMS did not explain how pharmacies should account for any discounts that might be available, and certainly did

not suggest that individualized discounts offered through customer-initiated price-matching or membership-club pricing must be considered when determining the beneficiary's out-of-pocket cost. Indeed, CMS *rejected* a suggestion that "the U&C price should be the amount typically charged to … cash customers who are directly given some sort of discount as an inducement to make a purchase from a given supplier." 70 Fed. Reg. 4194, 4270 (Jan. 28, 2005).

Later, CMS explicitly recognized that not all discounted prices are U&C prices. Pharmacies may offer "a non-U&C special discounted price." 74 Fed. Reg. 54,634, 54,666 (Oct. 22, 2009).

b. If a pharmacy has a contract with a sponsor or PBM, the pharmacy is in-network, and the contract establishes the reimbursement metric. Reimbursement may be based on U&C prices, which may be defined in the contract (or not). CMS is prohibited from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and … sponsors; [and] may not require a particular formulary [or] institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i)(1-3).

Contracts between pharmacies and sponsors or PBMs vary widely. Often, when U&C price is the reimbursement metric, such contracts define U&C to exclude certain discounted prices. That was true for one of the largest PBMs, Express Scripts. Its contractual definition explicitly "exclude[d] a Pharmacy's competitor's matched price discounts (Price Match)." SJA39-44, 261. Other PBM contract definitions were less specific—sometimes defining U&C as the "retail" price, without elaboration or reference to discounts, or adding that U&C should include "applicable dis-

counts" or "discounts available to the public," without defining what discounts qualified. JA37-38.

PBMs did not understand these general definitions of U&C as including discounted prices like those available through respondents' price matching or membership clubs. In fact, nearly every PBM—aware of SuperValu's and Safeway's price matches and the "long-established" nature of that practice in the industry—confirmed that they did *not* view price-match discounts as meeting the U&C definition in their contracts. JA73-75 ("Argus did not expect that individualized, customer-initiated price matching … would have met the definitions of U&C"); JA89-92 (same for Express Scripts); JA77-81 (Optum); JA81-82 (Catamaran); JA84-86, 248-49 (MedImpact); JA242-45 (Prime Therapeutics). PBMs confirmed the same understanding for membership club discounts. JA245 (Prime "did not consider these opt-in prices to be 'applicable discounts'"); JA248-49 (MedImpact); see also SJA245-60.

There was just one, short-lived outlier. The PBM Medco had a separate pharmacy manual that, for one year of the relevant period, described "applicable discounts" as including a "competitor's matched price" and prices available through "clubs with nominal membership fees." *Schutte* Dkt. 176-32 (Medco Decl. ¶¶ 4-5). The "contract with Medco," however, "did not define [U&C] price." *Schutte* Pet. App. 83a. Regardless, Medco removed this language from its pharmacy manual the following year, and was subsequently acquired by Express Scripts, which explicitly excluded price matches from U&C prices. Medco Decl. ¶¶ 1, 5.[2]

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[2] The Medco contract is not directly at issue in *Proctor*. "[T]he only contracts in the … record were consistent with Safeway's objectively reasonable interpretation of the law." JA254. In

C. Contemporaneous Guidance And Understanding Regarding U&C Prices.

Price-matching and membership clubs were well-known to the federal government and industry stakeholders. JA25-26, 237-40. Indeed, many stores openly advertised these programs. JA25-26, 73-74, 77-78; SJA22-28. Yet, during the time SuperValu and Safeway provided the discounts at issue, no statute, regulation, binding agency guidance, or court addressed whether price-matched or membership-club discount transactions affected U&C prices. Existing sources generally indicated that individualized or otherwise limited discounts need not be factored into the U&C price.

The Government Accountability Office described U&C price as "the *undiscounted* price individuals without drug coverage would pay" as part of an analysis in which it "obtained average monthly [U&C] prices" in certain states. GAO, *Prescription Drugs: Trends in Usual and Customary Prices for Drugs Frequently Used by Medicare and Non-Medicare Enrollees* 1, 3 (Oct. 6, 2004), https://tinyurl.com/38un8469 (emphasis added). CMS repeatedly indicated that not all discounted prices are U&C prices, *supra* pp.6-9, including rejecting suggestions to define U&C to include discounts given "as an inducement to make a purchase from a given supplier." 70 Fed. Reg. at 4270.

Major industry stakeholders agreed. One, Academy of Managed Care Pharmacy, interpreted U&C price to exclude individual discounts. Its "Guide" stated that U&C is the "retail" or "undiscounted price that individuals without drug coverage would pay at a re-

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Schutte, the district court also rejected relators' claims concerning Medco. *Schutte* Pet. App. 84a.

tail pharmacy." AMCP, *Guide to Pharmaceutical Payment Methods* 17 (Oct. 2007), https://tinyurl.com/2em7tb73.

Contemporaneous federal district and state court decisions were similar. One court found it "apparent" that the U&C price was "the retail price of the drugs" or "shelf price," while noting "[n]either the federal nor state regulations expressly define the phrase ['general public']." *United States* v. *Bruno's Inc.*, 54 F. Supp. 2d 1252, 1257-58 (M.D. Ala. 1999). Another found "usual and customary charges" in a contract was most sensibly read to *exclude* discounts. *Holland* v. *Trinity Health Care Corp.*, 791 N.W.2d 724, 726-28 (Mich. Ct. App. 2010); see also *Comer* v. *Life Ins. Co. of Ala.*, No. 08-cv-228, 2010 WL 2232204, at *3-4 (D.S.C. June 2, 2010) (finding the term "charge" "patently ambiguous because it is susceptible of more than one meaning"). Another, addressing a separate legal question, credited testimony from a former Division Director of CMS's predecessor agency that "'[t]here is generally no requirement that [a] discount be offered to Medicare,' and that '[t]here's no absolute guidelines … for setting that standard.'" *Klaczak* v. *Consol. Med. Transp.*, 458 F. Supp. 2d 622, 679-80 (N.D. Ill. 2006).

D. Respondents' Approach to U&C Charges.

1. SuperValu and Safeway treated across-the-board discounted prices as U&C prices. For example, after Walmart began offering 30-day supplies of certain generics for $4, some SuperValu stores began offering similar prices on generics for all customers. JA56-57; SJA29-31. Safeway also ran a Walmart-style $4 generics program in certain regions for a few years. JA203, 205. Safeway set the $4 price across the board, with "[n]o membership" required, "no other

discounts, no other advantages." JA220. Both companies reported these $4 generics transactions as their U&C price for those drugs. JA56-57; SJA29-31; *Proctor* Pet. App. 6a.

These automatic across-the-board prices were different from price-matching and membership discounts. The latter types of programs reflected an effort to compete effectively without abandoning the list price available to the general public. As a SuperValu executive explained, price matching was an "exception" to its ordinary pricing offered to the general public, and as long as price matching did not "deviate to a process that [wa]s more 'rule' or routine" it would not "affect the integrity of [SuperValu's] U&C price." SJA3; JA208. For Safeway, switching from a $4 generic program to a membership club requiring affirmative enrollment would "protect" its "[U&C] price." SJA264 (noting the "majority of [Safeway's] contracts" would reimburse at the U&C price).

Some employees discussed what was required in this complex and uncertain legal area. See, *e.g.*, SJA216 ("[W]hat are your thoughts?"); SJA212-13 ("Does anyone think we have an issue here?"); SJA227-28 (asking legal to "please chime in"). These conversations—which relators and the government paint as nefarious—reflect attempts to understand ambiguous U&C requirements. For example, an employee suggested that Safeway should "keep a low profile" while sorting out possible "issues with U&C and state Medicaids with price matching," but the senior executive with whom he corresponded stated that the employee's concern was "inconsistent with previous understanding, practice by other retailers, etc." SJA227-32. The exchange ended with a request for legal to weigh in. SJA227-28. Another Safeway employee wondered "how the state of Nebraska will

know that we offered to match any price," only after explaining his view that "because we are matching competitor pricing which is not our usual and customary price there is no issue with the governmental programs that we participate in." SJA213-15.

Employees likewise discussed how discounts could impact U&C pricing. They sometimes, for example, referred to price matching as a "stealth" program, but not because they hid it from the government or PBMs. Part of the point of these programs was to *avoid* displacing the list prices offered to the general public; attracting media or other attention could undermine that goal. *Proctor* Dkt. 188-24. Respondents wanted to limit the customers requesting price matching to ensure it remained "an 'exception'" and did not become the price to the general public or "affect the integrity of … U&C price." SJA2-3.

2. State agencies and PBMs actually *confirmed* the distinction between across-the-board pricing and special discounts.

When several states changed their U&C definitions during the relevant period, SuperValu sought clarification. The states confirmed that price-matched prices would not be considered U&C charges. Oregon officials, for example, confirmed that its U&C price "revision d[id] not apply to SuperValu's price matching advertisement model." SJA49-53; JA46-55. Idaho similarly confirmed that it "would not consider" SuperValu's price matching as its "[U&C] charge." SJA46-48.

When Massachusetts changed its U&C definition in 2009 to seemingly encompass price matching, on the other hand, SuperValu[3] changed the way it reported

[3] Safeway does not operate pharmacies in Massachusetts.

U&C in Massachusetts. SuperValu reviewed its claims and reimbursed the Massachusetts Medicaid agency for $2,855.03 in possible overpayments that had resulted from not reporting a price-matched price as the "lowest price" under the revised regulation. JA42-45.

Respondents also heard that Part D plans did not consider price-matching discounts to be included in U&C. One of the largest PBMs clarified, in response to an inquiry, that price-matched prices were not U&C. After a "network update" revising a U&C definition from CVS Caremark, a SuperValu executive asked CVS whether SuperValu's price-matched discounts needed "to be taken into consideration with regard to the revised definition of" U&C. JA96-98. A CVS Director responded that "[p]rice matches will not be in conflict" with the contract's "revised definition of U&C." JA96-97.

E. Audit and Recoupment Authority.

If a pharmacy overcharges for a prescription drug, all possible counterparties may audit for and recover overpayments. Contrary to state amici's claim that "Medicaid billing operates largely on the honor system," State Br. 13, audits are a core aspect of both Medicaid and Medicare.

HHS is *required* to contract with entities to perform audits and identify overpayments under the Medicaid Integrity Program. 42 U.S.C. § 1396u-6. Each state also must "operat[e] a medicaid fraud and abuse control unit," *id.* § 1396a(a)(61), and retain auditors to review for overpayments, *id.* § 1396a(a)(42)(B); 42 C.F.R. § 455.502(b). States "must take reasonable actions to attempt to recover" identified overpayments, *id.* § 433.316(b), and must refund the federal share of identified overpayments to CMS. *Id.* § 433.312(a)(1).

HHS also must contract with auditors to identify and recoup Medicare Part D overpayments. 42 U.S.C. § 1395ddd(h)(1). Part D sponsors are required to establish procedures to investigate "compliance problems as identified in the course of … audits," 42 C.F.R. § 423.504(b)(4)(vi)(G); see also *id.* § 423.504(b)(4)(vi)(G)*(1)*. PBMs likewise audit and recoup overpayments. Cong. Rsch. Serv., *Medicare Part D Prescription Drug Benefit* 53 (Dec. 18, 2020), https://tinyurl.com/yc3kx2vh.

PBMs and state Medicaid agencies audited respondents extensively. JA41-42, 211-12, 234-37; SJA32-38. SuperValu was audited 12,433 times during the relevant period, or approximately 100 times per month. JA41-42. The audits recovered an annual average of less than $150 per store. *Id.*; SJA32-38 (47 of which were State Medicaid audits). No audit raised concerns regarding U&C prices.

II. PROCEDURAL BACKGROUND.

1. Petitioners are private relators who filed these *qui tam* actions in 2011. After nearly four years of investigation, the federal government and every state at issue declined to intervene. *Schutte* Dkt. 20; *Proctor* Dkts. 23, 25.

2. While the cases were pending, the Seventh Circuit became the first court of appeals to consider the impact of discounts on pharmacy U&C prices. *United States ex rel. Garbe* v. *Kmart Corp.*, 824 F.3d 632 (7th Cir. 2016). The case involved discounted prices available through Kmart's pharmacy membership program, which made up 89% of its cash business. *United States ex rel. Garbe* v. *Kmart Corp.*, 73 F. Supp. 3d 1002, 1018 n.10 (S.D. Ill. 2014). The court held that those discounted prices were U&C prices.

Garbe adopted a universal definition of the U&C price—the "cash price offered to the general public." 824 F.3d at 643. It did not rely on relevant state Medicaid provisions or PBM contracts defining U&C charges. Instead, it derived that one-size-fits-all definition from a 2005 CMS regulation—even though that regulation applies only to out-of-network charges for drugs under Medicare Part D. *Id.* In addition, *Garbe* deferred to a footnote in a CMS Manual—debuted in 2006, and deleted in 2013—and the supposed "purpose of the statutory and regulatory structure." *Id.* at 643-45.

