# IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of its members; and CATHOLIC MEDICAL ASSOCIATION, on behalf of its members,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and LISA J. PINO, in her official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services,

On Appeal from the United States District Court for the Eastern District of Tennessee

### SUPPLEMENTAL BRIEF FOR APPELLEES

BRIAN M. BOYNTON

Principal Deputy Assistant Attorney General

CHARLES W. SCARBOROUGH MCKAYE L. NEUMEISTER

Attorneys, Appellate Staff
Civil Division, Room 7231
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530
(202) 514-8100

# TABLE OF CONTENTS

		<u>Page</u>
TABLE OF AUTI	HORITIES	ii
INTRODUCTION	N AND SUMMARY	1
STATEMENT		1
ARGUMENT		5
Health and	Whether the final rule promulgated by the Department o Human Services on May 6, 2024 (89 Fed. Reg. 37,522) has will render any of appellants' claims moot	
complaint st	If the rule moots some but not all of appellants' claims, pecific member of each organization identified in the till retains a live claim upon which appellants can assert I standing.	12
	Whether the court may consider the new rule in assessing od that any of appellants' members face a credible threat of nent action, and if so, whether the new rule reduces such ri	Ē
CONCLUSION		18
CERTIFICATE C	OF COMPLIANCE	
CERTIFICATE C	OF SERVICE	

# TABLE OF AUTHORITIES

Cases:	Page(s)
Ammex, Inc. v. Cox, 351 F.3d 697 (6th Cir. 2003)	15-16
Anderson v. Green, 513 U.S. 557 (1995)	13
Arizonans for Official English v. Arizona, 520 U.S. 43 (1997)	6
Barber v. Charter Twp. of Springfield, 31 F.4th 382 (6th Cir. 2022)	5, 13
Brown v. Buhman, 822 F.3d 1151 (10th Cir. 2016)	7
Campbell-Ewald Co. v. Gomez, 577 U.S. 153 (2016)	6
Church of Our Lord & Savior Jesus Christ v. City of Markham, 913 F.3d 670 (7th Cir. 2019)	14
Davis v. Colerain Township, 51 F.4th 164 (6th Cir. 2022)	12
Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167 (2000)	7
Graveline v. Benson, 992 F.3d 524 (6th Cir. 2021)	13
Kentucky Press Ass'n v. Kentucky, 454 F.3d 505 (6th Cir. 2006)	10
Kentucky v. Yellen, 54 F.4th 325 (6th Cir. 2022)	7, 11
Kiser v. Reitz, 765 F.3d 601 (6th Cir. 2014)	
Miller v. City of Wickliffe,  852 F.3d 497 (6th Cir. 2017)	11

New Hampshire Lottery Comm'n v. Rosen, 986 F.3d 38 (1st Cir. 2021)
OverDrive Inc. v. Open E-Book Forum, 986 F.3d 954 (6th Cir. 2021)
R.K. ex rel. J.K. v. Lee, 53 F.4th 995 (6th Cir. 2022), reh'g denied, No. 22-5004, 2022 WL 18434486 (6th Cir. Dec. 28, 2022)
Resurrection Sch. v. Hertel, 35 F.4th 524 (6th Cir.), cert. denied, 143 S. Ct. 372 (2022)
Rice v. Village of Johnstown, 30 F.4th 584 (6th Cir. 2022)
Salvation Army v. Department of Cmty. Affairs of N.J., 919 F.2d 183 (3d Cir. 1990)
Speech First, Inc. v. Schlissel, 939 F.3d 756 (6th Cir. 2019)
Trump v. New York, 592 U.S. 125 (2020)
2016 Primary Election, In re, 836 F.3d 584 (6th Cir. 2016)
Walmart Inc. v. U.S. Dep't of Justice, 21 F.4th 300 (5th Cir. 2021)
Regulations:
45 C.F.R. pt. 81
45 C.F.R. § 92.3(c)
45 C.F.R. § 92.302
45 C.F.R. § 92.302(a)
45 C.F.R. § 92.302(b)
45 C.F.R. § 92.302(b)(1)-(3)

45 C.F.R. § 92.302(c)
45 C.F.R. § 92.302(d)
45 C.F.R. § 92.302(e)
45 C.F.R. § 92.302(e)-(f)
Other Authorities:
Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022)
Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024)
Safeguarding the Rights of Conscience as Protected by Federal Statutes, 89 Fed. Reg. 2078 (Jan. 11, 2024)
13B Charles Alan Wright & Arthur R. Miller,  Federal Practice and Procedure Jurisdiction § 3532.7,  Westlaw (3d ed. database updated Apr. 2023)

#### INTRODUCTION AND SUMMARY

Defendants-appellees respectfully submit this supplemental brief in response to this Court's order of May 8, 2024, instructing the parties to address three questions arising from the promulgation by the Department of Health and Human Services (HHS) of a final rule regarding Section 1557 of the Affordable Care Act. *See Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024) (Final Rule).

