

No. 16-5145

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

FILED
Jun 12, 2017
DEBORAH S. HUNT, Clerk

LEO PARRINO,)
)
Plaintiff-Appellant,)
)
v.)
)
DEPARTMENT OF HEALTH AND HUMAN)
SERVICES, Secretary of Department;)
DEPARTMENT OF HEALTH AND HUMAN)
SERVICES, Inspector General,)
)
Defendants-Appellees.)

ON APPEAL FROM THE
UNITED STATES DISTRICT
COURT FOR THE WESTERN
DISTRICT OF KENTUCKY

BEFORE: SUHRHEINRICH, BATCHELDER, and STRANCH, Circuit Judges.

ALICE M. BATCHELDER, Circuit Judge. Leo Parrino, a licensed pharmacist, pleaded guilty to the misdemeanor crime of introducing misbranded drugs into interstate commerce. The Secretary of the Department of Health and Human Services (“HHS”), acting through the Office of the Inspector General (“OIG”), notified Parrino shortly thereafter that, due to his guilty plea, he would be excluded from participating in federal health care programs for five years, as required under 42 U.S.C. § 1320a-7(a). Parrino filed this lawsuit, alleging that the exclusion violated his Fifth Amendment substantive due process rights and that HHS acted arbitrarily and capriciously in excluding him. The district court dismissed his suit, and Parrino appealed. We affirm.

I

Leo Parrino worked as a licensed pharmacist for National Respiratory Services, LLC (“NRS”) from 2002 to 2006 and thereafter became a consulting pharmacist for NRS’s patients in Michigan, where he worked for several months. At NRS, Parrino was responsible for preparing medications, mainly inhalers. After leaving employment with NRS, Parrino was contacted by the Federal Drug Administration and the Federal Bureau of Investigation, which were investigating several reports concerning the potency of prescriptions filled and medications produced by NRS. These reports showed that NRS was consistently filling prescription medications for Pulmicort, a steroid used for the treatment of asthma, with a sub-potent amount of the active ingredient budesonide.

Parrino cooperated with the investigation, and in September 2011, he pleaded guilty to an information charging him with the crime of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 352(a), and 18 U.S.C. § 2. This crime is a strict liability misdemeanor with a maximum penalty of one year in prison, a \$1,000 fine, and one year of supervised release. Parrino was sentenced only to one year of probation and had to pay a \$25 assessment. The court also ordered Parrino to pay \$14,098.24 in restitution to the Centers for Medicaid and Medicare Services for the misbranded drugs that they had reimbursed.

In May 2013, HHS¹ notified Parrino that it was “required to exclude [him] from participation in any capacity in the Medicare, Medicaid, and *all* Federal health care programs as defined in section 1128B(f) of the Social Security Act (Act).” The letter also stated, “The scope of an exclusion is broad and, if implemented, would have a significant effect on [Parrino’s]

¹ Parrino sued the Department of Health and Human Services, naming both the Secretary and the Inspector General as defendants. The Secretary, who is the party actually vested with the authority to exclude Parrino under the statute, acted through the Inspector General in this case. Thus, for the sake of simplicity, we refer throughout this opinion to “HHS” in referring to the actions of either the Secretary or the Inspector General.

ability to work in the health care field.” HHS notified Parrino that the exclusion would be for at least five years, as provided for under 42 U.S.C. § 1320a-7(a), which mandates exclusion for certain individuals (*i.e.*, the “mandatory” exclusion).²

Parrino’s attorney replied to HHS’s letter, arguing that the applicable subsection of 42 U.S.C. § 1320a-7 was the “permissive exclusion” found in 42 U.S.C. § 1320a-7(b), not the mandatory exclusion in subsection (a). HHS responded several months later, in December 2013, again notifying Parrino that his conviction fell within the ambit of the mandatory provision, 42 U.S.C. § 1320a-7(a), because it was “a criminal offense related to the delivery of an item or service under . . . Medicare.”

In January 2014, Parrino requested a hearing before an administrative law judge (“ALJ”) to challenge his exclusion. Parrino argued that HHS violated his due process rights by excluding him under 42 U.S.C. § 1320a-7(a) when he lacked any *mens rea* to commit a crime and was convicted of a strict liability misdemeanor. The ALJ upheld HHS’s decision and Parrino sought review by the Department Appeals Board, which ultimately affirmed HHS’s decision to exclude Parrino under 42 U.S.C. § 1320a-7(a). *Leo Parrino*, DAB No. CR3287 (HHS), 2014 WL 3899327, at *1, *3-4 (2014).