3. After *Garbe*, relators in SuperValu's case moved for partial summary judgment that SuperValu's claims were false under the FCA because they did not include the price-match discounts in the calculation of U&C. The district court recognized that price matches "were not the majority" of SuperValu's "cash transactions and only a nominal percentage—about 2%—of all" sales. JA3. But the court sided with relators, noting it could not "disregard applicable Seventh Circuit precedent." JA15.[4]

4. Both SuperValu and Safeway then moved for summary judgment on scienter. The companies pointed to the state Medicaid laws and PBM contracts at issue. *E.g.*, *Schutte* Dkts. 172-1 at 10-22, 176-1 at 11-25; *Proctor* Dkt. 176 at 5-6. Both argued that the law regarding U&C pricing was unclear at least until *Garbe* and remained unclear given differences between *Garbe* and these cases. *E.g.*, *Schutte* Dkts. 172-1 at 29-31, 176-1 at 31-34; *Proctor* Dkt. 65 at 1-3. Invoking the framework that this Court set out in *Safeco*, respondents argued that their actions

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[4] In *Proctor*, the district court held that relator could not prove scienter and did not decide falsity.

were consistent with an objectively reasonable interpretation of ambiguous legal requirements and not knowing.

The district court followed "every court of appeals" to apply *Safeco*, and entered summary judgment for respondents. *Proctor* Pet. App. 78a; *Schutte* Pet. App. 73a-74a.

5. In separate appeals, the Seventh Circuit likewise joined "[e]very other circuit court to discuss the relevance of *Safeco*'s scienter standard to the FCA." *Schutte* Pet. App. 16a; *Proctor* Pet. App. 13a. The court of appeals saw "no reason why" the same scienter standards—from "knowingly" to "reckless disregard"—"should not apply to the same common law terms used in the FCA." *Schutte* Pet. App. 15a.

The court stressed the narrowness of this holding. "Under *Safeco*, a defendant will be successful only if (a) it has an *objectively* reasonable reading" of an ambiguous legal requirement "and (b) there was no authoritative guidance warning against its erroneous view." *Schutte* Pet. App. 21a-22a. This "test does not shield bad faith defendants that turn a blind eye to guidance indicating that their practices are likely wrong," nor does it excuse defendants who "remain ignorant" of ascertainable facts like a company's "claims processes and internal policies." *Id.* 22a.

The court then held that the law surrounding U&C pricing was ambiguous before *Garbe*. "Federal regulations do not elaborate beyond [a] cursory definition" of "charges to the general public" or "guide pharmacies on identifying the 'general public' when they charge customers various prices for the same prescription." *Schutte* Pet. App. 23a. Thus, "the U&C price definition is open to multiple interpretations." *Id.* 24a. SuperValu's approach of setting the retail

price "as the 'price that it charged to the general public'" was reasonable. *Id.* 24a-25a. The court rejected relators' attempt to "overexten[d]" *Garbe*, which "did not hold" that its interpretation "was the *only* objectively reasonable interpretation." *Id.* 25a. And relators could not belatedly rely on "the various formulations of U&C price" in PBM contracts, because they had taken the "opposite position" before the district court. *Id.* 23a n.8.

The court then held that no authoritative guidance warned SuperValu away from its conduct. It again joined sister circuits in reasoning that, "at minimum," "authoritative," guidance "must come from a governmental source—either circuit court precedent or guidance from the relevant agency." *Schutte* Pet. App. 27a-28a. Additionally, the guidance "must have a high level of specificity to control an issue." *Id.* 29a. An inapposite footnote in the CMS Manual did not qualify. *Id.* 30a-31a.

Proctor followed. "For the same reasons," the Seventh Circuit held that "Safeway's interpretation" of U&C to exclude price matching "also passes muster." *Proctor* Pet. App. 17a. The "analysis [was] similar" for membership club prices. *Id.* The court also noted the due process "dilemma" that would arise by applying "treble damages liability" in this case. *Id.* 23a-24a.

SUMMARY OF ARGUMENT

I. Proceeding under an objectively reasonable interpretation of ambiguous legal obligations is not "knowing" misconduct under the FCA.

Two aspects of the statute's scienter provision are decisive. One is the three-part definition of "knowingly" as actual knowledge, deliberate ignorance, or reckless disregard. In *Safeco*, this Court considered a

civil scienter provision that covered the same range of mental states—from knowing to reckless—in the context of an ambiguous and unsettled legal obligation. The Court held that following an objectively reasonable interpretation is not knowing or reckless conduct. No one can *know* (or ignore) what is *unknowable* (and undiscoverable). The same reasoning governs the FCA's definition of "knowing" conduct.

The second textual signal is what the statute says must be known—namely, that "the information" provided in the claim is false. If one is to "know" that "information" is false, then—both as a matter of ordinary meaning and in the particular context of the FCA—the "information" at issue must be objectively discernible. When referring to ambiguous legal rules, authoritative guidance—appellate court decisions, properly promulgated agency guidance, etc.—provides the "information" that is necessary to make the claim knowingly false.

The common law reinforces this commonsense understanding of the text. For centuries, the common law has recognized that, generally speaking, a misrepresentation about what the law means is not fraud. No private person is uniquely situated to speak to that. And when the law is ambiguous and unsettled, a statement about its content is no more than a prediction about what a court or agency will later decide. Although relators and the government dedicate pages to the common law, they ignore what it says about misrepresentations of law or ambiguous legal obligations. Everything they say and cite is about reasonably discernible *facts*, which are not at issue here.

Relators' and the government's contrary arguments are baseless. Their attempts to relegate *Safeco* to a one-off decision boomerang: *Safeco*'s reasoning ap-

plies *more* strongly to the punitive FCA, with its "rigorous" and "strict" scienter requirements, than to the statute at issue in that case. Relators' bid to displace the FCA's express scienter provisions by way of the word "fraudulent" in another section of the statute goes nowhere. Their worries about hypothetical head-in-the-sand fraudsters or "post hoc" boogeymen evaporate once Congress, courts, or regulators produce authoritative legal guidance, and have nothing to do with the actual circumstances of this case. And their claim that subjective belief is always sufficient to show actual knowledge is both wrong and irreconcilable with the government's own successful argument in *Safeco*: "[o]nly if the defendant's failure to comply with the law was objectively reckless would it become necessary for a court to probe … the defendant's subjective good faith." U.S. Br. 23, *Safeco Ins. Co. of Am.* v. *Burr*, No. 06-84 (Nov. 13, 2006) ("U.S. *Safeco* Br.").

II. Seven years ago, this Court assured that "concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the [False Claims] Act's … scienter requirements.'" *Escobar*, 579 U.S. at 192. Relators and the government ask this Court to abandon that promise.

Abiding principles require that regulated entities have fair notice before suffering punishment for misconduct, as the FCA inflicts. The government's routine enforcement tools—audits and other enforcement actions—are not at issue here. Properly adjudicated overpayments can be recovered according to law. But the FCA's scienter provisions must be construed strictly against the government to ensure that regulated parties are not punished for failing to predict whether an objectively reasonable interpretation of ambiguous laws will later be deemed "false."

Authoritative guidance provides the requisite fair notice. That means guidance that carries the force of law and is sufficiently specific to warn regulated entities away from a course of conduct. Anything less does not suffice. Private parties cannot be punished for failing to predict whether tomorrow's administration will regulate consistently with the informal commentary of today's agency employee. Indeed, the regime the government envisions would permit the government to create ambiguity, allow it to linger, and then set loose bounty hunters to collect enormous punitive awards based on reasonable conduct within the scope of government-created ambiguity. That is the opposite of the fair notice that *Escobar* embraced and due process requires when governmental punishment is at stake.

III. The judgments below should be affirmed because the court of appeals—like every court of appeals before it—got the law exactly right. Respondents acted consistent with an objectively reasonable view of the ambiguous U&C pricing regime, and no authoritative guidance warned them away. Summary judgment was therefore properly entered for respondents.

ARGUMENT

I. THE FALSE CLAIMS ACT DOES NOT PENALIZE ACTIONS CONSISTENT WITH OBJECTIVELY REASONABLE UNDERSTANDINGS OF AMBIGUOUS LEGAL OBLIGATIONS.

A. The FCA's Text Establishes that An Objectively Reasonable Interpretation of Ambiguous Legal Obligations Cannot Be "Knowingly" False.

The FCA imposes liability on entities that "knowingly present[] … false or fraudulent claim[s] for payment" to the government or its contractors. 31 U.S.C. § 3729(a)(1). The statute splits the definition of "knowingly" into three tiers. To act "knowingly," "a person, with respect to information," must

> (i) ha[ve] actual knowledge of the information;
>
> (ii) act[] in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) act[] in reckless disregard of the truth or falsity of the information.

Id. § 3729(b)(1)(A). Under none of these three definitions may a person who acted consistent with an objectively reasonable interpretation of an ambiguous legal obligation be said to have "knowingly" presented false or fraudulent claims to the government.

1. *Safeco*'s Reasoning Tracks the FCA's Scienter Provision.

Interpreting the Fair Credit Reporting Act, *Safeco* applied much the same scienter taxonomy codified in the FCA to a company's compliance with an objectively reasonable view of ambiguous legal obligations not

authoritatively settled. The text of the FCA supports the same conclusion here.

The first FCA scienter tier is "actual knowledge." Although the statutory term at issue in *Safeco* was "willfully," the Court made clear that, when "willfulness is a statutory condition of civil liability," it covers "knowing violations." 551 U.S. at 57, 70 n.20. The Court also made clear how that standard applies to a regulated entity "who followed an interpretation that could reasonably have found support in the courts": "Congress could not have intended"—indeed, "it would defy history and current thinking"—to treat such an entity "as a knowing … violator." *Id.* at 70 n.20.

That holding reflects a basic principle that this Court has repeatedly enforced: absent authoritative guidance, a party cannot *actually know* what an unsettled legal obligation requires. "[T]o have 'actual knowledge' of a piece of information, one must in fact be aware of it." *Intel Corp. Inv. Policy Comm.* v. *Sulyma*, 140 S. Ct. 768, 776 (2020). Until authoritative guidance answers the unsettled question, a party's thoughts or beliefs about the true or even best answer are, at most, "'potential, possible, virtual, conceivable, theoretical, hypothetical, or nominal'" outcomes. *Id.* Actual knowledge requires "*more than*" such prediction. *Id.* (emphasis added). It is one thing to act "in open defiance or in reckless disregard of a [legal] requirement which has been made specific and definite," but even "willful conduct cannot make definite that which is undefined." *Screws* v. *United States*, 325 U.S. 91, 105 (1945) (plurality opinion); see also *Iron Silver Mining Co.* v. *Reynolds*, 124 U.S. 374, 384 (1888) ("between mere belief and knowledge there is a wide difference").

These maxims apply equally to tier (ii)'s "deliberate ignorance" standard. "Persons who know enough to blind themselves to direct proof of critical facts in effect have actual knowledge of those facts." *Glob.-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 766 (2011). But when it comes to unsettled legal questions, by definition, there are no places to look to get an authoritative answer; the statutes, regulations, and cases do not provide one. "[L]egal argumentation and possibility" about unsettled law are not "facts" that "could [be] reasonably classif[ied] as true or false." *United States ex rel. Siewick* v. *Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000). There is, therefore, no such thing as "direct proof of critical facts" to which the regulated entity could "blind" itself. *Glob.-Tech*, 563 U.S. at 766. There is no "necessary knowledge" that can be "acquired." U.S. Br. 17. There is just "an unknowable something." *Screws*, 325 U.S. at 105.

The third and "loosest" tier is "reckless disregard." *Purcell*, 807 F.3d at 288. Although the term "is not self-defining," it is the "high risk of harm, *objectively assessed*, that is the essence of recklessness at common law." *Safeco*, 551 U.S. at 68-69 (emphasis added). And *Safeco* has made clear that an objectively reasonable understanding of unsettled law does not present a "high risk" of being wrong. When a defendant's interpretation of unsettled law is "not objectively unreasonable," the conduct "falls *well short* of raising the 'unjustifiably high risk' of violating the statute necessary for reckless liability." *Id.* at 70 (emphasis added). The Court did not "need to pinpoint the negligence/recklessness line" in *Safeco*, because it was enough to recognize that a regulated entity's "reading of the statute, albeit erroneous, [is] not objectively unreasonable." *Id.* at 69.

2. The Statutory Term to Which "Knowingly" Attaches—"the Information"—Confirms The Need for an Objectively Falsifiable Threshold.

Statutory context further confirms the application of *Safeco*'s objective baseline to the FCA. Beyond defining "knowingly," the scienter provision also states *what* must be known: "information." 31 U.S.C. § 3729(b)(1)(A). That statutory term, repeated in each of the three subclauses, requires that "the information" in the "claim" for payment be objectively falsifiable.

