

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 24-1203

DR. TIMOTHY BAXTER,

Plaintiff – Appellant,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary, Department of Health and Human Services; JULIET T. HODGKINS, in her official capacity as Acting Inspector General, Department of Health and Human Services,

Defendants – Appellees.

Appeal from the United States District Court for the Eastern District of Virginia, at Richmond. Roderick Charles Young, District Judge. (3:23-cv-00092-RCY)

Argued: October 29, 2024

Decided: April 29, 2025

Before AGEE, RICHARDSON, and BERNER, Circuit Judges.

Affirmed by published opinion. Judge Richardson wrote the opinion, in which Judge Agee and Judge Berner joined.

ARGUED: Thomas M. Johnson, Jr., WILEY REIN LLP, Washington, D.C., for Appellant. Rebecca Sara Levenson, OFFICE OF THE UNITED STATES ATTORNEY, Alexandria, Virginia, for Appellees. **ON BRIEF:** Brandon J. Moss, Jeremy J. Broggi, Michael J. Showalter, William Turner, WILEY REIN LLP, Washington, D.C., for Appellant. Maddie J. Bainer, Senior Counsel, Office of Counsel to the Inspector General, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C.; Jessica D. Aber, United States Attorney, Jonathan T. Lucier, Assistant

United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Richmond,
Virginia, for Appellees.

RICHARDSON, Circuit Judge:

This appeal turns on a little-known provision of the Social Security Act, 42 U.S.C. § 1320a-7(a). That subsection adds an additional consequence to certain healthcare-related crimes by commanding the Health Secretary to ban persons who commit them from working with federal healthcare programs. Among the covered offenses are those “related to the delivery of an item or service . . . under any State health care program.” 42 U.S.C. § 1320a-7(a)(1).

Dr. Timothy Baxter faces the business end of such a ban. While working for a pharmaceutical company called Indivior, Baxter distributed misinformation to Massachusetts’s Medicaid program about the safety of new opioid drugs. That is a federal offense. And when federal prosecutors caught up with him, Baxter pleaded guilty. On the back of that prior offense, the Secretary subsequently banned him from working with federal healthcare programs for five years.

Now, Baxter challenges his exclusion. He floats an interpretation of the additional-consequence statute’s subsection (a) on which that subsection mandates exclusion only if his crime *categorically* relates to the delivery of an item or service under a state healthcare program. No federal court of appeals has adopted this argument. We will not be the first. The text and context of the mandatory-exclusion subsection make clear that it looks to what the individual actually did, not to offenses in the abstract. It thus requires only that the *actual* conduct be “related to” the specific acts listed in the statute. Baxter’s actual conduct satisfies that requirement and thereby triggered mandatory exclusion.

I. Background

A. At Indivior, Baxter Misbrands Opioids

Baxter used to be the Global Medical Director at Indivior, a pharmaceutical company that produces the opioid drugs Suboxone and Subutex.¹ Suboxone and Subutex are designed to help wean those who struggle with addiction off other, more dangerous opioids. Both drugs have saved lives. But they aren't risk-free. Like the drugs they seek to replace, these drugs still contain opioids. So one of the drugs—Suboxone—contains a second substance that induces withdrawal symptoms when insufflated or injected. Yet though Suboxone reduces the risk of adult misuse this way, it still endangers children who mistakenly take the pills.

To address this problem, Indivior introduced a new drug called Suboxone Film. As the name suggests, Suboxone Film is the same drug. But rather than being packaged as pills, it's a strip that dissolves under the tongue. Indivior hoped that children would be less likely to take individually wrapped film by accident than to swallow pills (thinking they were food or candy).

This case began with Indivior's efforts to sell Suboxone Film in Massachusetts. Doing that depended on MassHealth, Massachusetts's state-run Medicaid program. If MassHealth put a drug on its "preferred" drug list, more doctors would prescribe it—or so the theory went. And getting Suboxone Film on that list depended on persuading MassHealth that Film was better than its competition. Indivior's plan was straightforward:

¹ Indivior is a successor entity to Reckitt Benckiser Pharmaceuticals.

persuade MassHealth to cover more Suboxone Film prescriptions by giving MassHealth data showing that Film had better pediatric-exposure figures than its predecessors.

But in trying to do that, Indivior ran into a problem. The data didn't show what Indivior wanted it to show. Rather than proving that Suboxone Film posed the lowest risk to children, the data suggested that Subutex—the oldest drug in Indivior's stable—posed the lowest risk to children.

So Indivior doctored the numbers. It added the child-exposure rates for both pills—Suboxone and Subutex—and compared the *sum* to Suboxone Film's child-exposure rate. This incorrectly suggested that Film was less risky than either older drug. Then Indivior employees packaged the data into a chart and sent it to MassHealth. Eventually, MassHealth placed Suboxone Film on its “preferred” list, making it available to more patients.

B. Baxter Pleads Guilty as a Responsible Corporate Officer

In 2020, federal prosecutors charged Baxter with misdemeanor drug misbranding in violation of 21 U.S.C. § 331(a). That statute makes it a federal crime to cause “[t]he introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.” *Id.* And a drug counts as misbranded if its manufacturer distributes “exhibits, literature, . . . or visual matter,” 21 C.F.R. § 202.1(l)(2), that are “false or misleading in any particular,” 21 U.S.C. § 352(a)(1).

Baxter faced liability under that statute even though he didn't personally prepare or send the misleading data. Under what we have called the “responsible corporate officer doctrine,” *United States v. Ming Hong*, 242 F.3d 528, 531 (4th Cir. 2001), he was liable

for what his company did just because of his supervisory role—even if he didn’t know about the misbranding or do it himself. *United States v. Park*, 421 U.S. 658, 672–73 (1975).²

Baxter pleaded guilty. As part of his plea agreement, he admitted that he “caused the introduction and delivery for introduction into interstate commerce of Suboxone Film.” J.A. 346. He likewise admitted that Suboxone Film was misbranded and that the misbranding caused MassHealth to cover it.