Parrino then filed a complaint in the United States District Court for the Western District of Kentucky, alleging that his exclusion from all federal health care programs due to his guilty plea to a strict liability misdemeanor was a violation of his substantive due process rights and

² Specifically, 42 U.S.C. § 1320a-7(a)(1) states, “The Secretary shall exclude the following individuals and entities from participation in any Federal health care program . . . [a]ny 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.”

that HHS violated the Administrative Procedure Act (“APA”) by excluding him arbitrarily and capriciously.³

At the request of the parties, the district court evaluated Parrino’s claims and dismissed the case because it found that HHS’s action affected no substantive due process right. *Parrino v. Sebelius*, 155 F. Supp. 3d 714, 717 (W.D. Ky. 2015). The district court found that Parrino’s exclusion from federal health care programs for five years did not implicate a property interest “in continued participation or reimbursement” because “health care providers are not the intended beneficiaries of the federal health care programs.” *Id.* at 720-21. The court further found that Parrino’s exclusion did not implicate a liberty interest. *Id.* at 721-22. The court concluded that HHS had not acted arbitrarily and capriciously because its decision to exclude Parrino was “not so shocking as to shake the foundations of this country.” *Id.* at 723 (citation and internal quotation marks omitted). Parrino filed a timely appeal.

II

We review de novo the district court’s decision to dismiss the complaint. *Ley v. Visteon Corp.*, 543 F.3d 801, 805 (6th Cir. 2008). We construe the complaint in the light most favorable to the plaintiff, accepting all well-pleaded factual allegations as true. *Id.*; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

³ Meanwhile, Parrino also moved to vacate his criminal conviction on ineffective-assistance-of-counsel grounds. Parrino argued that his original attorney failed to advise him of the full consequences of pleading guilty to 21 U.S.C. § 331(a). The district court denied Parrino’s motion because it found that his original attorney had sufficiently advised Parrino of the risk of exclusion following a guilty plea. *United States v. Parrino*, No. 3:11-MJ-218-DW, 2015 WL 4272022 (W.D. Ky. July 13, 2015). We affirmed. *Parrino v. United States*, 655 F. App’x 399 (6th Cir. 2016).

III

A

The Due Process Clause of the Fifth Amendment to the U.S. Constitution prohibits the federal government from depriving individuals of “life, liberty, or property, without the due process of law.” The Due Process Clause⁴ “clothes individuals with the right to both substantive and procedural due process.” *Prater v. City of Burnside, Ky.*, 289 F.3d 417, 431 (6th Cir. 2002) (citing *United States v. Salerno*, 481 U.S. 739, 746 (1987)). Because Parrino does not argue that HHS failed to provide him notice or adequate procedures by which he could contest his exclusion, we focus only on his substantive due process claim.⁵

Substantive due process is “[t]he doctrine that governmental deprivations of life, liberty, or property are subject to limitations regardless of the adequacy of the procedures employed.” *Bowers v. City of Flint*, 325 F.3d 758, 763 (6th Cir. 2003) (citation omitted). It protects the individual from “the exercise of power without any reasonable justification in the service of a legitimate governmental objective.” *Cty. of Sacramento v. Lewis*, 523 U.S. 833, 846 (1998) (citation omitted). In particular, substantive due process “protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation’s history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed.” *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997) (internal citations and quotation marks omitted). In order for a plaintiff to state a claim alleging a violation of his substantive due process rights, we generally require him to “demonstrate a deprivation of a

⁴ Throughout this opinion, we cite to cases concerning the Due Process Clause of the Fourteenth Amendment, which is a restriction upon the States, because “those cases are also authoritative when adjudicating a Fifth Amendment claim against the federal government.” *Borkins v. U.S. Postal Serv. Emps.*, 97 F. App’x 32, 34 n.2 (6th Cir. 2004).

