

FOR PUBLICATION

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

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

v.

JUAN CARLOS ENRIQUEZ,

Defendant - Appellant.

No. 23-4424

D.C. No.
2:18-cr-00375-
AB-7

OPINION

Appeal from the United States District Court
for the Central District of California
André Birotte Jr., District Judge, Presiding

Argued and Submitted February 19, 2025
El Centro, California

Filed March 18, 2025

Before: Richard C. Tallman and John B. Owens, Circuit
Judges, and Ruth Bermudez Montenegro, District Judge.*

Opinion by Judge Tallman

* The Honorable Ruth Bermudez Montenegro, United States District
Judge for the Southern District of California, sitting by designation.

SUMMARY**

Criminal Law

The panel affirmed the district court’s denial of Juan Carlos Enriquez’s motion to dismiss an indictment charging him with conspiracy to receive healthcare kickbacks in violation of 18 U.S.C. § 371 and receiving prohibited payments in violation of the Anti-Kickback Statute (AKS).

Enriquez—a pharmacy technician employed by his alleged co-conspirator, Irina Sadovsky—was involved in a scheme to refer Medicare and Medi-Cal beneficiaries to Sadovsky’s pharmacies in return for a kickback.

Enriquez moved to dismiss the indictment for failure to state an offense or, alternatively, for lack of specificity, because the charging document had not negated the safe harbor for a bona fide employment relationship set forth in 42 U.S.C. § 1320a-7b(b)(3)(B). That safe harbor provides an affirmative defense that the AKS does not apply to conduct the statute otherwise prohibits if the kickbacks were payments from an employer to a bona fide employee for employment-related items or services.

Enriquez’s arguments relied on expanding in two ways the reach of *Ruan v. United States*, 597 U.S. 450 (2022), which held that Controlled Substances Act (CSA) Section 841’s exception for authorized prescriptions must be proven beyond a reasonable doubt. First, he argued that the statutory interpretive principles from *Ruan* should be applied

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

outside the CSA to the AKS. Second, he argued that the AKS bona fide employment safe harbor should be treated as a “quasi-element” not only for burden of proof and scienter purposes, as *Ruan* held for the CSA’s authorization exception, but also for purposes of pleading.

The panel declined to extend *Ruan* to (a) the AKS and (b) pleading requirements. Because *Ruan* provides no reason to stray from the bedrock principle that indictments need not allege affirmative defenses, the panel affirmed the district court’s denial of Enriquez’s motion to dismiss for failure to state an offense.

As to the indictment’s specificity, Enriquez argued that he was not put on notice as to why the AKS safe harbor did not protect him. The panel affirmed the denial of the motion to dismiss on this ground because all elements of the conspiracy crime were pled in adequate detail.

COUNSEL

Ethan A. Sachs (argued), Attorney, Appellate Section, Criminal Division; Alexis D. Gregorian and Siobhan M. Namazi, Trial Attorneys; Jeremy R. Sanders, Assistant Chief & Appellate Counsel; Criminal Division, Fraud Section; Steven S. Michaels, Trial Attorney; Lisa H. Miller, Deputy Assistant Attorney General; Nicole M. Argentieri, Principal Deputy Assistant Attorney General; E. Martin Estrada, United States Attorney; United States Department of Justice, Office of the United States Attorney, Washington, D.C.; David R. Friedman, Assistant United States Attorney, United States Department of Justice, Office of the United States Attorney, Los Angeles, California; for Plaintiff-Appellee.

David A. Schlesinger (argued), Jacobs & Schlesinger LLP,
San Diego, California, for Defendant-Appellant.

OPINION

TALLMAN, Circuit Judge:

Appellant Juan Carlos Enriquez was a pharmacy technician employed by his alleged co-conspirator, Irina Sadovsky. Enriquez was involved in a scheme to refer Medicare and Medi-Cal beneficiaries to Sadovsky's pharmacies in return for a kickback. The government charged Enriquez by indictment with conspiracy to receive healthcare kickbacks in violation of 18 U.S.C. § 371 and receiving prohibited payments in violation of the Anti-Kickback Statute ("AKS").