In dismissing this case for lack of subject-matter jurisdiction, the district court properly concluded that plaintiffs failed to establish standing or ripeness. This Court can affirm that dismissal on standing grounds without addressing the effect of HHS's new Final Rule. Alternatively, this Court can affirm the dismissal on mootness or ripeness grounds because the Final Rule makes even clearer that plaintiffs' identified individual members face no credible threat of enforcement given the new provisions the Final Rule has established for providers to rely upon religious exemptions for specific conduct and prospectively seek assurances of those exemptions.

#### **STATEMENT**

In its opinion granting the government's motion to dismiss, the district court referenced HHS's then-recent Notice of Proposed Rulemaking regarding Section 1557. *See* Op., R. 61, PageID 1224-1225; *Nondiscrimination in Health Programs and* 

Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022). On May 6, 2024, HHS issued the corresponding Final Rule.<sup>1</sup>

As relevant here, the Final Rule expressly recognizes the ability of healthcare providers to rely on federal religious freedom and conscience protections, including the Religious Freedom Restoration Act (RFRA). Section 92.3(c) provides that "[i]nsofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required." 45 C.F.R. § 92.3(c) (89 Fed. Reg. at 37,693). The Final Rule further clarifies that "a recipient may rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required, and does not violate section 1557 if it so relies." 89 Fed. Reg. at 37,659; see 45 C.F.R. § 92.302(a) (89 Fed. Reg. at 37,701-02) ("A recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular provision(s) of this part to specific contexts, procedures, or health care services shall not be required where such protections apply."). Indeed, the Final Rule states: "When a recipient acts based upon its good faith reliance that it is exempt from providing a particular medical service due to the application of relevant

<sup>&</sup>lt;sup>1</sup> On the same day that the Final Rule was published in the Federal Register, Plaintiff Catholic Medical Association brought a new lawsuit on behalf of its members in the Middle District of Florida seeking some of the same relief they seek in this case. *See* Complaint, *Florida v. HHS*, No. 8:24-cv-1080 (M.D. Fla. May 6, 2024), Dkt. No. 1.

religious freedom and conscience protections (e.g., RFRA), [HHS's Office for Civil Rights (OCR)] will not seek backward-looking relief against that recipient even if the recipient had not affirmatively sought assurance of an exemption under § 92.302(b)," and OCR will only "seek forward-looking relief as appropriate under the facts" if it determines after an investigation "that the recipient does not satisfy the legal requirements for an exception." 89 Fed. Reg. at 37,657.

Further, if a healthcare provider seeks further assurance that they are exempt, the Final Rule sets forth a process by which providers can request a written assurance from OCR of their religious- or conscience-based exemptions with respect to specific conduct. See 45 C.F.R. § 92.302 (89 Fed. Reg. at 37,701-02). Providers can submit a written notification to the Director of OCR, identifying "[t]he particular provision(s) of this part from which the recipient asserts they are exempt," and the legal and factual basis supporting the exemption. *Id.*  $\S$  92.302(b)(1)-(3) (89 Fed. Reg. at 37,702). Upon submitting this notification, the provider automatically receives a "temporary exemption from administrative investigation and enforcement." Id. § 92.302(c) (89 Fed. Reg. at 37,702). "If OCR makes a determination to provide assurance of the recipient's exemption from the application of certain provision(s) of this part or that modified application of certain provision(s) is required," OCR provides a determination in writing, and then "the recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision(s) as applied to the specific contexts, procedures, or health care

services provided." *Id.* § 92.302(d) (89 Fed. Reg. at 37,702). If OCR determines against providing the requested assurance of exemption, the provider can appeal this determination within HHS and can seek judicial review in the event of a final adverse decision from the agency. *Id.* § 92.302(e)-(f) (89 Fed. Reg. at 37,702); *see* 45 C.F.R. pt. 81.

