

FOR PUBLICATION

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

United States of America ex rel.
ADVENTIST HEALTH SYSTEM OF
WEST, Relator, on behalf of the State
of California and other States,

Plaintiff - Appellant,

v.

ABBVIE INC.; ALLERGAN SALES,
LLC; ALLERGAN USA, INC.;
ASTRAZENECA, LP;
ASTRAZENECA
PHARMACEUTICALS, LP;
NOVARTIS PHARMACEUTICALS
CORPORATION; SANDOZ GROUP
AG; GENZYME CORPORATION;
SANOFI US SERVICES INC.;
SANOFI-AVENTIS U.S. LLC;
NOVARTIS AG; SANOFI S.A.,

Defendants - Appellees.

No.24-2180

D.C. No. 2:21-cv-
04249-DSF-SK

OPINION

Appeal from the United States District Court
for the Central District of California
Dale S. Fischer, District Judge, Presiding

Submitted April 10, 2025*
Pasadena, California

Filed March 17, 2026

Before: Consuelo M. Callahan, Roopali H. Desai, and Ana de Alba, Circuit Judges.

Opinion by Judge Desai

SUMMARY**

False Claims Act

The panel reversed the district court's dismissal for failure to state a claim and remanded for further proceedings in a *qui tam* action brought by Adventist Health System of West, asserting violations of the False Claims Act and state law analogues by drug manufacturers that participated in the Public Health Service Act's Section 340B Program and were subject to price ceilings for drugs they sold to certain health-care facilities.

Adventist, an operator of medical clinics and facilities and a covered entity under the Section 340B Program, bought drugs from defendants for its patients. Medicaid and Medicare reimbursed Adventist for the prices that

* The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

defendants charged Adventist for the drugs. Adventist claimed that defendants engaged in a fraudulent scheme to charge inflated prices that did not comply with the statutory ceiling.

Under *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 113 (2011), there is no private right of action under Section 340B for covered entities to sue drug manufacturers for overcharging and repayment. Rather, a covered entity must file a claim through the Section 340B Administrative Dispute Resolution process if it alleges a direct pricing violation against a drug manufacturer. Adventist, however, sought under the False Claims Act to recover losses incurred by the government, rather than losses that Adventist itself suffered. The panel concluded that because Adventist brought an action under the False Claims Act, the absence of a private right of action under Section 340B was immaterial; Adventist was not “in essence” suing to enforce Section 340B; and barring Adventist’s claims would undermine the False Claims Act. Accordingly, Adventist’s claims under the False Claims Act were not barred by Section 340B or *Astra*.

The panel also held that Adventist plausibly pleaded falsity under the False Claims Act, and therefore reversed the district court’s dismissal and remanded for further proceedings.

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OPINION

DESAI, Circuit Judge:

Adventist Health System of West (“Adventist”) appeals the district court’s dismissal of its *qui tam* complaint asserting claims under the False Claims Act and state law analogues (collectively, “FCA”)¹ against four drug manufacturers: AbbVie, AstraZeneca, Novartis, and Sanofi. Defendants are participants in the Public Health Service Act’s Section 340B Program and are subject to price ceilings for drugs they sell to certain health-care facilities (“covered entities”), like Adventist. *See* 42 U.S.C. § 256b(a)(1). Adventist claims that defendants fraudulently inflated drug prices, causing the federal and state governments to wrongly pay millions of dollars through Medicaid, Medicare, and government-funded clinics.

Defendants argue that Adventist’s claims fail because they arise under Section 340B, and there is no private right of action under Section 340B. According to defendants, covered entities like Adventist may only seek relief for pricing-related claims through Section 340B’s

¹ The district court and the parties do not distinguish between the FCA and its state law analogues and any differences between the two are not relevant to our analysis. We thus jointly refer to them as the FCA in this opinion.

administrative enforcement mechanism. In the alternative, defendants argue that even if Adventist can bring FCA claims, Adventist's claims fail as a matter of law because Adventist's first amended complaint ("FAC") does not plausibly plead falsity under the FCA. Because Adventist asserts legally cognizable claims for relief under the FCA and has satisfied the necessary pleading requirements, we reverse and remand.