C. The Secretary Excludes Baxter from Federal Healthcare Programs

After Baxter’s conviction, the Secretary of Health and Human Services told Baxter that he was “required . . . to exclude [Baxter] from participation in all Federal health care programs.” J.A. 527. Exclusion means that “no payment may be made by any Federal health care program,” like Medicaid, “for any items or services” that Baxter “furnishes, orders, or prescribes.” *Id.* (cleaned up). In the Secretary’s view, that exclusion arose from 42 U.S.C. § 1320a-7(a), which provides that “[t]he Secretary [of HHS] shall exclude . . . from participation in any Federal health care program . . . any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under [Medicare] or under any State health care program.” Baxter tried and failed to persuade the Secretary otherwise. His agency appeals failed as well.

² This doctrine has sparked controversy in some quarters. But Baxter rightly does not challenge it here in this collateral proceeding.

D. Baxter Sues

Next, Baxter challenged the exclusion in federal district court. He argued that his “conviction” did not “relate[] to the delivery of an item or service,” J.A. 69, and that the Secretary’s contrary decision breached the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). He also protested that the Secretary violated the Fifth Amendment by excluding him, a strict-liability misdemeanor, from the federal programs. Last, Baxter added an argument premised on the major questions doctrine. But the district court rejected his claims and granted the Secretary’s summary judgment motion.

Baxter now appeals.³

II. Discussion

Many statutes threaten additional consequences when an offender has one or more criminal convictions. These “additional-consequence statutes” come in various forms. One common form is a recidivism statute, like the Armed Career Criminal Act, which enhances an offender’s criminal sentence if he already has “three previous convictions . . . for a violent felony or a serious drug offense.” 18 U.S.C. § 924(e)(1). Another form is a criminal statute that applies only to individuals with certain convictions on their records.

³ The district court had jurisdiction to review the Secretary’s decision under 42 U.S.C. § 1320a-7(f)(1) and § 405(g). We have jurisdiction under 28 U.S.C. § 1291. *See also* 42 U.S.C. § 405(g). Though our statutory mandate to review Baxter’s case comes from § 405(g), *see id.* § 405(h), our procedure on review is governed by the Administrative Procedure Act, *see Almy v. Sebelius*, 679 F.3d 297, 302 (4th Cir. 2012). On review of a district court’s decision applying the APA, our review is *de novo*. *Ren v. U.S.C.I.S.*, 60 F.4th 89, 93 (4th Cir. 2023). We “shall decide all relevant questions of law [and] interpret constitutional and statutory provisions.” 5 U.S.C. § 706. And in so doing, we do not defer to agencies’ legal conclusions. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 392 (2024).

For example, § 922(g)(9) makes it unlawful for anyone “who has been convicted . . . of a misdemeanor crime of domestic violence” to possess “firearm[s] or ammunition.” And a third form is a civil statute that alters an offender’s status or privileges upon a criminal conviction. In this vein, the Immigration and Nationality Act provides that “[a]ny alien who is convicted of an aggravated felony at any time after admission is deportable.” 8 U.S.C. § 1227(a)(2)(A)(iii).⁴ Though their forms differ, these additional-consequence statutes share an important feature: They require us to look at an individual’s prior offenses.⁵

The Social Security Act includes one of these additional-consequence provisions. That provision instructs that the Secretary of Health and Human Services “shall exclude”

⁴ We speak only of “statutes.” But we recognize that the federal courts of appeals have interpreted various provisions in the United States Sentencing Guidelines to function similarly, enhancing the suggested Guidelines range when the defendant already has one or more convictions. *See, e.g., United States v. Ward*, 972 F.3d 364, 368 (4th Cir. 2020) (interpreting U.S.S.G. § 4B1.1(a), which imposes a career-offender sentencing enhancement on any defendant who has “at least two prior felony convictions of either a crime of violence or a controlled substance offense”).

⁵ Closely related is § 924(c)(1)(A), which punishes an offender who “uses or carries a firearm” during a “crime of violence or drug trafficking crime.” Such a statute is structurally similar to the additional-consequence statutes described above because it adds a consequence to what *looks* like a separate crime. But although § 924(c) requires a factfinder to conclude that a defendant charged with § 924(c) has engaged in conduct amounting to a separate “crime of violence or drug trafficking crime,” that separate crime need not be charged—nor is a conviction for that separate crime needed to trigger § 924(c). Put another way, someone can be convicted under § 924(c) without any separate conviction. Because of its structural similarity, however, the Supreme Court has interpreted § 924(c) alongside various additional-consequence statutes without differentiation, drawing on the same set of precedents. *See United States v. Davis*, 588 U.S. 445, 451–52 (2019). We do the same in this opinion, consulting the text of § 924(c) and cases interpreting it where helpful.

certain individuals “from participation in any Federal health care program,” like Medicare or Medicaid. 42 U.S.C. § 1320a-7(a). The exclusion is triggered after the individual has been “convicted of a criminal offense related to the delivery of an item or service under [Medicare] or under any State health care program.” *Id.* § 1320a-7(a)(1).

Read straightforwardly, this provision covers Baxter. Baxter pleaded guilty to misdemeanor drug misbranding (“convicted of a criminal offense”) in violation of 21 U.S.C. § 331(a). His wrongdoing was that he exhibited false or misleading statistics for Suboxone Film, resulting in the delivery of that drug (“delivery of an item”) under MassHealth insurance (“under any State health care program”). Baxter’s misbranding offense thus “related to” the comparator trigger in § 1320a-7(a)(1), “delivery of an item or service under [Medicare] or under any State health care program.” It thereby qualified as a predicate offense, triggering subsection (a)’s additional consequence. So the Secretary was required to exclude him from participation in federal healthcare programs. This straightforward reading would end Baxter’s case.

Understandably, Baxter tries to sidestep this simple chain of reasoning. His main argument is that this particular provision of the Social Security Act requires us to assess whether his offense triggers exclusion under a “categorical approach.” We disagree. The text of § 1320a-7(a) does not compel us to assess Baxter’s offense categorically.⁶ So his exclusion from federal healthcare programs was proper.