Enriquez moved to dismiss the indictment for lack of specificity and failure to state an offense because the charging document had not negated the statutory safe harbor for a bona fide employment relationship. 42 U.S.C. § 1320a-7b(b)(3)(B). That safe harbor provides an affirmative defense that the AKS does not apply to conduct the statute otherwise prohibits if the kickbacks were payments from an employer to a bona fide employee for employment-related items or services. *Id.*

The district court denied Enriquez's motion. Enriquez pleaded guilty but reserved the right to appeal the denial of his pretrial motion to dismiss. Following the entry of Enriquez's conditional plea, the district court sentenced him to one day of imprisonment followed by two years of

supervised release and ordered him to pay \$121,115 in restitution.

On appeal, Enriquez contends the district court erred in denying his motion to dismiss the indictment because it failed to state an offense or, alternatively, was insufficiently specific. Both arguments rely on expanding the reach of *Ruan v. United States*, 597 U.S. 450 (2022), which held that Controlled Substances Act (“CSA”) Section 841’s exception for authorized prescriptions must be proven beyond a reasonable doubt. Enriquez argues that under *Ruan*’s logic, any “facially applicable” exception must be treated as a “quasi-element” and alleged in the indictment. More specifically, he argues that because his indictment alleged an employee-employer relationship, the government was required to plead facts alleging why the AKS bona fide employment relationship safe harbor did *not* apply. Because his indictment failed to allege the safe harbor’s inapplicability, Enriquez argues, the indictment failed to state an offense and the district court therefore erred by denying his motion to dismiss the indictment. We disagree that *Ruan* supports Enriquez’s position, and we affirm the denial of his motion to dismiss.

I

The district court had jurisdiction under 18 U.S.C. § 3231. We have jurisdiction under 28 U.S.C. § 1291.

II

When, as here, a defendant has challenged an indictment before trial, we review the challenge *de novo*. *United States v. Qazi*, 975 F.3d 989, 992 (9th Cir. 2020). In so doing, we assume that an indictment’s allegations are true and then assess whether the charged conduct satisfies all elements of

the criminal offense without considering extrinsic evidence beyond the charging document’s “four corners.” *United States v. Kelly*, 874 F.3d 1037, 1047 (9th Cir. 2017). A count that does not set forth all elements fails to state an offense—a fatal flaw requiring dismissal. *United States v. Du Bo*, 186 F.3d 1177, 1179 (9th Cir. 1999).

III

Enriquez asks us to view the AKS safe harbor as a “quasi-element” akin to Section 841’s authorization exception—the provision considered in *Ruan*. Section 841 is a provision of the CSA that makes it a crime for any person to knowingly or intentionally manufacture, distribute, or dispense a controlled substance, “[e]xcept as authorized[.]” 21 U.S.C. § 841(a). The “except as authorized” clause spares from liability doctors who may lawfully prescribe a controlled substance “for a legitimate medical purpose . . . in the usual course of [their] professional practice.” 21 C.F.R. § 1306.04(a) (2020). The issue before the Supreme Court involved what state of mind the government must prove to convict doctors of dispensing controlled substances outside their therapeutic authorization—not for a legitimate purpose—in violation of Section 841. *Ruan*, 597 U.S. at 454.

The Court held that Section 841’s “knowingly or intentionally” *mens rea* applies to the authorization exception. *Id.* “After a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.” *Id.* The Court reasoned that because the “except as authorized” clause distinguished legal from illegal dispensing, it “is sufficiently like an

element in respect to [scienter] as to warrant similar legal treatment[.]” despite “differing from an element in some respects.” *Id.* at 464. In addressing the concurrence’s point that the authorization exception is unlike an element, the majority emphasized its holding was limited to scienter, which “has little or nothing to do” with the indictment or burden shifting responsibilities set forth in Section 885. *Id.* at 462–64. Section 885 expressly states that the government need not “negative” any exception in an indictment or other pleading, and at trial, the burden of production lies not with the government but with the party claiming the exception. 21 U.S.C. § 885.

Enriquez asks this Court to extend *Ruan*’s reasoning in two ways. First, Enriquez argues that the statutory interpretive principles from *Ruan* should be applied outside the CSA to the AKS. Second, Enriquez argues that the AKS bona fide employment safe harbor should be treated as a “quasi-element” not only for burden of proof and scienter purposes, as *Ruan* held for the CSA’s authorization exception, but also for purposes of pleading. Neither argument is convincing.