Separately, HHS declined to import the Title IX religious exception into the Final Rule, providing a thorough explanation for this decision. 89 Fed. Reg. at 37,530-34. In doing so, HHS clarified that "the decision not to import the title IX religious exception does not compel any individual provider or covered entity with religious or conscience-based objections to provide abortion or any other care to the extent doing so would conflict with a sincerely-held belief." *Id.* at 37,533. And HHS noted that it "has taken important steps to address religious freedom and conscience protections beyond those in the 2016 Rule," including by adopting § 92.3(c) and § 92.302, and the issuance of a final rule entitled *Safeguarding the Rights of Conscience as Protected by Federal Statutes*, 89 Fed. Reg. 2078 (Jan. 11, 2024). 89 Fed. Reg. at 37,532; *see id.* at 37,533 ("Rather than importing the title IX religious exception into section 1557, ... the process set forth in § 92.302 respects religious freedom and conscience protections.").

In explaining its decisions in the preamble to the Final Rule, HHS repeatedly reiterated its respect for religiously affiliated providers and its goal of protecting their religious freedom: "Religiously affiliated hospitals and health care facilities play a large

role in the health care system, and OCR recognizes the critical patient care needs they provide, particularly in reaching underserved communities." 89 Fed. Reg. at 37,658; see id. at 37,533 ("OCR appreciates that many religiously affiliated hospitals and providers are providing vital services in areas where people are in the most need and are often motivated by their faith to provide this important care."). HHS explained that "OCR seeks to ensure Federal civil rights protections are fulfilled and has consulted with the appropriate staff regarding the application of religious freedom and conscience protections during this rulemaking and will continue to engage such staff during OCR's enforcement of the final rule." Id. at 37,658; see id. at 37,533 ("We are committed to affording full effect to Congress's protections of conscience and religion, as detailed in § 92.302 and the Department's issuance of its final rule, Safeguarding the Rights of Conscience as Protected by Federal Statutes. 89 [Fed. Reg.] 2078.").

#### **ARGUMENT**

Question 1. Whether the final rule promulgated by the Department of Health and Human Services on May 6, 2024 (89 Fed. Reg. 37,522) has rendered or will render any of appellants' claims moot.

As the district court correctly determined, plaintiffs had not established standing as of the time the relevant complaint was filed. *See* Op., R. 61, PageID 1214-1226; *see also Barber v. Charter Twp. of Springfield*, 31 F.4th 382, 390, 392 n.7 (6th Cir. 2022) (observing that standing is assessed as of the time the relevant plaintiff was

added to the action). But even if plaintiffs could be thought to have established a credible threat of enforcement as of that time, their identified members will no longer face any such threat when the Final Rule takes effect and all of plaintiffs' claims will thus soon be moot.<sup>2</sup> See 89 Fed. Reg. at 37,693 (effective date of July 5, 2024). Accordingly, this Court need not address standing and can instead affirm the district court's dismissal on mootness grounds. See Arizonans for Official English v. Arizona, 520 U.S. 43, 66-67 (1997) (resolving whether there remained a live case or controversy without first addressing appellate standing); In re: 2016 Primary Election, 836 F.3d 584, 587 (6th Cir. 2016) (observing that this Court has "discretion to address jurisdictional issues in any sequence we wish" (quotation marks omitted)).

Under Article III's case-or-controversy requirement, "an actual controversy [must] be extant at all stages of review, not merely at the time the complaint is filed." *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 160 (2016) (quotation marks omitted). Although "ultimately separate from standing," "[m]ootness can be described as 'the doctrine of standing set in a time frame." *Rice v. Village of Johnstown*, 30 F.4th 584, 594

<sup>&</sup>lt;sup>2</sup> As explained in the government's principal brief, plaintiffs have not identified a specific, non-religious member of the American College of Pediatricians (ACP) whose objections to the asserted practices are alleged to not be based on religious grounds. Gov't Br. 29-30. Accordingly, plaintiffs have not established that the credible threat of enforcement on which to premise jurisdiction can be assessed as to *any* identified member without properly taking account of RFRA. In their reply brief, plaintiffs did not refute this assertion or otherwise continue to insist that they could establish standing premised on a non-religious member and without regard to RFRA. *See Resurrection Sch. v. Hertel*, 35 F.4th 524, 530 (6th Cir.) (en banc) ("[A]rguments in support of justiciability can be forfeited."), *cert. denied*, 143 S. Ct. 372 (2022).