⁶ Until now, we—and at least four other circuits—have proceeded under this statute without applying the categorical approach. *See Morgan v. Sebelius*, 694 F.3d 535, 537–38 (4th Cir. 2012); *Parrino v. Price*, 869 F.3d 392, 400 (6th Cir. 2017); *Travers v. Shalala*, (Continued)

A. Additional-Consequence Statutes Require a Three-Step Matching Exercise

By definition, an additional-consequence provision like § 1320a-7(a) cannot apply to a person unless that person has been convicted of a predicate offense. Determining *whether* a prior offense counts as such a predicate requires a three-step matching exercise. First, we must define the comparator terms in the additional-consequence statute (here, “offense related to the delivery of an item . . .”). Then, we must determine the relevant aspects of the prior offense (here, drug misbranding). Last, once we understand the two things to be compared, we do the comparison: We check to see if the additional-consequence provision’s comparator terms and the prior offense relate to one another in the way the additional-consequence statute requires. *See generally Taylor v. United States*, 495 U.S. 575 (1990) (running through the first two steps of the matching exercise before remanding for the lower court to perform the third step). If the required relationship exists, the prior offense serves as a predicate that triggers the additional consequence. We apply each step in turn to Baxter’s case.

1. Defining the comparator terms of the additional-consequence provision

Figuring out whether an offense triggers some additional-consequence provision requires understanding what that provision looks for. To do that, we first must define that provision’s comparator terms. There are two primary ways in which comparator terms can

20 F.3d 993, 998 (9th Cir. 1994); *Stern v. Shalala*, 14 F.3d 148, 149–50 (2d Cir. 1994); *Patel v. Thompson*, 319 F.3d 1317, 1319 (11th Cir. 2003) (per curiam). And, notably, one more has considered and rejected the categorical reading Baxter proposes. *Friedman v. Sebelius*, 686 F.3d 813, 820–24 (D.C. Cir. 2012).

be defined: Some comparator terms refer to so-called “generic crimes,” and others refer to specific acts. *See Nijhawan v. Holder*, 557 U.S. 29, 33–34 (2009) (comparing “a generic crime, say, the crime of fraud or theft in general” to “the specific acts in which an offender engaged on a specific occasion, say, *the* fraud that the defendant planned and executed last month”). The distinction is straightforward: Sometimes, the comparator term says specifically what it covers, and other times it furnishes only broad labels—labels that must be defined.

We can tell that a statute uses generic crimes as comparators “when [it] refers generally to an offense without specifying its elements.” *Shular v. United States*, 589 U.S. 154, 158 (2020). For example, the Armed Career Criminal Act explicitly lists “burglary” as a comparator, meaning that three prior convictions for the state crime of burglary will trigger additional consequences upon a fourth arrest for being a felon in possession of a firearm. 18 U.S.C. § 924(e)(2)(B)(ii). But what counts as “burglary?” Given that ACCA does not say, courts define “burglary” *generically* for ACCA purposes by abstracting out the key elements of burglary that prevailed among state criminal codes at the time ACCA was enacted. *See Taylor*, 495 U.S. at 592–93. This creates a uniform definition of “burglary” that does not vary from case to case—a problem that would arise if “burglary” were simply understood as any crime that a state *calls* “burglary,” since “the criminal codes of the States define burglary in many different ways.” *Id.* at 580. Calling ACCA “burglary” a “generic crime,” then, recognizes two related propositions. First, the statute does not define burglary for us. And second, rather than try to apply state definitions, the federal courts have created one uniform *federal* definition for ACCA purposes.

By contrast, we can tell that an additional-consequence statute refers to specific acts rather than generic offenses when the comparator terms *do* define what we’re looking for. In *Shular*, for example, the comparator was “manufacturing, distributing, or possessing with intent to manufacture or distribute, a controlled substance.” 589 U.S. at 161 (quoting § 924(e)(2)(A)(ii)). Unlike a term like “burglary,” the listed terms “are unlikely names for generic offenses” since “States define core drug offenses with all manner of terminology, including: trafficking, selling, giving, dispensing, distributing, delivering, promoting, and producing.” *Id.* (quotation omitted). But those terms *do* naturally describe specific acts. So the Court determined that this was the better reading.

Baxter’s case presents no possibility of a generic definition, and Baxter wisely does not contend that it does. The comparator terms in § 1320a-7(a) are “the delivery of an item or service under [Medicare] or under any State health care program.” Such language does not “refer[] generally” to the name of a crime. *Shular*, 589 U.S. at 158. The requirement of “delivery” is more akin to the *Shular*’s list of “manufacturing, distributing, or possessing with intent to manufacture or distribute” than it is to “burglary.” And § 1320a-7(a)’s further requirement that the delivery be “under any State health care program” is a “detailed qualifier[] far too specific to refer to [a] generic crime[].” *United States v. Simms*, 914 F.3d 229, 244 (4th Cir. 2019) (en banc). So § 1320a-7(a)’s comparator terms refer to specific acts. With one piece of the matching exercise in hand, we move on to the second.

2. Determining the relevant aspect of the prior offense

This second step is the heart of Baxter’s appeal. The question is how § 1320a-7(a) tells us to think about Baxter’s prior conviction for drug misbranding. Additional-

consequence statutes can look to either of two aspects of the underlying criminal offense. Some additional-consequence statutes look to the *actual conduct* of the offender when committing the prior offense and see if it satisfies the comparator terms. This first method is the “circumstance-specific” approach.⁷ Others look to the *elements* of the statute of conviction for the prior offense, ignoring the factual particulars of how the offender did the crime. This second method is the “categorical approach.”⁸

In other words, “[u]nder the categorical approach, a court assesses whether a crime [matches the additional-consequence statute’s comparator terms] ‘in terms of how the law

⁷ Although both step one and step two of the additional-consequence statute matching exercise involve a choice between concrete activity and a legal abstraction, don’t be confused. At step one, we’re defining the comparator terms, and the terms may be referring to specific acts or to generic crimes. At step two, we’re looking at the prior criminal offense, and the relevant aspect of the offense may be the actual conduct committed or the elements of the underlying statute of conviction.