Each prong of the statutory definition speaks of the "falsity of the information." Subclauses (ii) and (iii) ask explicitly about the "truth or falsity of the information." *Id.* Subclause (i) likewise requires "actual knowledge" of the falsity "of the information," because true "information" is not actionable. By tying each mental state to the "falsity of the information," therefore, the scienter provision naturally requires that "the information" that is "known" be falsifiable. Dictionary definitions are in accord with the statute's use of the term "information," indicating that "information" must be objectively discernible. *E.g.*, *Webster's New Collegiate Dictionary* 587 (1981) ("facts, data"); *Webster's Third New International Dictionary* 1160 (1986) ("facts or figures").[5]

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[5] "Information" is alternatively defined as "knowledge obtained from investigation, study, or instruction." *Webster's New Collegiate Dictionary* 587. But that definition would make "information" redundant in the statute—requiring "actual knowledge of the [knowledge]." *See Duncan* v. *Walker*, 533 U.S. 167, 174 (2001) (this Court is "reluctant to treat statutory terms as surplusage in any setting," particularly "when the term" is "pivotal" to "the statutory scheme" (cleaned up)).

The Court's discussion of "information" in *Escobar* confirms that it refers to objectively falsifiable and discernible subject matter. The Court hypothesized a government order for guns that "must actually shoot." 579 U.S. at 191. The guns' shooting capacity qualifies as objective "information" that could support FCA liability "because a *reasonable person* would realize the imperative of a functioning firearm," meaning that "a defendant's failure to appreciate the materiality of that condition would amount to 'deliberate ignorance' or 'reckless disregard' of the 'truth or falsity of *the information*.'" *Id.* (emphases added). The Court did not hypothesize a situation where a defendant could not verify the information because that would make no sense. Scienter turns on the "information" being discernible, falsifiable subject matter: *e.g.*, whether guns shoot or not.

Escobar also discusses falsity allegations premised on noncompliance with legal obligations. Even in that context, the "information" in the claim was "specific representations about the goods or services provided," which could be rendered false based on a "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements." *Id.* at 190. In *Escobar*, representations and codes in the claims corresponded to staff's specialized training and qualifications. *Id.* at 189. "By using payment and other codes that conveyed this *information* without disclosing … many violations of basic staff and licensing requirements," the claims were knowingly false. *Id.* at 190 (emphasis added). The "information" referred to objectively falsifiable historical facts: the qualifications of those who provided medical services.

When the "information" is not objectively discernible or falsifiable, the statutory terms simply do not work. Neither relators nor the government explains

how someone can "actually know" that which cannot be known, or "deliberately ignore" that which no amount of deliberation can answer, or "recklessly disregard" that which cannot be regarded.

The government tries to shoehorn its argument into the text by suggesting that a company has knowledge of the falsity of the information in its claims when the company does not believe its claim reflects "the best interpretation" of ambiguous legal requirements. U.S. Br. 32. But what qualifies as "the best interpretation" is not objectively discernible "information." See *Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2439 (2019) (Gorsuch, J., concurring in the judgment) (acknowledging that executive officials "may choose to press the case for the side they represent instead of adopting the fairest and best reading" (cleaned up)). Nor does one private party's personal view of the "best" have any necessary relationship to how a court or agency will eventually resolve the issue—if it is in fact ever resolved. Recall here that CMS adopted its "usual and customary" regulation in 1975, and a court of appeals first weighed in 40 years later.

Safeco's approach is the only way to make sense of, and align with, the statutory text when the "information" in the claim reflects at most a prediction about how a court or regulator might eventually answer a disputed legal question. The "true" or even "best" answer is *not* objectively discernible. There is "only legal argumentation and possibility," which is fundamentally distinct from information that the claimant "could reasonably classify as true or false." *Siewick*, 214 F.3d at 1378. By contrast, the "falsity of the information" is objectively discernible when the threshold question is whether the defendant's position is objectively reasonable or not. Applying *Safeco*'s approach to the FCA thus also respects the

common and only sensible meaning of the statutory term "information."

3. Subjective Belief About the Accuracy of an Ambiguous Legal Position Cannot Make an Objectively Reasonable View "Knowingly" False.

A necessary corollary to the statute imposing an objectively verifiable threshold on "knowingly" false claims is that, below that threshold, subjective beliefs about an objectively *unknowable* legal obligation do not come into play.

The Court confronted precisely this question in *Safeco*. Notably, the Solicitor General's Office urged a view contrary to its present view: "*[o]nly if* the defendant's failure to comply with the law was objectively reckless would it become necessary for a court to probe … the defendant's subjective good faith." U.S. *Safeco* Br. 23 (emphasis added).

On the other side, the *Safeco* plaintiffs (whose view this Court rejected) sounded just like relators here (and the government now). They argued that "[p]roof that a defendant knew its conduct violated the law or understood that it was acting in the face of a substantial risk that its conduct violated the law obviously necessitates inquiry into the defendant's state of mind." Resp. Br. 44, *Safeco*, No. 06-84 (Dec. 18, 2006). Plaintiffs also represented that there was "direct evidence that [defendant] interpreted the statute exactly how we [*i.e.*, plaintiffs] do," Oral Argument Tr. 46:11-13, *Safeco* (Jan. 26, 2007)—plainly trying to show that defendants had acted in subjective bad faith.

In no uncertain terms, however, the Court held that it was "unsound" to "argue that evidence of subjective bad faith can support a willfulness finding even when the company's reading of the statute is objectively

reasonable." *Safeco*, 551 U.S. at 70 n.20. Such defendants simply do not act "knowing[ly] or reckless[ly]," "whatever their subjective intent may have been." *Id.*

Although lodged in a footnote, see Pet'r Br. 46, this discussion was integral to the Court's judgment. The Ninth Circuit had held "that a company would not be acting recklessly if it *diligently and in good faith* attempted to fulfill its statutory obligations and came to a tenable, albeit erroneous, interpretation of the statute." *Safeco*, 551 U.S. at 55-56 (emphasis added) (cleaned up). The court of appeals would have remanded to the district court for consideration of whether the defendant held its reasonable but erroneous interpretation of FCRA in good faith. *Id.* at 56. This Court's conclusion that "evidence of subjective bad faith" was irrelevant, *id.* at 70 n.20, necessitated reversal.

Safeco's reasoning applies equally here, notwithstanding the government's flip-flop from its position in that case. Indeed, "[i]n the face of an undefined and ambiguous regulatory requirement," it can be "no wonder that employees of the regulated entity [a]re concerned," *Purcell*, 807 F.3d at 290, or that discovery may produce evidence of internal doubts as to the "true" interpretation. But, just as in *Safeco*, such potential evidence of subjective beliefs has no bearing on the *objective* threshold requirement.

4. Relators and the Government Fail to Distinguish *Safeco*.

Relators and the government contend that, for several reasons, *Safeco*'s analysis is irrelevant to the Court's interpretation of the FCA. Pet'r Br. 41-45; U.S. Br. 22-25. They are wrong.

First, they argue that the FCA and the FCRA have "different language," because the FCRA says "willfully" and the FCA spells out three tiers of "knowingly." Pet'r Br. 42; U.S. Br. 24. That is true but immaterial. *Safeco* rooted its analysis in "the essence of recklessness at common law." 551 U.S. at 69. The Court held that, "where willfulness is a statutory condition of civil liability," it "generally … cover[s] not only knowing violations of a standard, but reckless ones as well." *Id.* at 57. That understanding of "willfulness" (the FCRA's term) thus plainly encompasses the entire scienter spectrum under the FCA—from "knowing" to "reckless." 31 U.S.C. § 3729(b)(1). And proceeding under an objectively reasonable interpretation of an ambiguous legal obligation is not "knowing or reckless." 551 U.S. at 70 n.20.

Second, relators and the government maintain that the FCA and the FCRA come from different "background[s]." Pet'r Br. 42-44; U.S. Br. 24-25. If anything, however, that difference cuts in the opposite direction. The FCA "is not an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 579 U.S. at 194. It is "essentially punitive in nature," and its scienter requirements are accordingly "rigorous" and must be "strict[ly] enforce[d]." *Id.* at 182, 192, 194 (cleaned up). The Court has not issued any comparable admonition about the FCRA or its scienter provisions.

As part of the "different backgrounds" argument, relators and the government chide *Safeco* for citing a Restatement provision concerning physical safety and endorse a different provision about fraud generally. Pet'r Br. 42-44; U.S. Br. 24-25. They miss the point. *Safeco* was obviously not about physical safety—the FCRA claims were "premised on initial rates charged

for new insurance policies." 551 U.S. at 60. The Court nevertheless cited the Restatement provision as one "*example*" of the "high risk of harm, objectively assessed, that is the essence of recklessness at common law." *Id.* at 69 (emphasis added). Indeed, the Court also cited "Prosser and Keeton §34," *id.*, and that provision is not about physical safety. The fraud provision that relators highlight, by contrast, does not "define 'knowingly' (or any of the common law scienter terms listed in [the FCA]." *Schutte* Pet. App. 17a.

Finally, relators and the government seek to distinguish the FCA from the FCRA based on *Heckler* v. *Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51 (1984), and the fact that the FCA implicates government funds. U.S. Br. 25; Pet'r Br. 44-45. This effort backfires. *Heckler* concerned the government's ability to recoup funds through ordinary-course regulatory enforcement after an ordinary-course audit revealed overpayments. 467 U.S. at 54-58. In that setting, the Court declined to find that the government was estopped from collecting money based on incorrect legal advice that one of its agents had given. *Id.* at 61. *Heckler* thus demonstrates that the government can (and does) deploy audits and regulatory enforcement tools to recover funds to which a regulated entity is not entitled. The FCA does not preclude or interfere with any of that.

Far from supporting reversal, therefore, *Heckler* makes clear that there is no need to water down the FCA's scienter provisions to enable overpayment recoupment. Relators and the government point to the adage that people "must turn square corners when they deal with the Government," particularly when "a private party seeks to spend the Government's money." *Id.* at 63. "But it is also true, particularly when so much is at stake, that 'the Government should

turn square corners in dealing with the people.'" *Dep't of Homeland Sec.* v. *Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020). Both here, in the context of U&C pricing, and in many other corners of the administrative state, the government lets confusion reign for decades. It is hardly a "square corners" move for the government, after allowing uncertainty to fester, to allow a bounty hunter to take the lead, take advantage of *post hoc* developments in the law, refuse to intervene and dismiss the *qui tam* suit, and then stand palms out to take its slice of a potentially staggering punitive award if a jury breaks for a relator. There is "no reason why the square corners should constitute a one-way street." *United States* v. *Winstar Corp.*, 518 U.S. 839, 886 n.31 (1996) (plurality opinion).

B. The Common Law Would Not Treat A Party Acting Consistent with an Objectively Reasonable View of the Law As Having Knowingly Violated Law.

When evaluating a statutory scienter term, this Court applies "the general rule that a common law term in a statute comes with a common law meaning, absent anything pointing another way." *Safeco*, 551 U.S. at 58; see also *Escobar*, 579 U.S. at 187 n.2. Just as the Court held in *Safeco*, the common law confirms that a company is not a "knowing or reckless" violator when it "follow[s] an interpretation that could reasonably have found support in the courts." 551 U.S. at 70 n.20.

1. The Common Law Would Not Support Fraud Liability Here.

"The general rule is that a misrepresentation as to a matter of law will not constitute a remediable fraud." 37 C.J.S. *Fraud* § 96 (2023). This general

rule—which has been applied for centuries[6]—stems from the fundamental difference between law, fact, and knowledge thereof: a statement alleged to be false because it rests on an erroneous understanding of law is not fraudulent. That principle governs here, because the falsity at issue here is "legal falsity," *Schutte* Pet. 13, meaning that respondents are alleged to have made "legally false claims[,] … which involve contested statutory and regulatory requirements." *United States ex rel. Sheldon* v. *Allergan Sales, LLC*, 24 F.4th 340, 350 (4th Cir.), *vacated*, 49 F.4th 873 (4th Cir. 2022).[7] That is, respondents' claims are alleged to be "false" because they combine true facts (*i.e.*, they accurately reflect prices that respondents charged) combined with an erroneous but reasonable interpretation of the law (*i.e.*, which of those prices must be included in the calculation of U&C). *Schutte* Pet. App. 8a; *Proctor* Pet. App. 5a-8a. The common law does not recognize fraud liability in such a setting.

First, the common law holds that no person has unique knowledge of what the law requires. Instead, "[t]he law is presumed to be equally within the knowledge of all parties." *Upton* v. *Tribilcock*, 91 U.S. 45, 50 (1875). So "[a] representation of what the law will or will not permit to be done is one on which the party to whom it is made has no right to rely; and if

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[6] The rejection of fraud liability for misrepresentations of law has been consistently recognized, from early English cases, *see Eaglesfield* v. *Marquis of Londonderry*, [1876] 4 Ch 693, 709-13, through modern American commentary, Dan B. Dobbs et al., *The Law of Torts* § 677 (2d ed. 2022).