Background

The Section 340B Drug Pricing Program was created by Congress in 1992 to improve access to care for low-income and uninsured patients at safety-net hospitals and clinics. Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943. Specifically, the Section 340B Program provides a "penny pricing" policy, which prohibits drug manufacturers from charging covered entities more than \$0.01 when the statutory ceiling price of a drug falls to at or below zero. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 61563, 61564 (Nov. 30, 2018). The Section 340B Program allows covered entities to purchase drugs at discounted or ceiling prices. *See* 42 U.S.C. § 256b(a)(1). Drug manufacturers may opt into the Section 340B Program by signing a pharmaceutical pricing agreement ("PPA") with the Secretary of Health and Human Services ("HHS"). *See id.* The Health Resources and Services Administration ("HRSA"), a unit of HHS, manages and oversees the Section 340B Program. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. at 61563.

Adventist is a nonprofit corporation that operates medical clinics and facilities in several states. It is a covered

entity under the Section 340B Program. Defendants are drug manufacturers that opted into the Section 340B Program by signing a PPA with HHS. Like other covered entities, Adventist bought drugs from defendants for its patients. Medicaid and Medicare reimbursed Adventist for the prices defendants charged Adventist for the drugs. *See* 42 C.F.R. § 447.502; 42 U.S.C. § 1395m(g)(1).

In its FAC, Adventist claims that defendants engaged in a fraudulent scheme by knowingly charging “materially false, unlawfully inflated prices” for their drugs “that bore no relation to the statutory formula.” According to Adventist, defendants fraudulently inflated drug prices for many years and only began to “change their ways” when HRSA issued a 2019 final rule that “imposed hefty civil penalties for non-compliance with the 340B Ceiling Price formula.”² Shortly after January 2019, Adventist discovered defendants’ scheme when “the [drug] prices charged by [d]efendants dropped precipitously to \$0.01 per unit.” Adventist claims that market forces and changes in the statutory formula could not cause the sudden price decreases. Rather, according to Adventist, the drop in prices could only be explained by defendants’ longtime and

² HRSA published the final rule, effective January 1, 2019, which imposed “civil penalties on manufacturers who charge more than \$0.01 when the statutory formula yields a Ceiling Price of zero.” *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. at 61563. But Adventist claims that this final rule “did not change (nor could it change) the statutory definitions and requirements for ceiling prices. Instead, the regulation provided monetary penalties for violating these statutory requirements, and it codified HRSA’s 2011 formal written guidance regarding ‘Penny Pricing.’”

systemic noncompliance with the statutory ceiling price formula “to the detriment of the government programs.”

There is no private right of action under Section 340B for covered entities to sue drug manufacturers for overcharging and repayment. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011). Rather, a covered entity must file a claim through the Section 340B Administrative Dispute Resolution (“ADR”) process if it alleges a direct pricing violation against a drug manufacturer. *See id.* at 115–16; 42 U.S.C. § 256b(d)(3); 42 C.F.R. §§ 10.3, 10.21. Upon the filing of a claim by a covered entity against a drug manufacturer for a direct pricing violation, an ADR panel of HRSA experts is responsible for adjudicating the claim and, if the panel finds there was a violation, it can impose sanctions against the manufacturer, including ordering reimbursement of overcharges to the covered entity or termination of the manufacturer’s PPA with the government. *See Astra*, 563 U.S. at 115–16; 42 C.F.R. § 10.23.

Adventist’s FAC does not seek to recover losses that it suffered, such as overcharges for Section 340B drugs defendants sold to Adventist. Rather, Adventist claims that defendants’ fraud “caused the federal and state governments to wrongly pay hundreds of millions of dollars.” And it seeks to recover the losses incurred by the government through its FCA claims against defendants.