⁸ “The categorical approach” is a misnomer. The definite article—*the*—implies that there is only one approach that looks to the elements of the underlying statute rather than the offender’s actual conduct. But the categorical approach is a family with various subspecies. The classic form of the categorical approach looks at the elements of the underlying statute and the elements alone when matching up with the comparator terms. *See, e.g., Moncrieffe v. Holder*, 569 U.S. 184, 190–91 (2013). But sometimes, the comparator terms may have a so-called “divisible” structure, listing elements in the alternative (*e.g.*, requiring A, B, and *either C or D or E*). In such cases, courts use the “modified” categorical approach and look to a limited set of record documents in addition to the elements of the underlying statute to ascertain which of the alternative elements were charged or pleaded to. *Shepard v. United States*, 544 U.S. 13, 26 (2005). And still other times, after looking at the elements of the underlying statute, a court is invited to “picture the kind of conduct that the crime involves in ‘the ordinary case,’” which may involve imagined conduct not strictly entailed by any element. *Johnson v. United States*, 576 U.S. 591, 596 (2015) (citation omitted); *see also id.* at 597 (holding unconstitutional a statutory provision that applied the “ordinary case” categorical approach); *Sessions v. Dimaya*, 584 U.S. 148, 158 (2018) (same); *United States v. Davis*, 588 U.S. 445, 453 (2019) (same). More subspecies of the categorical approach may exist.

defines the offense and not in terms of how an individual offender might have committed it on a particular occasion.” *Johnson*, 576 U.S. at 596 (quoting *Begay v. United States*, 553 U.S. 137, 141 (2008)). And because we pay no attention to the facts of the particular occasion, those facts play no role in determining whether the conviction triggers the consequence. Instead, “we must presume that the conviction rested upon nothing more than the least of the acts criminalized.” *Moncrieffe*, 569 U.S. at 190–91 (cleaned up). This means that when an offender’s actual conduct during a crime is not captured by the crime’s elements, the circumstance-specific approach and the categorical approach can diverge on the bottom line. In those cases, the choice of approach determines whether the additional consequence applies.

How, then, can we tell which method to use? As ever, we rely on statutory text. “[W]e apply the categorical approach only when the text of a statute signals the need for such an elements-based approach.” *United States v. Keene*, 955 F.3d 391, 398 (4th Cir. 2020). Absent such signals, we apply the circumstance-specific approach, as the categorical approach is “not a default rule.” *United States v. Pena*, 952 F.3d 503, 508 n.4 (4th Cir. 2020). Neither this Court nor the Supreme Court has articulated a full answer to what signals are necessary to compel the categorical approach. But three main textual guideposts mark the path.

a. Textual signals of the categorical approach

First, the categorical approach’s focus on the underlying statute of conviction requires a conviction in the first place. So an additional-consequence statute that requires the categorical approach will most naturally point at a “conviction.” *See, e.g., Taylor*, 495

U.S. at 600 (“Section 924(e)(1) refers to ‘a person who . . . has three previous convictions’ for—not a person who has committed—three previous violent felonies or drug offenses.”). This contrasts with text pointing to someone’s “conduct” or how a person “committed” the prior offense, which suggest the circumstance-specific approach. *See, e.g., United States v. Price*, 777 F.3d 700, 708–09 (4th Cir. 2015) (“[34 U.S.C. § 20911(7)(I)’s] explicit reference to the ‘conduct’ underlying a prior offense . . . indicates that Congress intended that the broader circumstance-specific analysis be applicable.”). For this reason, the word “conviction” has been treated as a “key textual driver of the categorical approach.” *Davis*, 588 U.S. at 491 (Kavanaugh, J., dissenting) (noting that “the Court zeroed in on the word ‘convictions’” (first citing *Taylor*, 495 U.S. at 600; then citing *Johnson*, 576 U.S. at 604–05)). While the word “conviction” is not necessary for the categorical approach, few additional-consequence statutes that require the categorical approach fail to use some form of the word.⁹

Second, the categorical approach looks at the elements of the underlying statute in the abstract. Thus, phrases in the additional-consequence statute that explicitly direct attention away from the specific facts of the prior offense are strong textual indicators. Two such phrases are commonly seen. The first phrase is a requirement that the prior offense have comparator terms “as an element.” *See, e.g., Taylor*, 495 U.S. at 600–01

⁹ *See, e.g.*, 8 U.S.C. § 1227(a)(2)(A)(iii) (“convicted of an aggravated felony”); 18 U.S.C. § 924(e)(1) (“has three previous convictions . . . for a violent felony or a serious drug offense”); *id.* § 922(g)(9) (“has been convicted in any court of a misdemeanor crime of domestic violence”); *id.* § 2252A(b)(1) (“has a prior conviction . . . relating to aggravated sexual abuse”); 21 U.S.C. § 841(b)(1)(B) (“prior conviction for a serious drug felony”).

(holding that § 924(e)(2)(B)(i), which refers to any crime that “‘*has as an element*’ . . . the use or threat of physical force,” employs the categorical approach (emphasis added)). The second phrase is a requirement that the prior offense have the comparator “by its nature.” *See, e.g., Davis*, 588 U.S. at 455–57 (holding that § 924(c)(3), which refers to “an offense” that “*by its nature*, involves a substantial risk that physical force,” employs the categorical approach).

By their plain texts, both phrases “require[] us to look to the elements and the nature of the offense of conviction, rather than to the particular facts.” *Leocal v. Ashcroft*, 543 U.S. 1, 7 (2004). Because both phrases would be “exceedingly strange way[s] of referring to the circumstances of a specific offender’s conduct,” it is unlikely Congress would employ them to signal a circumstance-specific approach. *Davis*, 588 U.S. at 457. Indeed, it’s almost impermissible as a matter of ordinary English to speak of someone’s conduct having anything “as an element.” And while it may be technically permissible to speak of the “nature” of conduct, *see Dimaya*, 584 U.S. at 227 & n.7 (Thomas, J., dissenting), this is not the most intuitive use of the word. In most usages, “[a]n offense’s ‘nature’ means its ‘normal and characteristic quality[,]’ . . . not what happened to occur on one occasion.” *Id.* at 165 (quoting *Webster’s Third New International Dictionary* 1507 (2002)). Unsurprisingly, then, when an additional-consequence statute references “elements” or “natures,” the interpretive question is often “not even close; the statutory text commands the categorical approach.” *Davis*, 588 U.S. at 456.