A

First, the CSA and AKS have substantial differences that counsel against extending *Ruan*’s logic to the AKS. While each statute contains a specific intent requirement, their placement differs in significant ways. Section 841 of the CSA includes its authorization exception, *mens rea* clause, and prohibited acts *in a single provision*.¹ In contrast, the

¹ The provision states: “Except as authorized . . . , it shall be unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense, or possess with intent to [do the same], a controlled substance.” 21 U.S.C. § 841(a)(1).

AKS' numerous exceptions (i.e., safe harbors) are each contained in their own *separate* provision (§§ 1320a-7b(b)(3)(A)–(L)). Congress chose to include each AKS safe harbor in a subsection full of statutory exceptions distinct from the prohibited conduct specified in Sections 1320a-7b(b)(1) and (b)(2). That choice is consequential because it puts the AKS within the “settled rule” that statutory exceptions are treated as affirmative defenses when they are contained in “a proviso or other distinct clause, whether in the same section or elsewhere[.]” *McKelvey v. United States*, 260 U.S. 353, 357 (1922); *see also United States v. Freter*, 31 F.3d 783, 787–88 (9th Cir. 1994) (even though contained in the same sentence as an element, an exception for “federally permitted” release of a hazardous substance is an affirmative defense because it is a distinct clause).

In light of the structural differences between the two statutes, courts treat the CSA exceptions differently than the AKS safe harbors. Even before *Ruan*, we treated the CSA's authorization exception as a statutory element the government must prove beyond a reasonable doubt. *See United States v. Feingold*, 454 F.3d 1001, 1006, 1012 (9th Cir. 2006); *United States v. King*, 587 F.2d 956, 965–66 (9th Cir. 1978) (“lack of authorization is an element of” Section 841); *United States v. Kim*, 298 F.3d 746, 750 (9th Cir. 2002) (confirming that *King* requires the government to plead “except as authorized” as an element in a Section 841 indictment).

In contrast, courts have repeatedly concluded that the AKS's bona fide employment relationship safe harbor is an affirmative defense. In an unpublished opinion, we affirmed a district court holding that the safe harbor is an affirmative defense, explaining that “[a] contrary holding would lead to absurd indictments requiring the government to plead the

negative of every enumerated safe harbor[.]” *United States v. Ekwebelem*, 669 F. App’x 868, 686 (9th Cir. 2016). Other circuits have reached the same conclusion² or indicated agreement with it.³ District courts to consider the issue are also in alignment that the AKS safe harbors are affirmative defenses.⁴

B

Second, Enriquez’s argument requires extending *Ruan*’s holding—limited to scienter and burden of proof purposes—to the government’s pleading obligations. But we read *Ruan*’s holding more narrowly than Enriquez suggests. *Ruan* does not treat Section 841’s authorization exception “like an element” for every purpose. In contrast, the majority describes how treating the authorization exception as an element for purposes of scienter and burden of proof at trial does *not* necessarily warrant the same treatment for other

² *United States v. Vernon*, 723 F.3d 1234, 1271 (11th Cir. 2013); *United States v. Turner*, 561 F. App’x 312, 319–320 (5th Cir. 2014) (“The safe harbor provision is an affirmative defense which the defendant must prove”); *United States v. Norton*, 17 F. App’x 98, 102 (4th Cir. 2001) (per curiam).

³ *United States v. George*, 900 F.3d 405, 413 (7th Cir. 2018) (“Once the government establishes the elements of a violation of the [AKS], the burden shifts to a defendant to demonstrate . . . that her conduct fell within the safe harbor provision of the statute.”); see also *United States v. Yielding*, 657 F.3d 688, 700 (8th Cir. 2011) (noting that the parties did not dispute that the bona fide employment relationship safe harbor provision creates an affirmative defense).