In its lawsuit, Adventist alleges that defendants harmed the government in three ways. First, Adventist claims that defendants sold drugs at inflated prices to covered entities, and then federal and state governments paid higher prices for the drugs through their Medicaid payments to the covered entities. Second, Adventist claims that defendants overcharged “critical access hospitals,” which in turn

overbilled Medicare at 101% of drug costs causing the government to pay the overcharges through Medicare payments. Third, Adventist alleges that defendants overcharged government-funded prisons and health clinics, resulting in the government paying fraudulently inflated drug prices.

Defendants moved to dismiss Adventist's claims, arguing that *Astra USA, Inc. v. Santa Clara Cnty.*, bars them. See 563 U.S. at 113. In other words, defendants contend that because *Astra* held that covered entities must use Section 340B's ADR process to challenge a drug manufacturer's pricing, Adventist—a covered entity—cannot sue defendants for violating the FCA. Defendants admit that Adventist's claims are based on alleged violations of the FCA, not direct violations of Section 340B as in *Astra*, but defendants nevertheless argue that *Astra*'s reasoning bars all claims arising from "purported violations of the 340B statute."

The district court granted defendants' motion to dismiss and dismissed Adventist's FAC with prejudice. Relying on *Astra*, the district court held that Adventist's claims were not cognizable because Section 340B lacks a private right of action and Adventist's claims are in essence claims to enforce Section 340B. The district court explained that allowing these claims to proceed would disrupt the ADR process that Congress created to enforce Section 340B. Adventist timely appealed.

Standard of Review

We review the district court's dismissal for failure to state a claim de novo, "crediting all factual allegations in the complaint as true and construing the pleadings in the light most favorable to . . . the non-moving party." *Tingley v.*

Ferguson, 47 F.4th 1055, 1066 (9th Cir. 2022). We disfavor dismissing a case at the pleading stage unless “there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory.” *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001); *see also Tingley*, 47 F.4th at 1066.

Analysis

I. Adventist’s FCA claims are not barred by Section 340B or Astra.

The FCA imposes civil liability on “any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim” to the United States government. 31 U.S.C. § 3729(a)(1)(A)–(B) (citation modified); *see also Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 768–69 (2000). A person who violates the FCA is liable for civil penalties for each false claim plus treble damages. *See* 31 U.S.C. § 3729(a)(1); *United States ex rel. Sutton v. Double Day Off. Servs., Inc.*, 121 F.3d 531, 533 (9th Cir. 1997).

The FCA is enforced through a “unique public-private scheme” where private parties—or “relators”—sue in *qui tam* actions that are “brought in the name of the [g]overnment,” *United States, ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 424 (2023), against “entities that have defrauded the government,” *United States ex rel. Barajas v. United States*, 258 F.3d 1004, 1005 (9th Cir. 2001). The government may choose to intervene in an FCA action, but regardless of the government’s decision to

intervene, “the relator is entitled to a share of any recovery in the action.” *Barajas*, 258 F.3d at 1005–06.

Under this established framework for righting financial wrongs against the government, Adventist filed the instant qui tam action against defendants to recover losses incurred by the government due to defendants’ allegedly fraudulent drug pricing scheme. Defendants argue that Adventist’s FCA claims are barred by statute and Supreme Court precedent. In their view, because Section 340B does not provide a private right of action but instead provides an ADR process for overcharge claims, covered entities such as Adventist are not permitted to sue drug manufacturers such as defendants for overcharges and repayment. *See Astra*, 563 U.S. at 113–14. Moreover, they insist that Supreme Court precedent clearly forecloses claims by covered entities arising under Section 340B to enforce PPAs, because a third-party suit to enforce a PPA is “in essence a suit to enforce [Section 340B] itself.” *Id.* at 118. In short, defendants argue that Adventist’s claims are merely repackaged Section 340B claims and are thus precluded by statute and the Supreme Court’s holding in *Astra*.