Third, the categorical approach ultimately seeks to compare the underlying statute with the additional-consequence statute’s comparator terms. This means the comparator

terms must themselves be susceptible of being read either as a whole crime or an element of one. This can occur in two ways, corresponding to the two possible interpretations of the comparator terms at step one. If the comparator terms are read to refer to a generic crime (*e.g.*, “burglary”), there’s no problem—the elements of the underlying statute of conviction can be matched with the elements of a generic crime. *See, e.g., Taylor*, 495 U.S. at 602 (applying the categorical approach to a generic crime under ACCA); *Gonzales v. Duenas-Alvarez*, 549 U.S. 183, 187 (2007) (applying the categorical approach to a generic crime under INA). The shared focus on elements and the intuitive ease of an apples-to-apples elements comparison is why reading the comparator terms to refer to a generic crime at step one strongly suggests, and is so often paired with, the categorical approach at step two.¹⁰

By contrast, if the comparator terms are read to refer to specific acts, things are less straightforward. If the acts are described at a high enough level of generality that they could reasonably be read to describe an element of a crime—*e.g.*, “the use, attempted use, or threatened use of physical force”—then an apples-to-apples match of the comparator with an element of the underlying statute is still possible. *See, e.g., Johnson v. United*

¹⁰ Although generic crimes and the categorical approach, as an empirical matter, go hand-in-hand, they are conceptually distinct. As an example, imagine a recidivism statute that read: “A person convicted of one or more prior crimes shall be subject to additional consequences if his actual conduct during the commission of a prior crime amounted to generic burglary.” Such a statute would require the combination of a generic-crime comparator with the circumstance-specific approach. That Congress has not written any statutes of this form as of today does not mean it will never do so. So it is important to keep clear that a generic comparator does not *necessarily entail* the categorical approach as a matter of logic. Despite their structural similarities, these are separate—though related—inquiries. *See Shular*, 589 U.S. at 158 n.1.

States, 559 U.S. 133, 136–38 (2010). In such cases, the categorical approach remains an option, though the comparator itself signals little one way or the other, being susceptible to both categorical and circumstance-specific matching.¹¹

However, if the acts are described with specificity at a granular level—*e.g.*, “committed by a current or former spouse, parent, or guardian of the victim . . . or by a person similarly situated”—the categorical approach will seldom make sense. *United States v. Hayes*, 555 U.S. 415, 420–21 (2009) (quoting § 922(g)(9)). This is because a “detailed qualifier[]” that is “far too specific” will rarely be an element of any underlying statute. *Simms*, 914 F.3d at 244. Applying the categorical approach, then, would require an oranges-to-apples match at step three. That would render an additional-consequence provision largely a “dead letter” given the paucity of qualifying underlying statutes. *Hayes*, 555 U.S. at 427 (quotation omitted). We do not generally assume that Congress legislates in “so limited and so haphazard a manner” as to enact an additional-consequence provision that is essentially a nullity. *Nijhawan*, 557 U.S. at 40. Thus, the more detailed the comparator terms, the less likely the additional-consequence provision compels the categorical approach.

With these three textual guideposts, we can sketch a map. To start, an additional-consequence statute’s reference to a prior offense by the word “conviction” or “convicted”

¹¹ In *Johnson*, the Court applied the categorical approach to § 924(e)(2)(B)(i), which lists “the use, attempted use, or threatened use of physical force against the person of another” as a comparator. 559 U.S. at 137. But nothing in the opinion suggested that the comparator itself drove the application. Instead, the much more likely candidate was § 924(e)(2)(B)(i)’s preceding phrase, which requires the underlying statute to “[have] as an element” such a comparator.

places the categorical approach on the table. That signal is all the stronger if “the relevant statutory language refers *only* to convictions, not to conduct or to ‘committing’ acts”—perhaps strong enough, in the absence of all other indications, to compel the categorical approach standing alone. *Prudencio v. Holder*, 669 F.3d 472, 482 (4th Cir. 2012) (emphasis added). But it will seldom stand alone. So we also look for phrases in the additional-consequence statute like “has as an element” and “by its nature,” which unambiguously direct attention to the underlying statute in the abstract and away from the particulars of any occasion. Finally, we check to see if the comparator terms defined previously at step one can be read as a whole crime or an element of one. If the comparator is a generic crime, that is a strong—if not dispositive—signal in favor of the categorical approach. On the other hand, if the comparator describes acts too specific to constitute an element of a crime, that is a strong signal against.

Although these guideposts are important, and will in many cases prove dispositive, we would be remiss not to identify three caveats. First, determining whether an additional-consequence statute compels the categorical approach is not a rigid checklist, nor do any particular words function as guaranteed “talisman[s].” *Simms*, 914 F.3d at 244. At bottom, we are attempting to discern which aspect of the prior offense—the actual conduct on the one hand, the elements of the underlying statute on the other—the additional-consequence statute is using for its matching exercise. How the statutory text conveys its focus may differ from statute to statute. To that point, the textual signals we have described are not an exhaustive list. Another signal, for example, can be seen in § 924(c)(1)(A), which refers to “a crime of violence . . . that *provides for* an enhanced punishment.” (emphasis added).