⁴ E.g., *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014) (AKS’s “safe harbors are affirmative defenses, and the defendant carries the burden of proof at trial”); *United States v. George*, 171 F. Supp. 3d 810, 818 (N.D. Ill. 2016) (government “need not prove, as an element of its case, that defendant’s conduct does not fit within a safe harbor” of the AKS).

purposes, including those related to indictments. *See Ruan*, 597 U.S. at 462–63 (stating that indictments and burdens of production “have little or nothing to do with scienter requirements”). Rather, per another CSA provision, Section 885, the government need not negative “any exemption or exception . . . in any complaint, information, indictment, or other pleading.” *Id.* at 462 (quoting 21 U.S.C. § 885). Thus, Section 885 “relieves the Government from having to disprove, at the outset of every Controlled Substances Act prosecution, every exception in the statutory scheme.” *Id.* at 464.⁵

Enriquez points to two district court cases to support his reading of *Ruan*. A District of Nevada court dismissed a Section 841 indictment for failure to state an offense because, even though it pleaded that the defendant’s conduct was unauthorized, it failed to plead the “*Ruan*-added *mens rea*, which is an element in the Ninth Circuit.” *United States v. Wells*, 672 F. Supp. 3d 1066, 1071 (D. Nev. 2023). In

⁵ Enriquez argues that *Ruan* did not require negative pleading of the authorization exception because Section 885 explicitly states it is not required. Absent a provision like Section 885, Enriquez argues, the government must plead around the AKS’s list of safe harbors. But the absence of a section analogous to Section 885 leads more logically to the opposite conclusion: that Congress intentionally omitted it because the AKS’s construction obviates the need for one. Unlike the CSA, the AKS’s safe harbors are contained in subsequent sections. Under well-established law, those are treated as affirmative defenses. As such, there would have been no reason for Congress to explicitly state that the government need not negative safe harbors in an AKS indictment. That’s not to say that Section 885 is merely statutory surplus. Rather, because Section 841’s authorization exemption is included in the *same provision* as the prohibited conduct, Congress saw it necessary to explicitly clarify that the government need not treat the authorization exception as an element it must plead in the indictment.

other words, “*Ruan*’s holding requires that indictments of medical practitioners under § 841 allege that a medical practitioner ‘knowingly and intentionally’ acted without authorization.” *Id.* at 1070. A District of Alaska decision similarly found that “lack of authorization, even if it is something of a ‘quasi-element,’” must be pled in the indictment. *United States v. Spayd*, 627 F. Supp. 3d 1058, 1062–63 (D. Alaska 2022).^{6,7}

But neither *Wells* nor *Spayd* advances Enriquez’s argument. *Spayd* misinterprets *Ruan* by extending its “quasi-element” treatment to pleading when the Supreme Court’s rationale for treating the authorization exception “like an element” was limited to burden of proof and scienter purposes. *Ruan*, 597 U.S. at 462–63. *Wells*, meanwhile, found that Section 841’s authorization exception must be pled in the indictment not because of *Ruan* but because Ninth Circuit precedent has required as much since 1978. *See King*, 587 F.2d at 965–66; *Kim*, 298 F.3d at 750. Because the authorization exception was already considered an element in the Ninth Circuit, *Ruan* merely extended Section 841’s “knowingly and intentionally” *mens rea* to the

⁶ In so finding, the court acknowledged that “although it is clear that *Ruan* altered what the Government must *prove* under § 841, it is not clear whether *Ruan* changed what the Government must *plead*” because *Ruan* did not squarely hold that Section 841’s authorization exception is an element of the offense. *Spayd*, 627 F. Supp. 3d at 1062. The court further explained that, despite the uncertainty coming out of *Ruan* and “[d]espite the language of § 885,” the government must plead the authorization exception to avoid the “risk that an indictment may describe conduct that is wholly on the permissible side of the criminal line.” *Id.* at 1063.

⁷ At least one district court outside this circuit has similarly concluded. *See United States v. Henson*, 2024 U.S. Dist. LEXIS 3549, at *5–12 (D. Kan. Jan. 5, 2024).

pleading requirement. *Wells*, 672 F. Supp. 3d at 1071. In contrast, as discussed *supra*, the Ninth Circuit has never treated the AKS safe harbors as elements. Thus, even if *Ruan* (and not just Ninth Circuit precedent) required the government to allege Section 841’s authorization exception in an indictment, the same does not follow for the AKS’ safe harbors, which no court has ever deemed to be an element or a “quasi-element” of the statute.