Neither Section 340B nor *Astra* bar Adventist’s qui tam claims against defendants. First, Adventist brings its action under the FCA, which confers an express right of action for any qui tam plaintiff to remedy fraud resulting in financial loss to the government. *See* 31 U.S.C. § 3730(b). Second, Adventist’s action is not “in essence” a suit to enforce Section 340B. *See Astra*, 563 U.S. at 118. Unlike plaintiff in *Astra*, Adventist brings a prototypical FCA action that does not assert that defendants are liable merely because of a direct violation of Section 340B. Finally, barring Adventist’s claims would undermine the FCA, a statute that courts interpret “broadly” and that does not exempt qui tam actions

by covered entities for alleged fraud against the government from the Section 340B Program. See *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1116 (9th Cir. 2020).

A. Because Adventist brings an FCA action, the absence of a private right of action under Section 340B is immaterial.

The absence of a private right of action for entities covered under Section 340B does not foreclose Adventist's claims. Adventist does not seek to enforce Section 340B directly; that is, Adventist is not seeking reimbursement for overcharges or otherwise seeking relief for violations of Section 340B. Rather, Adventist brings claims under the FCA, which are free-standing and independent of Section 340B. Thus, it is of no import that Section 340B does not provide covered entities like Adventist a mechanism to bring suit.

Our precedent makes clear that FCA claims are available to parties even when other statutory causes of action are unavailable. In *United States ex rel. Sutton v. Double Day Office Services, Inc.*, relator Sutton sued under the FCA and alleged that the defendant, Sutton's employer, knowingly made false statements to the government that it paid the prevailing wages required by the Service Contract Act ("SCA"). 121 F.3d at 533. Like Section 340B, the SCA contains no private right of action for covered entities. *Id.* But we held that the SCA did not bar Sutton's claim. *Id.* at 534. We explained that, because an "FCA plaintiff brings [its] action in the name of the United States," it was "irrelevant" that Sutton "happen[ed]" to be a covered employee who lacked a right of action under the SCA. *Id.* The FCA thus provided Sutton's right of action. *Id.*

So too here. Adventist does not seek compensatory damages as a covered entity under Section 340B. Rather, Adventist sues as a relator standing in the shoes of the government, the real party in interest, and seeks redress on behalf of the government. *See United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715, 720 (9th Cir. 1994). Adventist’s claims “belong[] to the government”—it does not matter that Adventist also happens to be a covered entity that lacks a right of action under Section 340B. *See Stoner v. Santa Clara Cnty. Office of Educ.*, 502 F.3d 1116, 1126 (9th Cir. 2007). In other words, the FCA is an independent mechanism through which Adventist can assert these claims representing the interests of the government. *See id.*; *see also* 31 U.S.C. § 3730(b).

B. Adventist is not “in essence” suing to enforce Section 340B.

Because Adventist seeks relief on behalf of the government and not itself, its claims are inapposite to those brought in *Astra*, which were held to be barred by Section 340B. In *Astra*, a plaintiff sued nine pharmaceutical manufacturers for breaching their PPAs with the government by overcharging covered entities for drugs. 563 U.S. at 116. The plaintiff claimed that the covered entities were third-party beneficiaries to the PPAs and thus entitled to compensatory damages for breach of contract. *See id.* at 117–18. But the Supreme Court held that the claims were barred by Section 340B. *Id.* at 114. Specifically, the Court held that the plaintiff’s action was “in essence a suit to enforce the [340B] statute itself” and that a plaintiff could not circumvent the absence of a statutory cause of action by suing to enforce the contract’s terms in a breach of contract suit. *Id.* at 118. Defendants here argue that the reasoning of *Astra* applies equally in this case because Adventist’s FCA

claims are merely repackaged Section 340B claims that seek to enforce Section 340B.

Not so. Adventist does not “in essence” seek to enforce Section 340B—it seeks to enforce the FCA. Indeed, Adventist brings a prototypical FCA action to remedy allegedly false or fraudulent claims resulting in financial loss to the government. *See e.g., United States ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017 (9th Cir. 2018); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017); *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1178 (9th Cir. 2006). This FCA action is categorically distinct from the action in *Astra*, a common law breach-of-contract suit to remedy alleged violations of Section 340B itself. 563 U.S. at 116-17. Stated simply, *Astra* has no bearing on Adventist’s claims.