Sitting en banc, this Court explained that the italicized language evoked the categorical approach because “only statutes, not conduct-specific facts, can ‘provide for’ an amount of punishment.” *Simms*, 914 F.3d at 242 (cleaned up). And there are surely other signals.¹²

Second, statutory provisions do not exist in a vacuum. The reading of one provision can be altered by the provisions surrounding it. “[O]ur reluctance” to imply that Congress has compelled the categorical approach “is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.” *Jama v. Immigr. & Customs Enf’t*, 543 U.S. 335, 341 (2005). We applied this context-sensitive reading in our decision in *Price*, where we interpreted the Sex Offender Registration and Notification Act, Pub. L. No. 109-248, 120 Stat. 587 (July 27, 2006) (SORNA). *Price*, 777 F.3d at 702–03. Subsection (7)(I) of SORNA extended to cover “[a]ny conduct that by its nature is a sex offense against a minor.” *Price*, 777 F.3d at 704 (quoting SORNA § 111(7)(I)). The express use of the word “conduct” in subsection (7)(I) already pointed us away from the categorical approach. *Price*, 777 F.3d at 709. But another one of the key textual signals came from outside subsection (7)(I) itself. We contrasted subsection (7)(I) with a different SORNA subsection, which covered any criminal offense that “has an element involving a sexual act or sexual contact with

¹² It should go without saying that canons and principles of statutory interpretation are also relevant here, just as they are in statutory interpretation generally. *See, e.g., Davis*, 588 U.S. at 460–61 (consistent usage); *Simms*, 914 F.3d at 241 (surplusage); *Price*, 777 F.3d at 709 (meaningful variation). And alongside textual considerations sit contextual ones—not just within a provision but between it and related law. *See, e.g., Davis*, 588 U.S. at 457 (explaining that “offense” should carry the same meaning through both § 924(c)(3)’s elements and residual clauses); *id.* at 455–56 (explaining that the Court will read statutes using similar language harmoniously); *Dimaya*, 584 U.S. at 163–64 (similar).

another.” *Id.* at 704 (quoting SORNA § 111(5)(A)(i)). The “structure” of SORNA, in using an explicit reference to “elements” in one place, made the “contrasting terminology” in subsection (7)(I) an even clearer indicator that the categorical approach did not apply. *Id.* at 708–09. The categorical approach inquiry thus cannot be restricted to just the provision in question.

Third and finally, a single provision in an additional-consequence statute can, in rare circumstances, be bifurcated, requiring both the circumstance-specific approach and the categorical approach. Section 921(a)(33)(A), for example, defines a “misdemeanor crime of domestic violence” as a misdemeanor that “has, as an element, the use or attempted use of physical force, or the threatened use of a deadly weapon, committed by a current or former spouse, parent, or [other specified relation to the victim].” In *Hayes*, the Supreme Court agreed that the “as an element” phrase compelled the categorical approach for the “physical force” clause. 555 U.S. at 421. But that didn’t mean the scope of the “element” phrase extended to the “familial” clause. The Court noted that “an element” took a singular referent, yet “[t]he manner in which the offender acts, and the offender’s relationship with the victim, are conceptually distinct attributes.” *Id.* (quoting *United States v. Mead*, 175 F.3d 215, 218 (1st Cir. 1999) (quotation marks omitted)). Nor did it make sense as a matter of syntax to think the familial clause modified the force clause since a “use” of force is not “committed by” an individual. *Id.* at 422–23. And to top it all off, the Court found that the familial clause was too specific to serve as a proper comparator for an element of an underlying statute. “Given the paucity of state and federal statutes targeting *domestic violence*,” applying the categorical approach would cover

“relatively few domestic abusers” contrary to “Congress’ manifest purpose” in passing the additional-consequence statute in the first place. *Id.* at 427.¹³ The Court thus read the familial clause to allow inquiry into the actual familial status of the offender, even if it was not part of the underlying statute’s elements. *Id.* at 429. So even after confirming that one part of an additional-consequence provision employs the categorical approach, courts must be aware that the text of other parts of the same provision may require different treatment.¹⁴

b. Section 1320a-7(a)’s text does not compel the categorical approach

Now to apply these guideposts and caveats to the additional-consequence statute in Baxter’s case, which covers “any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under [Medicare] or under any State health care program.” 42 U.S.C. § 1320a-7(a)(1). Other than the use of the word

¹³ To be sure, had the statute in *Hayes* unambiguously treated the relationship as an element, the case may have come out the other way despite the specificity. For instance, if the statute read, “has, as an element, the offender’s familial relationship to the victim,” it would be difficult to avoid the categorical approach regardless of how few domestic-violence statutes existed among the states. But as § 921(a)(33)(A)(ii) was written, it was implausible to apply the categorical approach to its entirety.

¹⁴ *Hayes* is one of the very few cases where we’ve seen the bifurcation of a single provision. The textual and contextual signals must be exceedingly strong for us to perform such bifurcation. For example, take § 924(e)(2)(B)(ii) which covers an offense that “is burglary, arson, or extortion, involves use of explosives, *or otherwise involves conduct* that presents a serious potential risk of physical injury to another” (emphasis added). The provision involves an explicit reference to conduct, and a comma offsets the so-called “residual clause” covering physical injury from the conceptually distinct list of generic crimes. Yet the Court has told us that the entire provision uses the categorical approach. *See, e.g., Johnson*, 576 U.S. at 596. So unless it is highly implausible to read an additional-consequence statute’s provisions together as a matter of syntax and application, we will avoid bifurcation.

“convicted,” none of subsection (a)’s text suggests a categorical reading. And the remainder of the provision outweighs any force that “convicted” alone might have. *Cf. Prudencio*, 669 F.3d at 482. The statute does not talk about the “elements” or “nature” of the prior offense. Nor does it give any other indication that it is directed at an underlying statute (rather than conduct). And, as we explained in step one above, the comparator terms refer to specific acts, not a generic offense.

The final nail in the coffin is that the specific acts listed in the comparator terms are “far *too* specific” to be compared to any element in an underlying statute of conviction. *Simms*, 914 F.3d at 244 (emphasis added). Few crimes—if any—require something akin to the delivery of an item or service under Medicare or a state healthcare program. Tellingly, even the state crimes Baxter offers as matches don’t come close to serving as predicate offenses under the categorical approach. None of his examples require delivery; they all require receipt. They take aim at patient-side fraud, *see, e.g.*, Kan. Stat. § 21-5930 (2024); Tex. Hum. Res. Code § 36.002(8) (2023); Md. Code Crim. Law § 8-515 (2024), or punish service providers for misappropriating patient funds, *see, e.g.*, S.C. Code § 43-7-80 (2024). Without requiring delivery in general, they cannot require delivery under any healthcare program in particular—which would leave 42 U.S.C. § 1320a-7(a) with an empty basket. We will not lightly presume that Congress passed a statute intending for it to do so very little. *See Quarles v. United States*, 587 U.S. 645, 653–544 (2019) (rejecting an interpretation of 18 U.S.C. § 924(e) that would rule out “many States’ burglary statutes . . . as predicate offenses”).