Furthermore, *Spayd* and *Wells* represent the minority view. Most courts to consider the issue have found that while *Ruan* requires the government to carry the burden regarding authorization, it does not require the government to negative the authorization exception in the indictment. See, e.g., *United States v. Fletcher*, No. 21-cr-63, 2023 WL 4097026, at *4 (E.D. Ky. June 20, 2023) (rejecting defendant’s motion to dismiss an indictment charging Section 841 because *Ruan* requires the government to prove a lack of authorization at trial, not in an indictment); *United States v. Goodman*, No. 22-cr-435, 2023 WL 5672834, at *3 (E.D. Pa. Sept. 1, 2023) (rejecting defendants’ motion to dismiss and explaining that “*Ruan* de[alt] with the Government’s burden . . . under § 841 at trial” and “did not alter any pleading standards”); *United States v. Och*, No. 21-cr-40026, Docket No. 53, Electronic Order (D. Mass. Jan. 31, 2023) (“*Ruan* did not modify the pleading standards for indictments under the Controlled Substances Act.”).

We decline to extend *Ruan* to (a) the AKS and (b) pleading requirements. Because *Ruan* provides no reason to stray from the bedrock principle that indictments need not allege affirmative defenses, *McKelvey*, 260 U.S. at 357, we affirm the denial of Enriquez’s motion to dismiss for failure to state an offense.

IV

The indictment provided fair notice to Enriquez to comport with due process of law and to permit him to prepare his defense. An indictment must satisfy certain minimal standards of specificity to avoid being dismissed under Rule 12(b)(3)(B)(iii). See *United States v. Cecil*, 608 F.2d 1294, 1296 (9th Cir. 1979) (per curiam). Even if an indictment has pled each of an offense’s essential elements, it still lacks requisite specificity if it “fails to allege sufficient facts to facilitate the proper preparation of a defense and to ensure that the defendant[] [is] prosecuted on facts presented to the Grand Jury.” *Id.* at 1297 (finding insufficient an indictment that merely tracked statutory language, named states in which the conspiracy occurred, and named some co-conspirators because it “clearly lacked a statement of the facts and circumstances that would inform the accused of the specific offenses with which they were charged”).

Enriquez argues that contrary to *Cecil*’s principles, he was not put on notice as to why the AKS safe harbor did not protect him. This argument is unconvincing. “The test for sufficiency of the indictment is not whether it could have been framed in a more satisfactory manner, but whether it conforms to minimal constitutional standards.” *United States v. Awad*, 551 F.3d 930, 935 (9th Cir. 2009) (quoting *United States v. Hinton*, 222 F.3d 664, 672 (9th Cir. 2000) (internal quotation marks omitted)). In a conspiracy indictment under Section 371, an indictment satisfies its constitutional requirements if it alleges (1) the agreement, (2) the unlawful object towards which the agreement is directed, and (3) an overt act in furtherance of the conspiracy. *United States v. Giese*, 597 F.2d 1170, 1177 (9th Cir. 1979) (citation omitted).

Here, the indictment alleged all three elements: (1) Paragraph 56 specifies that Enriquez and co-conspirators “knowingly combined, conspired, and agreed to” pay and receive kickbacks in violation of the AKS; (2) Paragraphs 53 to 55 describe the role each conspirator played while Paragraph 57 describes how the object of the conspiracy—receiving illicit kickbacks for financial gain—was carried out; and (3) Paragraph 58 lists an overt act—Enriquez received a kickback check in exchange for referring beneficiaries’ prescriptions to the pharmacy that employed him.

Because all elements of the conspiracy crime were pled in adequate detail, we affirm the district court’s denial of Enriquez’s motion to dismiss the indictment for insufficient specificity under Rule 12(b)(3)(B)(iii). *See Awad*, 551 F.3d at 935 (“An indictment is sufficient if it contains ‘the elements of the charged crime in adequate detail to inform the defendant of the charge and to enable him to plead double jeopardy.’” (citation omitted)).

We find no reason to stretch *Ruan* beyond its logical limits. Because the government is not required to plead affirmative defenses in an indictment, and it pleaded all elements of the conspiracy offense in detail, count nine of the indictment was sufficient. Accordingly, the district court properly denied Enriquez’s motion to dismiss for failure to state an offense and lack of specificity.

AFFIRMED.