⁵ Parrino did allege in his complaint that HHS “deprived [him] of his due process rights in that he had no notice of that [sic] his conviction would subject him to mandatory exclusion.” However, Parrino has not pursued a procedural due process challenge in this appeal, and we consider abandoned any procedural due process claim Parrino may have initially alleged. See *Enertech Elec., Inc. v. Mahoning Cty. Comm’rs*, 85 F.3d 257, 259 (6th Cir. 1996).

constitutionally protected liberty or property interest.” *Am. Exp. Travel Related Servs. Co. v. Kentucky*, 641 F.3d 685, 688 (6th Cir. 2011) (citation omitted).

Parrino does not have a fundamental right to participate in federal health care programs because he has neither a property nor a liberty interest in the programs. Parrino argues that he has a property interest in his pharmacy license, but that is simply not the issue here. Rather, the question we must address is whether Parrino has a property interest in being a provider in all federal health care programs. While we have not directly addressed this issue, several of our sister circuits have held that a provider does not have a property interest in continued participation in federal health care programs. *See Erickson v. U.S. ex rel. Dep't of Health & Human Servs.*, 67 F.3d 858, 862 (9th Cir. 1995); *Koerpel v. Heckler*, 797 F.2d 858, 863-65 (10th Cir. 1986); *Cervoni v. Sec'y of Health, Ed. & Welfare*, 581 F.2d 1010, 1018 (1st Cir. 1978). These courts have reasoned that health care providers are not the intended beneficiaries of the federal health care programs and they therefore do not have a property interest in continued participation or reimbursement. And though the Fourth Circuit has declared that providers do have a property interest in continued participation in federal health care programs, it provided no accompanying analysis for its conclusion. *Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986) (“Ram’s expectation of continued participation in the [M]edicare program is a property interest protected by the due process clause of the fifth amendment.”).⁶ We find persuasive the rationale of the First, Ninth, and Tenth Circuits in finding no property interest. This is because, although Parrino is suffering financial loss, this loss “do[es] not advance to the

⁶ The district court and Parrino both state that the Second Circuit has also held that providers have a property interest in participation in federal health care programs. *See Patchogue Nursing Ctr. v. Bowen*, 797 F.2d 1137, 1144 (2d Cir. 1986). However, the Second Circuit has since questioned whether providers have a property interest in participation in federal health care programs. *See Senape v. Constantino*, 936 F.2d 687, 690-91 (2d Cir. 1991).

level of a protected property right because no clear promises have been made by the government.” *Koerpel*, 797 F.2d at 864.

Parrino also fails to demonstrate that he has at stake a liberty interest—which he characterizes as his good name and professional reputation. We have previously stated that “a person’s reputation, good name, honor, and integrity are among the liberty interests protected by the due process clause of the [F]ourteenth [A]mendment.” *Quinn v. Shirey*, 293 F.3d 315, 319 (6th Cir. 2002) (citation omitted). “To establish a deprivation of a protected liberty interest in the employment context, [Parrino] must demonstrate stigmatizing governmental action which so negatively affects his . . . reputation that it effectively forecloses the opportunity to practice a chosen profession.” *Joelson v. United States*, 86 F.3d 1413, 1420 (6th Cir. 1996) (citing *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 573-74). Parrino must also have “allege[d] in his . . . complaint that the stigmatizing information was publicly disclosed.” *Id.* (citation omitted). Although Parrino has shown that he effectively has no ability to work as a pharmacist for the duration of his exclusion, he has not argued that this “stigmatizing information” was publicly disclosed, or alleged that HHS will disclose such information in the future.

The district court was therefore correct in finding that Parrino has no substantive due process right to participate in all federal health care programs.

B

Because Parrino has no fundamental right to participate in federal health care programs, his exclusion is subject only to rational basis review, meaning that it will be upheld provided it is “rationally related to legitimate government interests.” *Glucksberg*, 521 U.S. at 728. “This standard is highly deferential; courts hold statutes unconstitutional under this standard of review only in rare or exceptional circumstances.” *Doe*, 490 F.3d at 501.