[7] The Fourth Circuit vacated Judge Wilkinson's panel opinion when it granted en banc rehearing, and affirmed judgment for the defendant without opinion in an equally divided vote. 49 F.4th 873.

he does so it is his folly, and he cannot ask the law to relieve him from the consequences." *Id.* Indeed, this principle has particular force when, as here, the recipient of the information is the government: the entity that "makes the laws" can hardly rely on a private party's opinion as to the "meaning of an ambiguous law." *Buffington* v. *McDonough*, 143 S. Ct. 14, 19 (2022) (Gorsuch, J., dissenting from denial of cert.).

Second, the Restatement explains that a "statement of the legal consequences of … facts is a statement of opinion as to what a court would determine to be the legal consequences of the facts if the matter were litigated." Restatement (Second) of Torts § 545 cmt. a (1977). It is, in other words, a prediction of what a court or regulator—an entity cloaked with governmental authority—will eventually declare the law to be. But "fraud must relate to a present or preexisting fact," and cannot be predicated on predictions as to "the future." *Anderson* v. *Modica*, 73 A.2d 49, 52 (N.J. 1950). "Representations, although false, concerning matters not susceptible of actual knowledge," like a prediction of some future authoritative clarification of the law, "have been held to be non-actionable." *Harris* v. *Delco Prods.*, 25 N.E.2d 740, 742 (Mass. 1940).

Indeed, the Restatement is explicit on the prospect of fraud liability under the common law when one of two "bargaining adversaries" opines on an open legal question: "The recipient is not justified in accepting the opinion of a known adversary on the law and is expected to draw his own conclusions or to seek his own independent legal advice." Restatement (Second) of Torts § 545 cmt. d. Common-law sources across generations are fully in accord. *E.g.*, *Utah Power & Light Co.* v. *Fed. Ins. Co.*, 983 F.2d 1549, 1556 (10th Cir. 1993) ("[N]o one can be deceived by a misrepre-

sentation of law because everyone has access to the law and may be presumed to know it"); *Meacham* v. *Halley*, 103 F.2d 967, 971 (5th Cir. 1939) ("A misrepresentation as to a matter of law is ordinarily to be regarded as merely an expression of opinion, and will not support an action for fraud and deceit, there being no fiduciary relationship between the parties."); *Sorensen* v. *Gardner*, 334 P.2d 471, 473 (Or. 1959) (similar); *White* v. *Harrigan*, 186 P. 224, 228 (Okla. 1919) (similar); *Abbott* v. *Treat*, 3 A. 44, 46-47 (Me. 1886) (similar).

To be sure, some statements concerning the law can support a common-law fraud claim. For example, as in *Escobar*, where the defendant knows facts (there, that the service providers lacked the necessary qualifications) that make an express or implied statement of legal opinion (compliance with explicit legal requirements) false or misleading, there can be fraud. 579 U.S. at 181; *see* Restatement (Second) of Torts § 545 cmt. c. Additionally, a statement of legal opinion can support fraud liability "if the maker of the representation purports to have special knowledge of the law that the recipient does not have." Restatement (Second) of Torts § 545, cmt. d. Absent such circumstances, however, the common law would not impose fraud liability for an erroneous statement as to the meaning of an ambiguous law.

Nothing in the FCA abrogates the common law in this respect. Although the FCA does not incorporate the common-law element of reliance, it does expressly limit the definition of "knowing" to mean having knowledge of *information—i.e.*, subject matter that is knowable or objectively discernible. *Supra*, § I.A.2. Because a party's statement as to the meaning of an ambiguous law is no more than a prediction of what a court might determine "if the matter were litigated,"

Restatement (Second) of Torts § 545 cmt. a, it does not reflect objectively discernible "information" within the party's "knowledge." There is thus no basis to conclude that the FCA expands upon the scope of fraud liability to include statements that the common law made non-actionable.

2. The Common-Law Authorities Cited by Relators and the Government Are Not to the Contrary.

Although relators and the United States address the common law at length and repeatedly cite the Restatement, their arguments have a notable omission: Neither relators nor the government so much as *cite* Section 545 of the Restatement, which is directed at "Misrepresentation of Law." This oversight is particularly remarkable because all parties agree that the question presented in this case relates to a defendant's claims as to the "*lawfulness* of its conduct," Pet'r Br. i (emphasis added)—which is what Section 545 addresses.

Consistent with their failure to broach Section 545, their own common-law authorities fail to address fraud liability for claims premised on interpretation of an ambiguous law. Instead, those sources are limited to misrepresentations of *fact*. *E.g.*, 1 Joseph Story, *Commentaries on Equity Jurisprudence* § 203c, p.126 (1st English ed. 1884) ("a misrepresentation … must be as a matter of fact, and not merely a conclusion of opinion"); *Cooper* v. *Schlesinger*, 111 U.S. 148, 153 (1884) ("representation of existing facts"); Dan B. Dobbs et al., *The Law of Torts* § 665 ("defendant represents a fact knowing it to be false"). Relators and the government fail to confront the common law's different treatment of statements regarding discernible *facts* from statements as to the meaning of *law* that is

ambiguous. The sources on which they rely are thus beside the point.

The same is true of the authorities relators and the government cite for their argument that scienter can be established if the defendant did not "mak[e] an appropriate inquiry into whether the claims are truthful." Pet'r Br. 37; U.S. Br. 18, 25 n.4, 31. The common law found it relevant if a person "shut his eyes to the *facts*, or purposely abstained from inquiring into them." *Derry* v. *Peek*, [1889] 14 A.C. 337, 376 (Eng.) (emphasis added). In other words, a defendant cannot evade scienter by choosing not to investigate whether facts within its reach support its claims.

Relators and the government try but fail to graft the common-law duty to inquire into facts onto a fundamentally different context—ambiguous laws that the government has failed to authoritatively clarify. It does not follow from the duty to confirm factual support for one's own claims that there would also be a duty to seek out another party's views on the meaning of ambiguous laws. To the contrary, the law is "equally within the knowledge of all parties," *Upton*, 91 U.S. at 50, and a "bargaining adversar[y] … is expected to draw his own conclusions or to seek his own independent legal advice," and not to "accept[] the opinion" of a party on the other side. Restatement (Second) of Torts § 545 cmt. d.[8] Nor is there any duty to ask government employees to opine on what the law is. Even if the government purported to respond, any informal opinion provided would have no binding effect. That is why, as *Safeco* held, only "authoritative

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[8] A PBM's interpretation of an ambiguous law, *see* U.S. Br. 25 n.4, is no more "true" than respondents' interpretation and warrants no preferential treatment or weight. *Infra* § III.

guidance" from the government suffices for scienter. 551 U.S. at 70 & n.19.

C. Relators' and the Government's Remaining Contrary Arguments Are Meritless.

Relators and the government offer an assortment of arguments for the proposition that § 3729(b)(1) "require[s] proof of the defendant's subjective awareness" or "belief" under prongs (i) and (ii) (actual knowledge and deliberate indifference) but "can be satisfied … objectively" under prong (iii) (reckless disregard). U.S. Br. 17-18; Pet'r Br. 20. They all fail.

1. Relators' lead argument is a strange one. Claiming to have found an "easy way to resolve this case," relators invite the Court to "focus on what it means for claims to be 'false or fraudulent,'" because the "common-law definition of 'fraudulent'" supposedly "includes a mental component." Br. 23-24. Even setting aside relators' mistaken understanding of the common law, *supra* § I.B., this is no way to conduct statutory interpretation. According to relators, the Court should jettison the FCA's scienter provision expressly defining "knowingly" (§ 3729(b)(1)) in favor of a different word (fraudulent) from a different provision (§ 3729(a)(1)) that implicates a different claim element (falsity). Although that is reason enough to reject the invitation, *Escobar* also squarely forecloses it. As relators appreciate, that case "interpreted the phrase 'false or fraudulent.'" Br. 23. As relators ignore, however, *Escobar* went on to recognize that the "scienter requirement[]" comes from "[an]other part[] of the False Claims Act" and requires "rigorous" and "strict" enforcement. 579 U.S. at 192.

Next, relators contend that *Safeco*'s objective reasonableness baseline "collapses" the FCA's three scienter prongs and renders the first two "surplusage."

Br. 48-49. It does not. The three prongs remain "distinct and bear different meanings," but that "does not prevent the[m] from sharing a common requirement" when ambiguous legal obligations are at issue. *Schutte* Pet. App. 20a-21a. The three prongs also all target "information," but that commonality does not collapse them. *Safeco* recognizes that knowledge and recklessness are separate "subcategor[ies]" but still share a baseline: a defendant facing a "dearth of guidance" who follows an objectively reasonable interpretation is not "a knowing *or* reckless violator." 551 U.S. at 60, 70 & n.20 (emphasis added).

2. Relators and the government then introduce a series of arguments about a defendant's subjective thoughts and when it allegedly held them. None should move this Court.

First, they contend that a "subjective belief" alone qualifies as actual knowledge, and that a "subjectively … strong reason to believe" qualifies as deliberate indifference. U.S. Br. i, 13, 18; Pet'r Br. 4, 35. That is irreconcilable with *Safeco* and the government's own position in that case. As the government implored, inquiring into a defendant's "subjective good faith" was necessary "[o]nly if the defendant's failure to comply with the law was objectively reckless." U.S. *Safeco* Br. 23. The Court agreed. 551 U.S. at 70 n.20. Indeed, the Court would have had no reason to address recklessness in *Safeco* if, as relators and the government contend here, subjective evidence suffices to establish a "knowing" violation.

If more were needed, this Court long ago recognized the flaw in the government's newfound belief-is-knowledge equivalence. As the Court succinctly put it, "between mere belief and knowledge there is a wide difference." *Reynolds*, 124 U.S. at 384. The statute in that case required "knowledge of the existence

of a" particular (and knowable) fact—specifically, a "vein or lode within the boundaries" of a mining claim. *Id.* Even still, the Court refused to "mak[e] hopes and beliefs" the "equivalent" of, or "synonymous" with, a party's "knowledge." *Id.* Doing so would have "in effect incorporate[d] new terms into the statute." *Id.* The Court should reject the analogous request to rewrite the FCA.

Second, relators and the government insist that a defendant's interpretation of ambiguous laws must be held "at the time" it submitted claims for payment, including because the FCA "uses the present tense," U.S. Br. 19; Pet'r Br. 45-46. This is largely just more of the same—an appeal to subjective intent by another name by asking what beliefs were held and when. It is also the wrong question. The FCA regulates conduct, and the proper analytic focus is therefore on conduct—namely, whether the defendant's actions "*followed* an interpretation that could reasonably have found support." *Safeco*, 551 U.S. at 70 n.20 (emphasis added). That focuses on what the company actually *did* "at the time," not the thoughts of any stray employee.

The "at the time" argument also runs smack into the problems identified above, because a company cannot know the answer to an unsettled legal question "at the time" when the question has not yet been authoritatively settled. Relators and the government resist this logic, but their own hypotheticals and arguments expose the misstep. The government, for example, argues that a "courier who correctly believes he is transporting drugs cannot disprove his knowledge of that fact by showing that he never opened the package," or that a CFO "who intends to cook the books does not escape liability by insisting that she never double-checked the math herself." U.S.

Br. 28; see also Pet'r Br. 33 n.10 (similar). These putative fraudsters have nothing to do with this case, because each concerns immediately-verifiable historical facts—just open the package or do the math. That is worlds apart from a defendant facing unsettled legal obligations based on government-created ambiguity whose "true" resolution the government could have illuminated but did not.

Third, in yet another spin on the same point, relators and the government attack a defendant's supposed ability to generate objectively reasonable arguments "post hoc." See U.S. Br. 19-20; Pet'r Br. 53. This is a particularly odd refrain in this case, where the practices at issue were carried out in plain sight for decades, through thousands of audits, without any complaint from regulators. It is also especially odd to hear from the government in a case concerning government-tolerated ambiguity in agency-based legal obligations. This Court's precedents hold that it is the *government* and *its* "motivated attorneys" (U.S. Br. 31) who cannot offer "*post hoc* rationalization[s]" for its own "interpretation of ambiguous regulations to impose potentially massive liability." *Christopher* v. *SmithKline Beecham Corp.*, 567 U.S. 142, 155-56 (2012) (cleaned up). Yet that is exactly what relators and the government seek permission to do here—to use late-breaking clarifications of ambiguous legal obligations as a foothold for threatening massive FCA liability that few (if any) companies can risk litigating to a jury.