Looking to the provisions surrounding 42 U.S.C. § 1320a-7(a)(1) only confirms the lack of categorical approach signals. The adjacent provisions excluding other sets of individuals from participation in federal healthcare programs do not differ substantially in their language and structure. *See* § 1320a-7(a)(2) (“offense relating to neglect or abuse of patients”); *id.* § 1320a-7(a)(3) (“offense . . . in connection with the delivery of a health care item or service” committed after August 1996); *id.* § 1320a-7(a)(4) (“offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance” committed after August 1996). So nothing suggests that (a)(1) should be read more categorically in comparison. Both text and context therefore lead us to hold that § 1320a-7(a)(1) employs the circumstance-specific approach and allows us to look at Baxter’s actual conduct in committing his prior misbranding misdemeanor.¹⁵

3. Checking for the required relationship between the comparator terms and the prior offense

The third and final step of the matching exercise for any additional-consequence statute is to check for the required relationship between the comparator terms and the prior offense. If and only if the required relationship exists will the prior offense serve as a predicate offense that triggers the additional consequence.

¹⁵ For completeness, we also note that § 1320a-7(a) gives no indication that one portion of the provision is circumstance-specific while another portion is categorical. The statute in *Hayes* contained two “conceptually distinct” portions offset from one another within the provision by a comma. 555 U.S. at 421. And the Court noted that it would be syntactically awkward to distribute the prefatory language across both portions. *Id.* In contrast, the statute here reads as a seamless whole.

Most additional-consequence statutes require one of just a handful of relationships. At the most restrictive, an additional-consequence statute can use the word “is” to require that the entirety of the prior offense be “the same as, or narrower than” a comparator term. *Descamps v. United States*, 570 U.S. 254, 257–58 (2013) (discussing 18 U.S.C. § 924(e)(2)(B), which takes as a predicate offense “any crime . . . [that] *is* burglary, arson, or extortion” (emphasis added)). Such a requirement will most often appear alongside a list of generic crimes. In a similar vein, the additional-consequence statute can require the prior offense “have” the comparator terms as an element. *See Stokeling v. United States*, 586 U.S. 73, 75 (2019).

More relaxed is the requirement that the prior offense “involve” or “include” the comparator terms in some way. If the categorical approach is being used at step two, such a relationship is satisfied when commission of the prior offense necessarily entails the comparator terms—even if the prior offense does not expressly have the comparator terms as elements. *See Kawashima v. Holder*, 565 U.S. 478, 484 (2012). If the circumstance-specific approach is being used, the relationship is straightforwardly satisfied when the comparator terms were part of the individual’s actual conduct. *See Nijhawan*, 557 U.S. at 40.

And at the least restrictive, an additional-consequence statute can require merely that the prior offense “relat[e] to” the comparator terms. *See United States v. Hardin*, 998 F.3d 582, 588 (4th Cir. 2021). We have explained that Congress’s use of such an “expansive term” means that the match between offense and comparator “need not be perfect.” *Id.* This tracks the ordinary meaning of “relat[e],” which means “to pertain; refer;

to bring into association with or connection with.” *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (quoting *Black’s Law Dictionary* 1158 (5th ed. 1979)). Such a relationship can be satisfied by a looser fit than inclusion.

The statute in Baxter’s case requires the last of these relationships. Per step one, we understand the statute’s comparator terms as referring to specific acts, not a generic crime. Per step two, we employ the circumstance-specific approach when looking at Baxter’s prior offense. So now, at step three, we compare the specific acts listed in § 1320a-7(a) to Baxter’s actual conduct, requiring only that Baxter’s conduct when committing his prior misbranding offense be “*related to the delivery of an item or service under [Medicare] or under any State health care program.*” § 1320a-7(a)(1) (emphasis added).

That loose relationship is satisfied in spades. Baxter pleaded guilty to “caus[ing] the introduction and delivery for introduction into interstate commerce of Suboxone Film.” J.A. 346. He also agreed that MassHealth, a state health care program, distributed at least some of the drugs that he caused to be delivered. And he admitted that these two things connected: that Indivior specifically sought to “persuad[e] MassHealth to expand coverage of Suboxone Film,” J.A. 341, and that the misbranding was part of that effort. That conduct is an offense “related to the delivery of an item or service . . . under any State health care program.” § 1320a-7(a)(1). So Baxter’s mandatory exclusion by the Secretary as an additional consequence was no error.

B. Baxter's counterarguments lack merit

Resisting this conclusion, Baxter musters a host of counterarguments. None persuades us that § 1320a-7(a) requires a categorical approach.¹⁶

Baxter first contends that reading § 1320a-7(a) to employ the circumstance-specific approach creates tension with other provisions in the Social Security Act. In his view, this would fit badly with the Act's civil-penalties provision, codified at 42 U.S.C. § 1320a-7a. Subsection (a)(1)(B) of that section, Baxter points out, covers similar conduct to § 1320a-7(a)'s mandatory-exclusion clause. And that subsection has a “knowingly” scienter requirement that the mandatory-exclusion clause lacks. True enough. But unlike § 1320a-7(a), § 1320a-7a(a)(1)(B) can trigger not just exclusion, but fines too. And there is no incongruity in pairing a stiffer penalty with a more-culpable mental state. *See Friedman*, 686 F.3d at 823.

Baxter retorts that precisely because § 1320a-7(a) contains no scienter requirement, we should read it narrowly absent a clear command from Congress. Applying this clear-statement canon would resolve any ambiguity in favor of the interpretation that captures fewer people—which would be the categorical approach.¹⁷ We indeed often hesitate to

¹⁶ Unspoken is the assumption that Baxter would escape from mandatory exclusion if the statute employed the categorical approach. Because we conclude that the statute does *not* employ the categorical approach, we take no position on the question.