(6th Cir. 2022) (quoting Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 189 (2000)). Accordingly, "[w]hether an 'intervening circumstance' arising after a suit has been filed causes a plaintiff's asserted injury to dissipate is really a question of mootness." Kentucky v. Yellen, 54 F.4th 325, 340 (6th Cir. 2022) (emphasis omitted).

As applied to cases seeking pre-enforcement review, courts inquire whether the intervening event has caused any imminent threat of enforcement that might have existed to dissipate. *See Kentucky*, 54 F.4th at 340 ("Treasury's disavowal of the money-is-fungible interpretation dispelled the States' claim that they run the risk of an imminent enforcement action[] ...."); *New Hampshire Lottery Comm'n v. Rosen*, 986 F.3d 38, 53 (1st Cir. 2021) (concluding that case was not moot where intervening event "does [not] offer the plaintiffs solace that the credible threat of prosecution has subsided"). Where the intervening event "render[s] the threat of prosecution so speculative that a live controversy no longer exist[s] for Article III jurisdiction," a preenforcement challenge becomes moot. *Brown v. Buhman*, 822 F.3d 1151, 1163 (10th Cir. 2016); *id.* at 1170-73 (finding case moot where the defendants adopted enforcement policy under which the plaintiffs would not be prosecuted and the plaintiffs moved out of state).

Here, the Final Rule confirms that plaintiffs' identified individual members do not face a credible threat of enforcement. The Final Rule adds even more speculative contingencies that must come to pass before any of plaintiffs' members might be

subject to an enforcement action, and thus makes clear that there is no longer a live dispute for purposes of Article III.

The Final Rule establishes a process whereby plaintiffs' members can seek assurances from OCR of their RFRA exemptions from "the application of particular provision(s) of this part to specific contexts, procedures, or health care services." 45 C.F.R. § 92.302(b) (89 Fed. Reg. at 37,702). They can seek such assurances even before any administrative complaint is filed and "before an[y] investigation is initiated." Id. (89 Fed. Reg. at 37,702). Where members avail themselves of this option in advance and obtain an assurance, they will face no threat of investigation or enforcement. Id. § 92.302(d) (89 Fed. Reg. at 37,702) ("[I]f granted, the recipient will be considered exempt from OCR's administrative investigation and enforcement ...."). If the members do not seek an assurance in advance, they may still rely on RFRA and, under § 92.3(c) and § 92.302(a), application of the Final Rule's provisions "to specific contexts, procedures, or health care services" to the members shall not be required where RFRA protections apply. Id. § 92.302(a) (89 Fed. Reg. at 37,701-02). If any administrative complaint is filed regarding their conduct or any investigation is otherwise initiated, the members "may, during the pendency of that investigation, similarly notify OCR of their belief they are entitled to an exemption under the process provided at § 92.302(b)." 89 Fed. Reg. at 37,658.

Accordingly, in order for any of plaintiffs' members to potentially be subject to an enforcement action—once they have undergone the already attenuated chain of

events preceding the initiation of an investigation into their conduct, see Gov't Br. 19, 41-42—the following must still occur: (1) OCR must deny the assurance request; and (2) assuming the member does not voluntarily forgo its appeal rights, an HHS administrative hearing examiner must affirm the denial in a final agency action that would still be subject to judicial review, 45 C.F.R. § 92.302(e)-(f) (89 Fed Reg. at 37,702).<sup>3</sup> If the member availed itself of the assurance process in advance as well as its administrative and judicial review rights, it could be subject to potential enforcement only after a federal court has already determined that it does not merit an assurance that the conduct at issue is exempt from Section 1557 under RFRA. If the member did not seek an assurance in advance and instead waited to invoke the § 92.302(b) process until after OCR initiated an investigation, OCR will grant a temporary exemption from administrative investigation and enforcement until a final agency determination is issued. Id. § 92.302(c), (e) (89 Fed. Reg. at 37,702). And if a court ultimately finds that the member is entitled to the requested assurance, OCR would of course be bound by that ruling and the member would be exempt from

<sup>&</sup>lt;sup>3</sup> These events must come to pass notwithstanding plaintiffs' allegations that the sincerely held religious beliefs of their members "prohibit them from engaging in or facilitating in the 'objectionable practices," that their "exercise of religion" would be "substantially burden[ed]" by requiring them to do so, and that their members' "provision of healthcare in accord with their religious beliefs prevents no one from obtaining gender transition interventions from other providers." Am. Compl. ¶¶ 428, 433, 438, R. 15, PageID 189-190.