Halo Electronics, Inc. v. *Pulse Electronics, Inc.*, 579 U.S. 93 (2016), is not to the contrary. Contra U.S. Br. 26-28; Pet'r Br. 46-48. As usual, the particular context and text of the specific statute drove the analysis. Section 284 of the Patent Act grants district courts discretion to award enhanced damages without

any scienter limitation. *Halo Elecs.*, 579 U.S. at 103-04. In that setting, particularly since "'bad-faith infringement' *is* an independent basis for enhancing … damages," the Court declined to adopt a standard that would "impermissibly encumber[] the statutory grant of discretion to district courts." *Id.* at 104, 106 n.*. The FCA's scienter provision, by contrast, imposes a "rigorous" limit on liability with no room for discretion. *Escobar,* 579 U.S. at 192. In fact, what is *discretionary* under the Patent Act *after* liability is found—namely, awarding "up to" three times the amount of damages—is *mandatory* under the FCA upon a *finding of liability*. Given that, "the gap between the FCA and the Patent Act is much wider than that between the FCA and the FCRA—both of which include an explicit scienter standard (covering both knowledge and recklessness) that speaks to liability rather than damages." *Sheldon*, 24 F.4th at 348-49.

3. Finally, relators appeal to epistemology (the theory of knowledge) and legislative history. To the extent these subjects are even relevant, relators are wrong about both.

As for epistemology, relators contend that "'knowledge' [is] true belief." Br. 31-32. But that is just not true. In 1963, a seminal epistemology paper *proved* that a true belief is not equivalent to knowledge. Edmund L. Gettier, *Is Justified True Belief Knowledge?*, 23 Analysis 121 (1963). Many sources recognize this, including, ironically, relators' own. *E.g.*, Joseph Blocher, *Free Speech and Justified True Belief*, 133 Harv. L. Rev. 439, 444 n.26 (2019) ("Gettier effectively proved that [justified true belief] alone cannot provide a satisfactory account of knowledge."). Epistemology tilts decidedly against relators' position.

As for legislative history, it is not clear what take-away relators prefer from this exercise in "looking over [the] crowd and picking out [their] friends." *Exxon Mobil Corp.* v. *Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005). Relators discuss a "duty to inquire" (Br. 37-38), but any such "duty" was supposed to be "limited," not "burdensome," and "only … 'reasonable and prudent under the circumstances.'" S. Rep. No. 99-345, at 21 (1986); see also 132 Cong. Rec. S11238, S112343 (daily ed. Aug. 11, 1986) (Sen. Grassley) (referring to defendants "who ignore[] or fail[] to inquire about *readily discoverable facts*") (emphasis added). More fundamentally, relators point to nothing in the legislative history discussing ambiguous or unsettled legal obligations, and nothing discussing "subjective awareness" (Br. 35) of such obligations. Legislative history does not help relators.

II. THE BURDEN OF RESOLVING REGULATORY AMBIGUITY AND PROVIDING FAIR NOTICE RESTS WITH THE GOVERNMENT.

Escobar promises that "concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's … scienter requirements," which are "rigorous." 579 U.S. at 192; see also *United States* v. *Moore*, 612 F.3d 698, 703 (D.C. Cir. 2010) (Kavanaugh, J., concurring) ("Proper application of statutory mens rea requirements and background mens rea principles can mitigate the risk of abuse and unfair lack of notice in prosecutions under … regulatory statutes."). This case calls for that "strict enforcement," and authoritative guidance is the only way to provide regulated entities with the necessary "fair notice."

A. The Government Must Provide Regulated Parties Fair Notice of the Scope of Ambiguous Laws.

It is a "fundamental principle in our legal system … that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC* v. *Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). Notwithstanding that fundamental principle, "[f]or various reasons, regulations may be genuinely ambiguous," perhaps due to "the well-known limits of expression or knowledge." *Kisor*, 139 S. Ct. at 2410 (plurality opinion). This case is not about whether such ambiguities preclude government recoupment or other enforcement proceedings that seek to adjudicate its view. This is an FCA case threatening punitive sanctions. *Escobar*, 579 U.S. at 182. And "[w]here the imposition of penal sanctions is at issue," due process bars "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) (Scalia, J.). An ambiguous regulation may not be applied to penalize a defendant in a manner that "would result in … the kind of 'unfair surprise' against which [the Court's] cases have long warned." *Christopher*, 567 U.S. at 156. "It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable." *Id.* at 158-59.

This reflects an application of the longstanding rule of lenity. Under it, "no citizen should be held accountable for a violation of a statute whose commands are uncertain, or subjected to punishment that is not clearly prescribed." *United States* v. *San-*

tos, 553 U.S. 507, 514 (2008) (plurality opinion). That is why, "this Court has long held, statutes imposing penalties are to be construed strictly against the government and in favor of individuals." *Bittner* v. *United States*, 143 S. Ct. 713, 724 (2023) (opinion of Gorsuch, J.) (cleaned up). Lenity applies "to all 'penal' laws—that is, laws inflicting any form of punishment, including ones we might now consider 'civil' forfeitures or fines." *Wooden* v. *United States*, 142 S. Ct. 1063, 1086 n.5 (2022) (Gorsuch, J., concurring in the judgment); see also Scalia & Garner, *Reading Law* 297 (2012) (lenity "applies not only to crimes but also to civil penalties"). And while this case involves the civil FCA, 18 U.S.C. § 287 similarly imposes criminal liability for "knowing" submission of false claims to the federal government.

The approach advocated by relators and the government is inconsistent with these fundamental precepts. It is undisputed that respondents' calculations of U&C prices complied with a reasonable reading of the prevailing regulatory scheme, albeit not the one later adopted by the Seventh Circuit. Relators and the government thus seek to do exactly what this Court has forbidden: penalize respondents for failing to "divine" which of multiple reasonable interpretations of the unclear U&C regulations would ultimately be declared the winner. *Christopher*, 567 U.S. at 158-59. Here, the FCA's scienter requirement must be "construed strictly against the government," *Bittner*, 143 S. Ct. at 724 (opinion of Gorsuch, J.), so that FCA penalties do not attach to conduct that was consistent with unclear regulatory requirements.

"Vague laws invite arbitrary power." *Sessions* v. *Dimaya*, 138 S. Ct. 1204, 1223-24 (2018) (Gorsuch, J., concurring). In the FCA context, that arbitrary power would be wielded by unelected, unappointed rela-

tors—"private persons acting … under the strong stimulus of personal ill will or the hope of gain," *United States ex rel. Marcus* v. *Hess*, 317 U.S. 537, 541 n.5 (1943), and who are "motivated primarily by prospects of monetary reward rather than the public good," *Hughes Aircraft Co.* v. *United States ex rel. Schumer*, 520 U.S. 939, 949 (1997). To allow such individuals to pursue claims like the ones presented here—arising from acknowledged regulatory ambiguity—would absolve the government of any accountability for creating unclear regulatory requirements. The "law" would no longer be promulgated through appropriate channels, but instead would place every regulated party in the crosshairs of hired guns seeking a payday.

The government dismisses the applicability of these constitutional principles with startling indifference. Without a single citation, the government argues that a defendant's subjective beliefs preclude it from "justifiably complain[ing] about a lack of fair notice." U.S. Br. 30-31. This is a headscratcher. The whole point of requiring sufficient notice is to protect defendants from punishment for failing to divine which reasonable interpretation will later be declared "true." Relatedly, the government returns to the "square corners" principle to argue that due process fair notice principles evaporate for anyone "who request[s] federal funds." *Id.* at 31-32. This is more alarming still. *Heckler* certainly does not support it—that case concerned mere recoupment of overpayments, not any form of penalty—and the government cites no authority for the proposition that the burden of legal ambiguity switches from the government to the regulated party just because "federal funds" are implicated.

B. The *Safeco* Standard Ensures That Regulated Entities Have the Requisite Fair Notice.

Safeco's scienter standard avoids these concerns, because it "duly ensures that defendants must be put on notice before facing liability for allegedly failing to comply with complex legal requirements." *Sheldon*, 24 F.4th at 350. By requiring "authoritative guidance" as to what is required under ambiguous legal rules, 551 U.S. at 70, the government must announce its position about what the law means—or a defendant must act objectively unreasonably—before any FCA penalty is imposed.

In *Safeco*, this Court unanimously explained that "no court of appeals had spoken on" the disputed legal "issue, and no authoritative guidance ha[d] yet come from the" relevant agency "that might have warned [the defendant] away from" its position. *Id.* Instead, there was a "dearth of guidance" that "allow[ed] for" defendant's "reasonable interpretation." The Court drew upon the "clearly established" prong of qualified immunity and rejected reliance on a nonbinding letter that did not "canvass the issue." *Id.* at 70 & n.20 (citing *Saucier* v. *Katz*, 533 U.S. 194, 202 (2001)); see also U.S. *Safeco* Br. 23 n.19 (recognizing that the government's proposed test was "similar to the qualified-immunity inquiry").[9]

Following this Court's lead, the courts of appeals have coalesced around a straightforward test that

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[9] Under the Fourth Amendment, for an inquiry "not as forgiving as" qualified immunity, the Court similarly asks whether an officer's "error of law" is "*objectively* reasonable" and, if so, "do[es] not examine the subjective understanding of the particular officer involved." *Heien* v. *North Carolina*, 574 U.S. 54, 66-67 (2014).

equates "authoritative guidance" with an answer that carries the force of law. The inquiry focuses on: (1) circuit court precedent or formal guidance from the relevant agency, and (2) whether the guidance "'canvass[es] the issue' with sufficient specificity to be able to function as a warning." See, *e.g.*, *Sheldon*, 24 F.4th at 353-54 (collecting cases); *Schutte* Pet. App. 29a-31a (guidance must have enough "specificity to control an issue"). This also aligns with ordinary administrative-law principles: to be "entitle[d] … to controlling weight," agency "regulatory interpretation[s] … must be the agency's 'authoritative' or 'official position.'" *Kisor*, 139 S. Ct. at 2416. "[A]uthoritative" guidance, then, logically "must at the least emanate from those actors, using those vehicles, understood to make authoritative policy in the relevant context." *Id.*

Guidance that lacks the force of law, by contrast, is not sufficiently "authoritative" to warn regulated entities away from objectively reasonable positions. That was the case in *Safeco*. The proffered guidance was "nonbinding," and the agency had "only enforcement responsibility, not substantive rulemaking authority, for the provisions in question." 551 U.S. at 70 & n.19. Such "interpretations contained in policy statements, agency manuals, and enforcement guidelines … lack the force of law." *Christensen* v. *Harris Cnty.*, 529 U.S. 576, 587 (2000).

There are additional compelling reasons to keep the authoritative-guidance line where *Safeco* put it.

First, agencies are more likely to speak with specificity and "canvass an issue" when using more formal procedures. Subjecting interpretations to public comment, for instance, often leads an agency to speak in a "far clearer" fashion than in "scattershot guidance," which can frequently change and "fail[] to ar-

ticulate a coherent position." *United States ex rel. Streck* v. *Allergan, Inc.*, 746 F. App'x 101, 108-10 & n.5 (3d Cir. 2018). Such procedures also ensure that guidance accounts for reliance interests on "longstanding conduct that the agency had never before addressed," *Kisor*, 139 S. Ct. at 2418—like price-match discounts—and "reflect[s] the agency's fair and considered judgment on the matter in question," *Christopher*, 567 U.S. at 155.

Second, a requirement of authoritative guidance amply addresses concerns about defendants being "able to bury their heads in the sand" and "ignore or fail to inquire about red flags." Pet'r Br. 34-35. *Safeco*, of course, "does not shield … defendants that turn a blind eye to guidance." *Sheldon*, 24 F.4th at 350; *Schutte* Pet. App. 22a. In cases involving ambiguous legal requirements, authoritative guidance *is* the red flag. But, if an agency "fail[s] to clarify and thereby maintain[] strategic ambiguity," *Sheldon*, 24 F.4th at 354, there is no flag to ignore and no sand to bury one's head in.

Relators call the authoritative-guidance principle "made-up," "arbitrar[y]," and "bespoke." Pet'r Br. 49-52. Far from "made-up," however, the words "authoritative guidance" and their concomitant meaning come directly from *Safeco*, 551 U.S. at 70, and are reinforced by *Kisor*, 139 S. Ct. at 2416. The court of appeals correctly applied that authority here.

For its part, the government says that it "cannot feasibly address in advance every potential ambiguity." U.S. Br. 31-32. Perhaps, but it does not follow that the burden should be on regulated entities like respondents to make "inquiries" as to what the law requires of them or else suffer punitive sanctions. *Id.* The government has it backwards: "the benefit of the doubt" in these circumstances *always* goes to regulat-

ed entities, because "the state makes the laws." *Buffington*, 143 S. Ct. at 19 (Gorsuch, J.). The burden of clarifying ambiguous laws *before* imposing punishment properly rests on the government.

Respondents are not asking the government to address "every potential ambiguity in advance." This case is limited to the scope of punitive FCA liability when the government has not—deliberately or due to limited resources or for any other reason—authoritatively addressed a particular "ambiguity in advance." The government has other avenues to pursue non-punitive redress. But if the government offers no guidance or only non-authoritative guidance that cannot bind even the government, *Heckler*, 467 U.S. at 63-66, then regulated entities have not been "warned away" from any objectively reasonable position.