¹⁷ The categorical approach captures only a subset of the individuals captured by the circumstance-specific approach. By definition, the actual conduct of the individual during the prior offense must at least include the offense's elements. *See Moncrieffe*, 569 U.S. at 190–91 (“We must presume [in applying the categorical approach] that the conviction rested upon nothing more than the least of the acts criminalized.” (cleaned up)). So looking at actual conduct can only expand the set of prior offenses that will qualify as predicates.

interpret statutes as imposing *criminal* penalties without a scienter requirement. *See Morrisette v. United States*, 342 U.S. 246, 256 (1952); *Staples v. United States*, 511 U.S. 600, 618 & n.15 (1994). But § 1320a-7(a) is not a criminal penalty; it's a *civil* consequence. And our crime-specific interpretive canons do not reach this far. So the clear-statement rule has no effect here.

Unable to advance an argument that shows that the *best* reading of § 1320a-7(a) employs the categorical approach, Baxter changes tack. He argues instead that a categorical reading is at least a *plausible* interpretation of the statute. And so, he says, we are forced to adopt that plausible interpretation under the constitutional-avoidance canon because the circumstance-specific reading raises two Fifth Amendment Due Process concerns. *See Shepard*, 544 U.S. at 25 (applying the “rule of reading statutes to avoid serious risks of unconstitutionality”). First, Baxter says, mandatory exclusion from federal healthcare programs is too big a consequence for a mere strict-liability misdemeanor. Second, exclusion takes his property without due process.

Even assuming that we could plausibly read § 1320a-7(a) the way Baxter wants, his constitutional arguments would get him nowhere. The first point, that mandatory exclusion is too harsh, is simply the scienter requirement argument from above repackaged in a constitutional wrapper. And as it failed above, so too does it fail here. While we indeed are wary of strict-liability criminal statutes, this is a principle of statutory interpretation, not a constitutional cap on penalties for strict-liability offenses—much less a cap on collateral civil consequences. *See Morrisette*, 342 U.S. at 256.

Baxter makes no more constitutional headway by arguing that the Secretary couldn't suspend his right to participate in federal programs. True, a panel of this Court held decades ago that a doctor's "expectation of continued participation in [federal healthcare programs] is a property interest protected by the due process clause of the fifth amendment." *Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986). But it's not necessarily unconstitutional to take someone's property. Rather, "once it is determined that the Due Process Clause applies, the question remains what process is due." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985) (quotation marks omitted) (quoting *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972)). For property rights like Baxter's that come from the government, the process due is "notice and opportunity for hearing." *Mullane v. Cent. Hanover Bank & Tr.*, 339 U.S. 306, 313 (1950). And that's just what the additional-consequence statute provides: When Baxter was excluded, he was "entitled to reasonable notice and opportunity for a hearing thereon by the Secretary." § 1320a-7(f)(1). So this constitutional claim fails too.¹⁸

¹⁸ To be sure, other constitutional problems have persuaded courts to read statutes categorically. But none of these well-known problems arises here. Often, categorical readings are compelled by constitutional concerns unique to criminal penalties. "Sixth Amendment concerns . . . arise from sentencing courts' making findings of fact that properly belong to juries" under the circumstance-specific approach. *Descamps*, 570 U.S. at 267. Yet on the other side, conjuring a vision of "the kind of conduct that [a] crime involves in the ordinary case" risks the sort of "indeterminacy" that violates the Fifth Amendment. *Johnson*, 576 U.S. at 596–597 (quotation omitted). These concerns cut in different directions. Sixth Amendment worries suggest that we *should* use the categorical approach. For one way to avoid judicial factfinding is to rely on the brute fact of conviction. See *Almendarez-Torres v. United States*, 523 U.S. 224, 247 (1998). But what sometimes comes next is an assessment of what conduct an offense usually involves. And that threatens a vagueness problem cutting *against* the categorical approach. In some cases, (Continued)

Finally, Baxter argues that even if we read § 1370a-7(a) to employ the circumstance-specific approach, he should escape exclusion. He quibbles that his prior misbranding offense cannot be a predicate offense because no one proved that “Dr. Baxter or his subordinate delivered an item or service to anyone enrolled in MassHealth” on account of “the misleading data.” Opening Br. at 43. But this misunderstands the required relationship. Section 1320a-7(a) does not require that Baxter’s prior offense *is* the delivery of an item under MassHealth. The statute instead merely requires that his prior offense be *related to* such a delivery. So there was no need to prove that Indivior shipped an item to an identified MassHealth insured. The causal chain that Baxter pleaded to—misbranding as an attempt to get MassHealth to cover Suboxone Film—is more than enough.

* * *

Section 1320a-7(a) requires that an individual be excluded from federal healthcare programs if he has a prior offense relating to certain specific acts. Baxter’s conduct during his misbranding offense fit the bill. He caused the delivery of items (drugs) under a state healthcare program (MassHealth) and received a criminal conviction for doing so. For that

then, “attempt[s] to avoid the Scylla of the Sixth Amendment steer[] . . . straight into the Charybdis of the Fifth.” *Dimaya*, 584 U.S. at 226 (Thomas, J., dissenting). Despite this tension, we often use the categorical approach to escape constitutional problems in criminal cases. And we have applied similar reasoning to immigration consequences. *See id.* at 156–57 (citing *Jordan v. De George*, 341 U.S. 223, 229 (1951)).

Yet Baxter faces a civil collateral consequence, not “a federal sentencing enhancement or an immigration consequence.” *Keene*, 955 F.3d at 395. His case does not increase the sentence or criminal penalty associated with a conviction—and accordingly does not implicate the Sixth Amendment. *See Shepard*, 544 U.S. at 24. And since the circumstance-specific approach poses no issue, we need not be concerned with any potential Fifth Amendment vagueness problem from the categorical approach.

reason, the Secretary had to exclude him from federal healthcare programs. So the judgment against him is

AFFIRMED.