Here too, our decision in *Sutton* is instructive. In that case, Sutton alleged that his employer did not pay the prevailing wages required by the SCA. *Sutton*, 121 F.3d at 533–34. However, Sutton did not allege that his employer was liable merely for this violation of the SCA. *Id.* at 533. Sutton brought an FCA claim, and “[t]he FCA attaches liability to the claim for payment,” not to the underlying violation of the statute. *Id.* at 534. Because Sutton’s employer was liable only if it “submitted a claim for payment to the United States falsely stating that it had complied with the SCA,” we held that Sutton’s action was not a repackaged SCA action “tr[ying] to make an end-run around the SCA’s bar” on actions alleging direct violations of the SCA. *Id.* at 533–34.

Likewise, Adventist does not allege that defendants are liable merely because they violated Section 340B. Unlike the suit in *Astra*, there is more to Adventist’s claims than the

mere enforcement of PPAs. 563 U.S. at 114 (“Though labeled differently, suits to enforce [Section] 340B and suits to enforce PPAs are in substance one and the same.”). Adventist alleges that defendants are liable for submitting false claims, causing the government to overpay millions of dollars through Medicaid, Medicare, and government-funded clinics. *See* 31 U.S.C. § 3729(a)(1)(A)–(B) (imposing FCA civil liability on any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim” to the government). It is true that the alleged violation of Section 340B’s ceiling price formula may be related to Adventist’s FCA claim that defendants “caused Covered Entities . . . to submit false claims [for reimbursement] to the Medicaid and Medicare Programs.” But Adventist seeks redress for the alleged false claims, not for the alleged violations of Section 340B’s ceiling price formula. *See Sutton*, 121 F.3d at 534 (“The violation of a statute does not itself create a violation of the FCA.”). In other words, Adventist brings FCA claims, not Section 340B claims “dress[ed]” in different “clothing.” *Astra*, 563 U.S. at 114.

Indeed, Adventist seeks damages consistent with an FCA action, not a Section 340B action. In a Section 340B action, a covered entity must file a claim through Section 340B’s ADR process if the entity alleges a direct pricing violation against a drug manufacturer. *Astra*, 563 U.S. at 115–16; 42 C.F.R. § 10.21. If the claim is meritorious, the ADR panel may require the manufacturer to directly reimburse the entity for the overcharges or terminate the manufacturer’s PPA. *See Astra*, 563 U.S. at 115–16; 42 C.F.R. § 10.23. This relief is akin to the compensatory

damages that the plaintiff sought in *Astra* for breach of contract. *See* 563 U.S. at 115–16.

But Adventist does not seek compensatory damages or cancellation of defendants’ PPAs. Adventist pled FCA damages for the government and FCA relator damages for itself. If Adventist prevails, defendants would be liable to the government for \$5,000 to \$10,000 for each false claim plus treble damages. *See* 31 U.S.C. §§ 3729(a)(1), 3730(d)(2). As the relator, Adventist would receive only 25 to 30 percent of those litigation proceeds. *See* 31 U.S.C. § 3730(d)(2).

In *Sutton*, this too distinguished Sutton’s action from other actions trying “to make an end-run around the SCA’s bar on private rights of action.” 121 F.3d at 533. We reasoned that if Sutton’s FCA action was “equivalent to an SCA action, then his damage would be his lost wages due to [the defendant’s] failure to pay prevailing wages.” *Id.* at 534. But, like Adventist, Sutton sought “a different kind of damage—damage to the United States plus statutory damages.” *Id.* Sutton’s claims were not repackaged SCA claims.

Standing in the shoes of the government, Adventist seeks statutory damages for the false or fraudulent claims that defendants caused covered entities to submit to the government, not compensatory damages for overcharges incurred as a result of defendants’ violations of Section 340B, as in *Astra*. 563 U.S. at 116. In sum, Adventist’s suit is not “in essence a suit to enforce [Section 340B].” *Id.* at 118.