Finally, relators and the government contend that, by treating only authoritative guidance as sufficient, non-authoritative guidance would become "categorically" irrelevant and regulated entities would have "*carte blanche* to ignore" other sources. U.S. Br. 32-34; Pet'r Br. 49-53. Wrong again. These sources may have a role to play, but only in defining the scope of objectively reasonable views of the law. See, *e.g.*, *Schutte* Pet. App. 23a-24a (considering, among other things, GAO Report in objective reasonableness analysis); *Alaska Dep't of Env't Conservation* v. *EPA*, 540 U.S. 461, 487-88 (2004) (guidance that "lack[s] the force of law" may be accorded a "measure of respect" in interpretation); *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944). Once it is determined that the relevant law is ambiguous and that the defendant's conduct conformed to an objectively reasonable understanding, only authoritative guidance can show that

it was reckless, or worse, for the defendant to have followed the objectively reasonable course.

C. Relators' Interpretation Would Upend Settled FCA Safeguards.

Relators contend that respondents' position "invite[s] bad-faith actors" to "pillage" the public by taking advantage of regulatory ambiguity. Pet'r Br. 21-22, 51, 53. These hyperbolic concerns are overblown and fundamentally misplaced.

This case is "narrowly cabined to legally false claims"; it does not concern the "paradigmatic FCA action" targeting "factually false claims." *Sheldon*, 24 F.4th at 349-50. Within the narrow confines of legal falsity, moreover, respondents' position is narrower in at least three more ways: it requires an *objectively reasonable* interpretation of an *ambiguous* or *unsettled* legal obligation for which the government has not issued *authoritative guidance*. *Id.* This does not "write defendants a blank check" or "shield bad faith" actors. *Id.* Perhaps that is why, in the 15 years since *Safeco*, fraudsters have not run amok, unconcerned with the FCA, even though lower courts quickly recognized *Safeco*'s application to this statute. See *United States ex rel. K & R Ltd. P'ship* v. *Mass. Hous. Fin. Agency*, 530 F.3d 980 (D.C. Cir. 2008). On the contrary, as the government and relators are quick to report, they collect billions of dollars *every year* from FCA defendants. *E.g.*, U.S. Dep't of Just., *False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022* (Feb. 7, 2023), https://tinyurl.com/3zmtpsd3.

Relators' position, by contrast, would risk turning the FCA into the "all-purpose antifraud statute" that it was never meant to be. *Escobar,* 579 U.S. at 194.

For starters, the government's proposed test is full of land mines. The government casually proposes that defendants should "approach the inevitable ambiguities [in the law] in good faith, following what they understand to be the best interpretation and seeking clarification when necessary." U.S. Br. 31-32. Here's what that means: to avoid FCA liability, a company operating under ambiguous laws must both (a) follow an objectively reasonable interpretation of those laws, and (b) be ready to present evidence to a jury that the company "understood" that interpretation to be "the best." But disagreement among individuals advising a company is to be expected. And once disagreement emerges, are juries supposed to divine what the "company" viewed as the "best" interpretation? How? Is it the interpretation the current administration is most likely to adopt? See *Kisor*, 139 S. Ct. at 2439 (Gorsuch, J.). Or two judges on a circuit court to be named later? Or five members of this Court? Or something else? This case exists precisely because the government left matters unclear. The same murkiness also obscures what is "best."

Then there is the privilege issue. As the government highlighted in *Safeco*, an objective baseline is critical to "minimiz[ing] the significant intrusions on attorney-client privilege that often attend inquiries into subjective good faith compliance with the law." U.S. *Safeco* Br. 23-24. Ambiguity breeds discussion and disagreement. Employees say things, and some (like future relators) may have perverse incentives. Ultimately, however, any employee concerns uncovered in discovery would almost certainly fail to reflect what *actually* motivated the company's decisions about how to proceed in the face of legal ambiguity, because most of *those* conversations would be privileged.

The Hobson's choice is clear. "[I]n light of the vast and complicated array of regulatory legislation confronting the modern corporation," businesses consult lawyers about ambiguous legal requirements, "particularly since compliance with the law [in general] is hardly an instinctive matter." *Upjohn Co.* v. *United States*, 449 U.S. 383, 392 (1981). But telling a complete story about a company's reasoning would unquestionably force defendants to waive the privilege. This would not only force uncomfortable intrusions into privileged communications in some FCA cases, but it would cripple the ability of regulated entities to take anything but the most government-friendly position of any ambiguous legal obligation. The risks and burdens of trial, plus the reputational harm, would prove too much for companies to bear.

III. THE COURT OF APPEALS' JUDGMENTS SHOULD BE AFFIRMED.

The court of appeals applied the law correctly to grant summary judgment to respondents.

1. There is no serious question that the legal rules governing U&C pricing were susceptible to multiple objectively reasonable interpretations. Such ambiguity is not unusual: the Medicare and Medicaid statutes are "among the most completely impenetrable texts within human experience." *Rehab. Ass'n of Va., Inc.* v. *Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). Similarly, implementing regulations are often "so complicated that the best intentioned plan participant could make errors in attempting to comply with them." *United States ex rel. Wilkins* v. *United Health Grp., Inc.*, 659 F.3d 295, 310 (3d Cir. 2011). Those descriptors could have been written for the tangle of sources—from federal statutes and regulations, to state Medicaid plans, to state statutes and regula-

tions and even sub-regulatory guidance, to Medicare contracts—that concern U&C pricing. *Supra* pp.6-12.

There is also no serious question that respondents followed an objectively reasonable interpretation of ambiguous laws. Federal agencies did not define "usual and customary charges to the general public" and actually made statements supporting *respondents'* reading. *Supra* pp.6-12. State law and private PBM contracts did too. *Supra* pp.9-10, 14-15. Some courts suggested the same. *E.g.*, *Holland*, 791 N.W.2d at 726-28; *Bruno's, Inc.*, 54 F. Supp. 2d at 1258.

Respondents' reading was also reasonable as a matter of common sense. Safeway and SuperValu operate hundreds of independently licensed pharmacies. Each dispenses hundreds of prescriptions each day. And pharmacies submit claims in real time, as customers fill prescriptions. As a practical matter, it is far from obvious that a pharmacy's U&C price in any given transaction must depend on what happens with a subsequent customer.

2. Respondents were not "warned away" from this reasonable view through authoritative guidance. Before *Garbe*, no court of appeals had addressed the impact of discounts on U&C prices at all. And, again, the federal government was either silent or made statements favoring respondents' approach, all while respondents contemporaneously sought and received confirmations about their practices. *Supra* pp.6-16.

To avoid this result, relators (but not the government) invoke the CMS Manual footnote on which the Seventh Circuit relied in *Garbe*. But the CMS Manual "lack[s] the force of law" and is not binding. See *Procter* Pet. App. 21a-22a. That alone makes it inadequate. It also "says nothing about price-match programs." *Schutte* Pet. App. 30a.

"Advi[ce]"or "guidance" from PBMs also is not authoritative. Contra Pet'r. Br. 51; U.S. Br. 15.[10] PBMs are private companies, with their own profit-based incentives to push prices down (without reducing cost for the public). A PBM often may "retain the difference between what it pays the pharmacy and what it charges the plan sponsor." *Tangled Web, supra*, at 32. That difference is called the "spread." *Id.* "Maximizing spread pricing can generate enormous revenues for PBMs." *Id.* at 29. There is thus no reason to prefer a PBM's unilateral interpretation of ambiguous legal requirements over a pharmacy's. On the contrary, *Heckler*'s reasoning precludes it: the government's agent, just like private-party PBMs, "could not resolve" a "doubtful question" about a regulation with "no clear meaning." 467 U.S. at 59, 64.

3. Respondents followed an objectively reasonable approach to ambiguous legal obligations concerning U&C prices and were not warned away from that approach. Now consider what they would face at the jury trial that relators and the government contend is necessary. The government thinks that the only correct value of damages in an FCA case is the total value of the false claims. So the starting point, in its view, is the amount of *every* Medicare and Medicaid dollar respondents were paid for every drug that they dispensed. Given the ubiquity of Medicare and Medicaid, by averages, that could amount to about half of all revenue from these pharmacies for nearly ten years. Treble damages are automatic, so that gets multiplied by three—no exceptions. Then there are the mandatory penalties per claim of up to (at the time) $11,000. Years of attorney's fees—also compul-

[10] Relators also waived reliance on PBM contracts, *Schutte* Pet. App. 23a n.8; JA104-05, 250-56, and the PBM contracts in the record do not help relators anyway.

sory—become a rounding error. The upshot could be literally billions of dollars of exposure. That is an untenable outcome for operating within an objectively reasonable view of ambiguous legal obligations.

CONCLUSION

For the foregoing reasons, the judgments below should be affirmed.

Respectfully submitted,

ROBERT N. HOCHMAN
TACY F. FLINT
JAIME L.M. JONES
CLAIRE G. LEE
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603

TYLER J. DOMINO
SIDLEY AUSTIN LLP
787 Seventh Ave.
New York, NY 10019

CARTER G. PHILLIPS*
KWAKU A. AKOWUAH
JOSHUA J. FOUGERE
JILLIAN S. STONECIPHER
ADAM KLEVEN
LAKEISHA F. MAYS
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
cphillips@sidley.com

Counsel for SuperValu, Inc., et al. & Safeway, Inc.

March 21, 2023

* Counsel of Record

APPENDIX

TABLE OF CONTENTS

Appendix A

PERTINENT STATE STATUTES, REGULATIONS, CMS-APPROVED MEDICAID STATE PLAN AMENDMENTS, & STATE AGENCY GUIDANCE

California (*Schutte* and *Proctor*)

California State Plan Amendment 05-027, Attachment 4.19-B, Supplement 2, p. 1 (eff. Oct. 1, 2005), approved by CMS June 6, 2006 [filed under seal May 21, 2018, Schutte Doc. 174-87, Ex. 85]

PAYMENT METHODOLOGY FOR PRESCRIPTIONS

The policy of the State Agency is that reimbursement for Pharmaceutical Services and Prescribed Drugs, as one category of health care or service from among those listed in Section 1905(a) of the Social Security Act that are included in the program under the plan, will be at the provider pharmacy's current charges to the general public, up to the State Agency's limits. The price providers charge the program shall not exceed that charged to the general public. The pharmacist, to the extent permitted by law, shall dispense the lowest cost, therapeutically equivalent drug product that the pharmacy has in stock, which meets the medical needs of the beneficiary.

* * *

Cal. Welf. & Insts. Code § 14105.455 (2009), added by 2009 Cal. Legis. Serv. 4th Ex. Sess. Ch. 5 (A.B. 5), § 39

* * *

(b) "Usual and customary charge" means the lower of the following:

(1) The lowest price reimbursed to the pharmacy by other third-party payers in California, excluding Medi-Cal managed care plans and Medicare Part D prescription drug plans.

(2) The lowest price routinely offered to any segment of the general public.

* * *

Cal. Code Regs. tit. 22, § 51513 – Pharmaceutical Services and Prescribed Drugs

* * *

(b) Payment for Legend and Nonlegend Drugs.

(1) Payment for legend and nonlegend drugs dispensed by licensed pharmacists in compliance with Section 51313 shall be in accordance with Welfare and Institutions Code, Section 14105.45. Payments for legend and nonlegend drugs dispensed by a clinic with a special permit pursuant to Business and Professions Code, Section 4063, and provided in compliance with Section 51313 shall consist of the cost of the legend or nonlegend drugs.

(A) The price charged to the program shall not exceed that charged to the general public.

* * *

Delaware (*Proctor*)

Delaware State Plan Amendment 09-002, Attachment 4.19-B, p. 14 (eff. Apr. 1, 2009), approved by CMS Jan. 24, 2011

* * *

The Delaware Medical Assistance (DMAP) program will reimburse pharmaceuticals using *the lower* of

- The usual and customary charge to the general public for the product,
- The Estimated Acquisition Cost (EAC) which is defined for both brand name and generic drugs as follows:
    - For Traditional Pharmacies: AWP minus *16%* plus dispensing fee per prescription, *effective for dates of service on or after April 1, 2009*
    - For Non-Traditional Pharmacies: AWP minus *18%* plus dispensing fee per prescription, *effective for dates of services on or after April 1, 2009*
- A State-specific maximum allowable cost (DMAC) and, in some cases, the Federally defined Federal Upper Limit (FUL) prices plus a dispensing fee.