As the government argues, excluding Parrino from federal health care programs for five years advances the government's legitimate interests in both patient health and fiscal responsibility. *See* S. Rep. No. 100-109, at 1 (1987) (explaining that the system of mandatory and permissive exclusions is meant "to protect [the government] from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and inappropriate or inadequate care"). Medicare insures some of the most vulnerable members of society—the elderly—and patients' reliance on medications that lack the prescribed pharmacological potency could result in injury and death. This legitimate government interest is rationally related to Parrino's five-year exclusion, regardless of whether Parrino knew what he was doing.⁷

The government also has an interest in not reimbursing pharmacists for sub-potent medications. Reimbursing pharmacists for medications with little or no therapeutic effect wastes government resources because the government is not paying for the medication that was actually prescribed. This could also lead to patients' having to take the medication more frequently (to achieve the desired therapeutic result), which in turn requires the government to reimburse for medications more frequently. This five-year exclusion is a reasonable way to advance the government's legitimate interest in preventing unwarranted reimbursements to pharmacists engaged in filling sub-potent prescription medications. Even if we were to find the exclusion severe, we must find that it passes rational basis review.

IV

Parrino's last argument is that his exclusion under the mandatory provision was arbitrary or capricious. At the outset, we note that it is unclear whether Parrino's contention is that his exclusion is a violation of the APA or substantive due process. In his complaint, Parrino alleged

⁷ Parrino challenges—for the first time on appeal—his exclusion as unconstitutional because it punishes him for a strict liability offense. This sounds more of an Eighth Amendment challenge (indeed, Parrino cites to several cases interpreting the Eighth Amendment). Because Parrino never raised such claims below, he has waived this argument.

both an APA violation and a substantive due process violation. He has not pursued his APA claim on appeal, however, and has therefore abandoned it. *See Enertech Elec., Inc. v. Mahoning Cty. Comm'rs*, 85 F.3d 257, 259 (6th Cir. 1996) (stating that those issues not raised in appellant's opening brief will not be considered on appeal). But Parrino has not abandoned his argument that HHS's decision to exclude him under the "mandatory" provision of 42 U.S.C. § 1320a-7 was so arbitrary and capricious that it violated his substantive due process rights.

Under 42 U.S.C. § 1320a-7(a)(1), Congress has mandated that the Secretary of HHS exclude "[a]ny individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under" Medicare. The statute also provides for mandatory exclusion of individuals or entities convicted of criminal offenses relating to patient abuse, felony health care fraud, and felonies relating to controlled substances. 42 U.S.C. § 1320a-7(a)(2)-(4). Congress further legislated a "permissive" exclusion, which gives the Secretary of HHS discretion to exclude certain individuals from participation in federal health care programs. 42 U.S.C. § 1320a-7(b).

Parrino has never disputed—and does not do so on appeal—that he was convicted of an offense "related to the delivery of an item or service under" Medicare. According to the plain language of the statute, then, HHS was required to exclude him from participation in federal health care programs. Thus, we cannot say that that HHS acted arbitrarily or capriciously by finding that it was required by the statute to exclude Parrino from participation in federal health care programs. *See Chevron, U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). HHS's

decision to exclude Parrino is consistent with the clear and unambiguous language of the statute, meaning that Parrino's exclusion was not arbitrary or capricious.

Parrino next contends that, under the rules of statutory construction, HHS's interpretation of § 1320a-7 would result in superfluity. "In particular," he argues, "if the mandatory exclusion applies to Appellant's offense, then the offenses under the so-called 'permissive' exclusion sections would all be subsumed into 42 USC 1320a-7(a)(1), since all of the 1320(a)-7(b) offenses necessarily relate to items or services under federal and state health care programs." This contention is simply without merit. Upon careful review of the statute, we do not agree that if Parrino's crime is classified as a predicate to invoke a mandatory exclusion it would absorb the permissive exclusion. And to the extent that other courts have analyzed Parrino's crime under the permissive exclusion, see *Friedman v. Sebelius*, 686 F.3d 813, 817 (D.C. Cir. 2012), we do not agree. Even if *Friedman* stands for the proposition that some misdemeanor misbranding convictions are subject to the permissive exclusion, *Friedman* did not address whether misdemeanor misbranding was subject to mandatory exclusion when HHS determined that it was a "program-related crime" under 42 U.S.C. § 1320a-7(b)(1). See *id.* at 817-22 (evaluating HHS's decision to exclude Friedman under § 1320a-7(b)).

Because HHS complied with the statutory language and does not appear to contravene any binding case law, we hold that the decision to exclude Parrino was neither arbitrary nor capricious.

V

For the foregoing reasons, the district court is affirmed.