C. Barring Adventist’s claims would undermine the FCA.

The FCA is “the federal government’s primary tool to combat fraud and recover losses due to fraud in federal programs.” Amicus Br. of Gov’t at 1. We interpret the FCA “broadly, in keeping with the Congress’s intention ‘to reach all types of fraud, without qualification, that might result in financial loss to the government.’” *Winter*, 953 F.3d at 1116 (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)). We have recognized that “the Supreme Court has consistently refused to accept a rigid, restrictive reading of the FCA and has cautioned courts against adopting a circumscribed view” of the Act. *Winter*, 953 F.3d at 1116 (citation modified). Here, precluding Adventist’s FCA claims would undermine Congress’s express intent for the FCA to reach “all types of fraud, without qualification.” *Id.*

When Congress intends to preclude FCA claims, it speaks with a clear voice, enacting specific exceptions limiting the types of cognizable claims, who can act as a relator, and against whom an FCA action can be brought. See 31 U.S.C. §§ 3729(d), 3730(e). For instance, the FCA expressly bars claims under the Internal Revenue Code; claims by an armed forces member against another member from the member’s service; and claims against members of Congress and members of the judiciary based on evidence or information known to the government at the time of the action. 31 U.S.C. §§ 3729(d), 3730(e). Notably, none of these exceptions apply here. As the Supreme Court has noted, “[w]hen Congress provides exceptions in a statute, it does not follow that courts have authority to create others.” *United States v. Johnson*, 529 U.S. 53, 58 (2000). Rather, “[t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the

ones set forth.” *Id.* Because the FCA is silent as to Section 340B claims, we do not read into the statute an exception barring Adventist’s claims. *Conn. Nat’l Bank v. Germain*, 503 U.S. 249, 253–54 (1992) (“We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there.”).

Moreover, precluding Adventist’s FCA claims would also require us to find that Section 340B “impliedly preempts the FCA.” *Sutton*, 121 F.3d at 535. But it is “a cardinal principle of statutory construction that repeals by implication are not favored.” *Id.* (quoting *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 154 (1976)). Because there is no “positive repugnancy” between the FCA and Section 340B, nor is there express language in either statute that Section 340B was meant to displace the FCA, we “must give effect to both.” *Sutton*, 121 F.3d at 535 (citation modified); *see also* 31 U.S.C. § 3729; 42 U.S.C. § 256b.

Congress enacted the FCA to “enlist the aid of” private relators “in combatting the rising problem of sophisticated and widespread fraud” resulting in financial loss to the government. *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993) (citation modified). It would contravene Congress’s intent to bar private relators like Adventist from bringing suit under the FCA simply because another statute, Section 340B, lacks a private right of action.

II. Adventist plausibly pleads falsity under the FCA.

Defendants alternatively contend that Adventist’s pre-January 1, 2019 claims are not viable because HRSA’s final rule only became effective on January 1, 2019. Defendants’ argument is unpersuasive because Adventist plausibly alleges that the plain text of the statutory formula did not

“authorize any pricing over \$0.01 regardless of the existence of a regulation.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 n.12 (2011) (“[T]o survive a motion to dismiss, respondents need only allege ‘enough facts to state a claim to relief that is plausible on its face.’” (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007))). The government also “formally adopted a written guidance in 2011 which expressly directed manufacturers to charge \$0.01 if the statutory formula resulted in a negative Ceiling Price.” See HRSA, Clarification of Penny Pricing Policy, Policy Release No. 2011-2 (2011). Thus, as Adventist argues, “the 2019 regulation did not change (nor could it change) the statutory definitions and requirements relating to Ceiling Prices.” This allegation is therefore plausibly pled.

Defendants also contend that HRSA’s price reporting and verification system “renders implausible” Adventist’s allegations that each defendant failed to charge penny prices after January 1, 2019. But defendants raise a merits argument that requires further discovery and turns on factual disputes that we may not reach at this stage. We thus decline to affirm the dismissal on this alternative ground.

Conclusion

We hold that Adventist asserts cognizable claims for relief under the FCA and has satisfied the necessary pleading requirements. We thus reverse the district court’s dismissal and remand for further proceedings.

REVERSED AND REMANDED.³

³ We grant the motion to withdraw as amicus curiae counsel (Dkt. 76).