* * *

Delaware State Plan Amendment 14-0008, Attachment 4.19-B, p. 14 (eff. Apr. 1, 2014), approved by CMS Jan. 5, 2015

The Delaware Medical Assistance Program (DMAP) will reimburse pharmaceuticals using the lower of:

- The usual and customary (U & C) charge to the general public for the product,
- National Average Drug Acquisition Cost (NADAC) or if a NADAC is not available the Average Wholesale Price (AWP) minus 19%,
- A State-specific maximum allowable cost (DMAC) when the purchase price is not appropriately represented by either the

NADAC or the Average Wholesale Price (AWP) minus 19%,

- The Federal Upper Limit (FUL) will not be used since the NADAC reflects the actual acquisition cost.

* * *

District of Columbia (*Proctor*)

District of Columbia State Plan Amendment 11-05, Attachment 4.19-B, p. 3a (eff. Oct. 1, 2011), approved by CMS Dec. 22, 2011

* * *

d. Methods established for determining prescription reimbursement are:

(1) Pharmacy claims for a retail pharmacy provider shall be reimbursed at the lower of the following:

(a) The allowable cost, established pursuant to sections 5b, 5c, or 5e of this Attachment, as appropriate, plus a dispensing fee of four dollars and fifty cents ($4.50) per prescription; or

(b) The pharmacy's usual and customary charge to the general public.

(2) Pharmacy claims for a nursing home pharmacy provider shall be reimbursed at the lower of the following:

(a) The allowable cost, established pursuant to section 5b, 5c, 5d.3 or 5e, as appropriate, plus a dispensing fee of four dollars and fifty cents ($4.50) per non-IV (intravenous) prescription or seven dollars and twenty-five cents ($7.25) for cassette, TPN (total parenteral nutrition) or container-related prescriptions); or

(b) The pharmacy's usual and customary charge to the general public.

* * *

D.C. Mun. Regs. tit. 29, § 2708.1 (2012). REIMBURSEMENT FOR MULTIPLE SOURCE DRUGS

The allowable cost for multiple source drugs designated by the Centers for Medicare and Medicaid Services (CMS) and included in its Medicaid Drug Rebate Program ("CMS listings") shall be the lower of the following:

(a) The Federal Upper Limit (FUL) for multiple source drugs other than those brand names for which a prescriber has certified in writing as "Medically Necessary" or "Brand Necessary"; or

(b) The Maximum Allowable Cost (MAC) established pursuant to § 2708.2 and 2708.3.

D.C. Mun. Regs. tit. 29, § 2709.1 (2012). REIMBURSEMENT FOR BRAND NAME DRUGS

Methods for determining costs of single source drugs are:

(a) The costs for prescribed drugs which shall not exceed the WAC, plus three percent (3%), if available;

(b) The costs for drugs that do not have a WAC shall be priced based on the direct price benchmark plus three percent (3%) as evaluated by DHCF using a national standard database; and

(b) The cost for the WAC which shall be the price, at the time of service, obtained from a nationally recognized comprehensive data file maintained by a vendor under contract with DHCF.

D.C. Mun. Regs. tit. 29, § 2708.2 (2018). REIMBURSEMENT FOR MULTIPLE SOURCE DRUGS

Reimbursement for multiple source drugs shall include a professional dispensing fee in the amount of eleven dollars and fifteen cents ($11.15) plus the lesser of:

(a) The Federal Upper Limit ("FUL") of the drug for multiple source drugs, with the exception of the following:

(1) Multiple source drugs that do not have FULs; and

(2) Brand name drugs for which a prescriber has certified in writing as "Dispense as Written" or "Brand Necessary," subject to the requirements set forth under § 2708.3;

(b) The National Average Drug Acquisition Cost ("NADAC") when available, which shall be published online at: https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html;

(c) The Wholesale Acquisition Cost ("WAC") plus zero percent (0%), which shall be kept by drug file pricing compendia vendors or drug databases approved by and in use at the federal level;

(d) The pharmacy's usual and customary charges to the general public; or

(e) The District Maximum Allowable Cost ("DMAC") established pursuant to §§ 2708.4 and 2708.5.

D.C. Mun. Regs. tit. 29, § 2709.1 (2018). REIMBURSEMENT FOR BRAND NAME DRUGS

Reimbursement for brand name drugs shall include a professional dispensing fee in the amount of $11.15 and the lesser of:

(a) The pharmacies' usual and customary charges to the general public; or

(b) The Actual Acquisition Cost (AAC), which shall be determined by DHCF in accordance with § 2709.2.

Hawai'i (*Proctor*)

Haw. Code R. § 17-1739.1-11 – Payment for drugs and related supplies

(a) The state medical assistance program shall determine reimbursement for the ingredient cost of prescription drugs using the following criteria:

(1) Single source drugs shall not exceed the lower of:

(A) The provider's invoice price;

(B) The provider's usual and customary charge to the general public; or

(C) The estimated acquisition cost (EAC).

(2) Multiple source drugs shall not exceed the lower of:

(A) The provider's invoice price;

(B) The provider's usual and customary charge to the general public;

(C) The EAC;

(D) The federal upper limit (FUL) price; or

(E) The state maximum allowable cost (SMAC).

* * *

State of Hawai'i Department of Human Services, Medicaid Provider Manual, Ch. 19, pp. 36-37 § 19.1.8.1 (Jan. 2011)

a) The maximum allowance for medications is the lowest of the following:

1. Single source drugs:
   - Estimated Acquisition Cost (EAC) plus a dispensing fee;
   - The billed charge; or
   - Provider's usual and customary charge to the general public.
2. Multiple Source Drugs:
   - The billed charge;
   - The provider's usual and customary charge to the general public;
   - The Federal Upper Limit (FUL) price plus dispensing fee; See Appendix 1 for CMS website for the FUL price list.
   - When no FUL available, the State Maximum Allowance Cost (SMAC) plus dispensing fee (see Appendix 1 for Pharmacy Fiscal Agent website for SMAC list); or
   - The Estimated Acquisition Cost (EAC) plus dispensing fee.
3. Over-The Counter (OTC) Drugs:
   - The billed charge;
   - The provider's usual and customary charge to the general public including any sale item which may be available on the day of service;

- When no FUL available, the State Maximum Allowable Cost (SMAC) plus a dispensing fee (see Appendix 1 for Pharmacy Fiscal Agent website for SMAC list);
- The Federal Upper Limit (FUL) price plus a dispensing fee; See Appendix 1 for CMS website for the FUL price list or
- The Estimated Acquisition Cost (EAC) plus a dispensing fee.

* * *

Hawai'i State Plan Amendment 11-008, Attachment 4.19-B, p. 6 (eff. Oct. 1, 2012), approved by CMS Apr. 13, 2012

* * *

a. Payment for medications:

1. Payment for ingredient cost of prescription drugs:

A. For single source drugs, shall not exceed the lower of:

i. The provider's invoice price;

ii. The provider's usual and customary charge to the general public; or

iii. The estimated acquisition cost (EAC).

B. For multiple source drugs, shall not exceed the lower of:

i. The provider's invoice price;

ii. The provider's usual and customary charge to the general public;

iii. The EAC;

iv. The Federal Upper Limit (FUL) price; or

v. The State Maximum Allowable Cost (SMAC).

* * *

Illinois (*Schutte* and *Proctor*)

225 Ill. Comp. Stat. Ann. 85/3 (2007). Definitions

* * *

(w) "Current usual and customary retail price" means the price that a pharmacy charges to a non-third-party payor.

* * *

Ill. Admin. Code tit. 89, § 140.12 – Participation Requirements for Medical Providers

The provider shall agree to:

* * *

h) Make charges for the provision of services and supplies to recipients in amounts not to exceed the provider's usual and customary charges and in the same quality and mode of delivery as are provided to the general public;

* * *

Ill. Admin. Code tit. 89, § 140.447 – Reimbursement

* * *

b) If a pharmacy gives discounts to the general public, it must provide the same to Public Aid recipients. If discounts are allowed only to a specific group of people, they shall be extended to a recipient if he or she is a member of the special discount group. Public Aid recipients can constitute a special group and receive a discount, but they cannot be excluded from a discount group just because they are recipients.

* * *

Illinois State Plan Amendment 12-018, Attachment 4.19-B, p. 32 (eff. July 1, 2012), approved by CMS Feb. 18, 2014

4. PRESCRIBED DRUGS:

a. REIMBURSEMENT: Except for Critical Clinic Providers described in Chapter 1, subsection (1)(e), pharmacies will be reimbursed for prescribed drugs at the lower of:

i. The pharmacy's usual and customary charge to the general public,

ii. The applicable methodology from among the following plus the applicable dispensing fee:

A. Single source legend drugs. Effective July 21 ~~February 1~~, 2012, the lower of:

Wholesale acquisition cost of national drug code on claim, ~~plus 1%~~.

The State upper limit.

B. Multiple source legend drugs. Effective July 21 ~~February 1~~, 2012, the lower of:

Wholesale acquisition cost of national drug code on claim, ~~plus 1%~~.

The federal upper limit.

The State upper limit.

* * *

Illinois Department of Healthcare and Family Services, Handbook for Providers of Pharmacy Services, Ch. P-200, Policy and Procedures for Pharmacy Services (Mar. 2016), at HFS P-200 (vi)

* * *

Usual and Customary (U & C) Charge: The usual and customary charge is the amount a provider would charge cash customers for a prescription, exclusive of sales tax.

Illinois Department of Healthcare and Family Services, Handbook for Providers of Pharmacy Services, Ch. P-200, Policy and Procedures for Pharmacy Services (Mar. 2016), at HFS P-202 (1)

* * *

Providers must charge the Department no more than their Usual and Customary Charge for any prescription or Over-the-Counter (OTC) drug or pharmacy item. The Usual and Customary Charge is the amount charged for the same prescription to cash customers exclusive of sales tax. The Department reimburses the lesser of the provider's charges or the Department's maximum allowable amount. The payment amount is returned to the pharmacy in the real-time response for claims billed electronically through NCPDP D.0, and is also included on the remittance advice.

Discounts provided to the general public must also be provided to Medical Assistance participants. If, however, discounts are allowed only to a certain defined group, then the discount should be extended to a Medical Assistance participant if they can be considered a member of the group. For example, if the pharmacy extends a discount to "senior citizens," then the pharmacy must extend the discount to all Medical

Assistance "senior citizens." A pharmacy cannot exclude a Medical Assistance participant from a discount group based solely on their status as a Medical Assistance participant. However, Medical Assistance participants can constitute a special group and receive a discount.

* * *

Illinois Department of Healthcare and Family Services, Handbook for Providers of Pharmacy Services, Ch. P-200, Policy and Procedures for Pharmacy Services (Mar. 2016), at HFS P-203 (1)

* * *

P-203.1 Reimbursement Methodology

Legend Drugs

The Department establishes upper limits on payments for all pharmacy items in accordance with federal regulations. The Department's payment limits are based on the Department's maximum allowable cost. Effective July 1, 2012, for legend (prescription) drugs, the Department shall pay the lower of:

- the pharmacy's usual and customary charge to the general public; or
- the Department's maximum price plus the established dispensing fee The Department shall pay only one dispensing fee per 30-day supply for those drugs dispensed in accordance with Section 140.443(h)

* * *

Over-the-Counter Products

For over-the-counter items that are covered, pharmacies will be reimbursed at the lowest of:

- The pharmacy's usual and customary charge to the general public;
- WAC + 25%; or
- The State Upper Limit.

* * *

Montana (*Proctor*)

Montana Department of Public Health & Human Services, Prescription Drug Program Manual, § 6.1 (Nov. 2004)

* * *

Reimbursement for covered drugs is the lessor of:

- The provider's usual and customary charge
- The estimated acquisition cost (EAC) plus a dispensing fee
- The maximum allowable cost (MAC) plus a dispensing fee

Usual and customary

The usual and customary charge is the price the provider most frequently charges the general public for the same drug. In determining "usual and customary" prices, the Department:

- Does not include prescriptions paid by third party payers, including health insurers, governmental entities, and Montana Medicaid, in the "general public".

- Includes discounts advertised or given (including but not limited to cash rebate, monetary price discount, coupon of value) to any segment of the general public.
- Uses the lower of the two pricing policies if a provider uses different pricing for "cash" and "charge" clients.
- Will use the median price if during an audit, the most frequent price cannot be determined from pharmacy records.

* * *

Montana State Plan Amendment 10-003, Attachment 4.19-B, p. 1 (eff. Mar. 1, 2010), approved by CMS Mar. 14, 2011

Reimbursement for drugs shall not exceed the lowest of:

1. The Estimated Acquisition Cost (EAC) of the drug plus a dispensing fee, or;

2. The State Maximum Allowable Cost (SMAC) of the drug, in the case of multi-source (generic), plus a dispensing fee, or,

3. The provider's usual and customary charge of the drug to the general public.

* * *

Mont. Admin. R. 37.86.1101 (2016) – OUTPATIENT DRUGS, DEFINITIONS

* * *

(14) "Usual and customary charge" means the price the provider charges a typical customer in the provider's typical course of business.

* * *

Nevada (*Proctor*)

Nev. Rev. Stat. Ann. § 439.915. Department to place on Internet website information concerning pharmacies and prices for prescription drugs; additional or alternative procedures for obtaining information concerning pharmacies and prices for prescription drugs.

1. Except as otherwise provided in subsection 2, the Department shall:

* * *

(c) Ensure that the usual and customary price that each pharmacy charges for each prescription drug that is on the list prepared pursuant to NRS 439.905 and that is stocked by the pharmacy:

(1) Is presented on the Internet website maintained by the Department in a manner which complies with the requirements of NRS 439.920; and

(2) Is updated not less frequently than once each calendar quarter.

Nothing in this subsection prohibits the Department from determining the usual and customary price that a pharmacy charges for a prescription drug by extracting or otherwise obtaining such information from claims reported by pharmacies to the Medicaid program.

* * *

4. As used in this section, "usual and customary price" means the usual and customary charges that a provider charges to the general public for a drug, as described in 42 C.F.R. § 447.331.

Nevada State Plan Amendment 17-004, Attachment 4.19-B, p. 3 (eff. Apr. 1, 2017), approved by CMS July 21, 2017

* * *

1. Payment for multi-source drugs shall be the lowest of (a) Federal Upper Limit (FUL) as established by the Centers for Medicare and Medicaid Services (CMS) for listed multi-source drugs plus a professional dispensing fee of $10.17 per prescription; (b) State Maximum Allowable Cost (MAC) plus a professional dispensing fee of $10.17 per prescription; (c) Actual Acquisition Cost (AAC) plus a professional dispensing fee of $10.17 per prescription; or (d) the pharmacist's usual and customary charge.

2. Payment for covered outpatient drugs other than multi-source drugs shall not exceed the lower of (a) AAC plus a professional dispensing fee of $10.17 per prescription; or (b) the pharmacist's usual and customary charge to the general public.

* * *

Nevada Medicaid Services Manual, Division of Health Care Financing and Policy, Addendum G (2017)

* * *

GENERAL PUBLIC

General Public is defined as the patient group accounting for the largest number of non-Medicaid prescriptions from a pharmacy. This excludes patients who purchase or receive prescriptions through third party payers such as Blue Cross, Aetna, PAID, PCS, etc. If a pharmacy discounts prices to specified customers, (e.g. 10% discount to senior citizens) these lower prices should be excluded from usual and

customary calculations unless they represent more than 50% of the store's prescription volume.

* * *

New Jersey (*Proctor*)

N.J. Admin. Code § 10:51-1-10 Provider's usual and customary charge or advertised charge

(a) The provider's usual and customary charge or advertised charge is an element considered in the calculation of the basis of payment for legend drugs (see N.J.A.C. 10:51-1.5, Basis of payment).

(b) The usual and customary charge to the Medicaid or NJ FamilyCare program is defined as the amount a provider charges the general public for a prescription for the same drug product (same NDC number) in the same quantity as the prescription being dispensed to a Medicaid or NJ FamilyCare beneficiary. "Usual and customary charge" means the actual charge made to the majority (51 percent) of the total patient population served by the individual pharmacy.

1. The provider shall not charge the programs more than would be charged to a cash customer when the general public, including private third party plans, accounts for more than 50 percent of a provider's total prescription volume.

i. In the event Medicaid, NJ FamilyCare and/or PAAD represent more than 50 percent of a provider's total prescription volume, then, for reimbursement purposes, the provider's usual and customary charge may be considered the amount the programs would reimburse for the same services.

New Jersey State Plan Amendment 09-05-MA, Attachment 4.19-B, pp. 10–10(g) (eff. July 1, 2009), approved by CMS Nov. 5, 2010

Payment for drugs shall be as follows:

1.16 Maximum Allowable Cost (Ingredient Cost) – legend drugs

(a) The Maximum Allowable Cost for legend drugs shall not exceed the lower of the Estimated Acquisition Cost (EAC); the Federal Upper Limit (FUL), as supplied by the reference drug file contractor, or the pharmacy's usual and customary charge.

* * *

1.18 Total Charge – legend drugs

The total charge to Medicaid for a legend drug prescription shall not exceed the lower of a drug's EAC, as described in 1.16 above plus a dispensing fee as described in 1.17 above; or a provider's usual and customary charge to the general public.

* * *

1.22 Maximum Allowable Cost (Ingredient Cost) – non-legend drugs

(a) The Maximum Allowable Cost for non-legend drugs shall not exceed the lower of the Estimated Acquisition Cost (EAC), as supplied by the reference drug file contractor, or the pharmacy's usual and customary charge.

* * *

1.24 Total Charge – non-legend drugs

The total charge to Medicaid for a non-legend drug prescription shall not exceed the lower of a drug's

EAC, as described in 1.22 above plus a dispensing fee as described in 1.23; or a provider's usual and customary charge to the general public.

New Mexico (*Proctor*)

N.M. Code R. § 8.324.4.16 (2010)

Reimbursement: Pharmacy providers must submit claims for reimbursement on the separate pharmacy claim form or its successor. ***

A. General reimbursement methodology:

* * *

(5) Usual and customary charge:

(a) The provider's billed charge must be its usual and customary charge for services. Over-the-counter items must be billed with the over-the-counter price as the usual and customary charge, unless it is labeled and dispensed as a prescription.

(b) "Usual and customary charge" refers to the amount that the individual provider charges the general public in the majority of cases for a specific procedure or service.

(c) Usual and customary charges must reflect discounts given to non-medicaid recipients for certain reasons, such as age or nursing home residents, when a medicaid recipient meets the standards for the discount. Medicaid must be given the advantage of discounts received by the general public, including promotions or items sold at cost to the general public, if these are the prices usually and customarily charged to non-medicaid recipients.

(d) Providers must not add additional costs for their time, paperwork, or anticipated turnaround time for payment.

* * *

D. Pharmacy price reductions: If the pharmacy provider offers a discount, rebate, promotion or other incentive that results in a reduction of the price of a prescription to the individual non-medicaid customer, the provider must similarly reduce its charge to MAD for the prescription.

* * *

New Mexico State Plan Amendment 12-06B, Attachment 4.19-B, p. 4 (eff. Jan 1, 2014), approved by CMS June 19, 2014

* * *

For the Medicaid Fee-For-Service Program, the Department reimburses the lesser of the computed price or the usual and customary charge. This pricing methodology does not apply to drug items reimbursed under Section 1915(b) Waiver for Managed Care.

* * *

New Mexico Human Services Department, Medical Assistance Division, Managed Care Policy Manual, p. 219 (2014)

* * *

A Medicaid-approved PCS agency will process billings in accordance with the MCO billing instructions. Reimbursement for PCS will be based on the negotiated rate with the MCO.

The agency's billed charge must be the usual and customary charge for services. "Usual and customary charge" refers to the amount an individual provider charges the general public in the majority of cases for a specific service and level of service.

* * *

Utah (*Schutte*)

Utah State Plan Amendment 11-014, Attachment 4.19-B, p. 19 (eff. Nov. 1, 2011), approved by CMS Aug. 2, 2012

* * *

Prescribed drugs will be reimbursed based on an established product cost plus a dispensing fee. The payment for individual prescriptions cannot exceed the amount billed. The amount billed must the usual and customary charge to the private pay patient. The following methodology is used to establish Medicaid payments:

> Effective for claims adjudicated on or after February 18, 2012, except for special category fees, and in addition to a reasonable dispensing fee, reimbursement will be as follows.
>
> If there is a Utah maximum allowable cost (UMAC), then the reimbursement is the lesser of the UMAC Ingredient Cost Submitted, or the provider's usual and customary charge (billed charge) to the general public. Otherwise reimbursement will be the lesser of the Ingredient Cost Submitted, Federal "Upper Limit," Utah estimated acquisition cost (EAC), or the provider's usual and customary charge (billed charge) to the general public.

* * *

Utah State Plan Amendment 16-0010, Attachment 4.19-B, p. 19 (eff. May 1, 2016), approved by CMS May 4, 2016

* * *

Prescribed drugs will be reimbursed based on an established product cost plus a dispensing fee. The payment for individual prescriptions shall not exceed the amount billed. The amount billed must be no more than the usual and customary charge (U&C) to the private pay patient. The following methodology is used to establish Medicaid payments:

> Effective for claims adjudicated on or after May 1, 2016, except for special category fees and in addition to a reasonable dispensing fee, reimbursement for covered outpatient drugs will be as follows:
>
> The lesser of the Utah Estimated Acquisition Cost (EAC), the Federal Upper Limit, Utah Maximum Allowable Cost (UMAC), or the Ingredient Cost Submitted.

* * *

Utah Admin. Code R. 414-60-2 (eff. Dec. 1, 2016) – Definitions

* * *

(5) "Usual and customary charge" means the lowest amount a pharmacy charges the general public for a covered outpatient drug, which reflects advertised savings, discounts, special promotions, or any other program available to the general public.

* * *

Virginia (*Proctor*)

12 Va. Admin. Code § 30-80-40 (2006). Fee-for-service providers: pharmacy.

Payment for pharmacy services shall be the lowest of items 1 through 5 (except that items 1 and 2 will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.331 (c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit of VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

* * *

3. The provider's usual and customary charge to the public, as identified by the claim charge.

* * *

Virginia State Plan Amendment 10-01, Attachment 4.19-B, pp. 7.3–7.4 (eff. Jan. 1, 2010), approved by CMS Apr. 21, 2010

* * *

Payment for pharmacy services shall be the lowest of items 1 through 5 (except that items 1 and 2 will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with he procedures set forth in the longstanding provisions formerly at 42 CFR 447.331(c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit of VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

* * *

3. The provider's usual and customary charge to the public, as identified by the claim charge.

* * *

12 Va. Admin. Code § 30-80-40 (2016). Fee-for-service providers: pharmacy.

Payment for pharmacy services (excluding outpatient hospital) shall be the lowest of subdivisions 1 through 5 of this section (except that subdivisions 1 and 2 of this section will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.512(c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit of VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

* * *

3. The provider's usual and customary charge to the public, as identified by the claim charge.

* * *

Washington (*Schutte*)

Wash. Admin. Code § 388-530-7000 (2007). Reimbursement.

(1) The department's total reimbursement for a prescription drug must not exceed the lowest of:

(a) Estimated acquisition cost (EAC) plus a dispensing fee;

(b) Maximum allowable cost (MAC) plus a dispensing fee;

(c) Federal upper limit (FUL) plus a dispensing fee;

(d) Actual acquisition cost (AAC) plus a dispensing fee for drugs purchased under section 340B of the Public Health Service (PHS) Act;

(e) Automated maximum allowable cost (AMAC) plus a dispensing fee; or

(f) The provider's usual and customary charge to the non-medicaid population.

* * *

(5) If the pharmacy provider offers a discount, rebate, promotion or other incentive which directly relates to the reduction of the price of a prescription to the individual non-medicaid customer, the provider must similarly reduce its charge to the department for the prescription.

* * *

Wash. Admin. Code § 182-530-1050. Definitions. (recodified from § 388-530-1050 in 2011)

* * *

"Usual and customary charge" – The fee that the provider typically charges the general public for the product or service.

* * *

Wash. Admin. Code § 182-530-7000 (2011). Reimbursement.

(1) The agency's reimbursement for a prescription drug dispensed through point-of-sale (POS) must not exceed the lesser of actual acquisition cost (AAC) plus a professional dispensing fee or the provider's usual and customary charge.

(2) The agency selects the sources for pricing information used to set POS AAC.

(3) The POS AAC is calculated as the lowest of:

(a) National average drug acquisition cost (NADAC);

(b) Maximum allowable cost (MAC);

(c) Federal upper limit (FUL);

(d) 340B Actual acquisition cost (340B AAC) for drugs purchased under section 340B of the Public Health Service (PHS) Act (see WAC 182-530-7900 for exceptions); or

(e) Automated maximum allowable cost (AMAC).

* * *

(9) If the pharmacy provider offers a discount, rebate, promotion or other incentive which directly relates to the reduction of the price of a prescription to the individual nonmedicaid customer, the provider must similarly reduce its charge to the agency for the prescription.

* * *

Washington State Plan Amendment 15-0023, Attachment 4.19-B, Supp. A, p. 1 (eff. July 1, 2015), approved by CMS Dec. 18, 2015

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B. Total reimbursement for a prescription drug does not exceed the lowest of:

1. Estimated acquisition cost (EAC) plus a dispensing fee;

2. Maximum allowable cost (MAC) plus a dispensing fee;

3. Federal Upper Limit (FUL) plus a dispensing fee;

4. Automated Maximum Allowable Cost (AMAC) plus a dispensing fee;

5. Actual acquisition cost (AAC) plus a dispensing fee for drugs purchased under section 340B of the Public Health Services (PHS) Act and dispensed to medical assistance clients; or

6. The provider's usual and customary (U&C) charge to the non-Medicaid population.

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