"OCR's administrative investigation and enforcement." *Id.* § 92.302(d) (89 Fed. Reg. at 37,702).

Moreover, even if the assurance were denied and the denial were appealed and affirmed, before a member could be subject to an enforcement action, OCR would still need to proceed with an investigation, evaluate the reasons for the member's conduct, and determine that it does not amount to a legitimate, non-discriminatory reason, that discrimination has occurred, and that Section 1557 was violated; and any efforts at informal, voluntary compliance must fail. There is no indication that this long, speculative series of contingencies—made even longer and less certain by the Final Rule—is likely to transpire for any identified member.

The addition of a new exemption process, like the one established in § 92.302, to an already attenuated chain of events that must occur before any of the identified individual members might be injured weighs heavily against finding that a future injury is sufficiently imminent to give rise to Article III jurisdiction. See R.K. ex rel. J.K. v. Lee, 53 F.4th 995, 999 (6th Cir. 2022) (relying on the existence of an accommodation process and "plaintiffs' failure to test the practical effect of the Act by seeking an accommodation" in concluding that plaintiffs lacked standing), reh'g denied, No. 22-5004, 2022 WL 18434486 (6th Cir. Dec. 28, 2022); Kentucky Press Ass'n v. Kentucky, 454 F.3d 505, 509-10 (6th Cir. 2006) (concluding that challenge was unripe where, by failing to petition state courts for access to proceedings, plaintiff had not demonstrated it was likely that challenged law entirely foreclosed such access); cf.

Miller v. City of Wickliffe, 852 F.3d 497, 506-07 (6th Cir. 2017) (finding no credible threat of enforcement for standing purposes where plaintiffs did not apply for license).

Moreover, the Final Rule reiterates HHS's strong commitment to comply with RFRA—and all other federal religious freedom and conscience protections—in its enforcement of Section 1557. Plaintiffs invoked HHS's treatment of religious accommodations in an earlier rulemaking in attempting to argue that there was a sufficiently imminent threat of enforcement at the time this action was brought.

See Opening Br. 27 ("HHS's decision not to import Title IX's religious exemption into Section 1557 through the 2016 Rule ... bolsters the credible threat of enforcement."); see also Reply Br. 4, 5. The Final Rule includes a thorough discussion of HHS's decision not to import the Title IX religious exception and the role of § 93.2(c) and § 92.302 in fully protecting religious freedom rights in place of the Title IX exception.

See 89 Fed. Reg. at 37,530-34. Thus, to the extent plaintiffs sought to rely on doubt about HHS's commitment to accommodating providers' sincerely held religious beliefs, the Final Rule dispels any plausible basis for such doubt.

Additionally, the Final Rule "resulted from the notice-and-comment process, and thus it may be rescinded only pursuant to that process as well," and there is "no evidence that [HHS] plans to pursue such rescission." *Kentucky*, 54 F.4th at 341; *Speech First, Inc. v. Schlissel*, 939 F.3d 756, 768 (6th Cir. 2019) ("Where regulatory changes are effected through formal, legislative-like procedures, we have found that to moot the

case the government need not do much more than simply represent that it would not return to the challenged policies."); Davis v. Colerain Township, 51 F.4th 164, 174-75 (6th Cir. 2022) ("This presumption"—that government defendants "will not resume their challenged conduct unless objective evidence suggests that they have made a bad-faith change to avoid judicial review"—"gains even more strength if the government has changed course through a formal process because the formalities involved make it more difficult to reinstitute the old policy later."). Because there is thus "no reasonable possibility" of HHS adopting a position under which plaintiffs' members cannot rely on RFRA or seek prospective assurances of RFRA exemptions as to specific conduct, plaintiffs' claims will soon be moot. See Resurrection Sch. v. Hertel, 35 F.4th 524, 530 (6th Cir. 2022) (en banc). When the Final Rule becomes effective, this Court can thus affirm the district court's dismissal on mootness grounds.

Question 2. If the rule moots some but not all of appellants' claims, whether a specific member of each organization identified in the complaint still retains a live claim upon which appellants can assert associational standing.

As explained, *see supra* pp. 5-12, the Final Rule will moot all of appellants' claims. Plaintiffs have not established that any identified individual member had standing at the time this action was filed (*see* Gov't Br. 14-39), but regardless the dispute will no longer be live once the Final Rule takes effect in light of the Final Rule's treatment of RFRA protections and the assurance process in § 92.302.

Plaintiffs did not clearly identify a non-religious individual ACP member—who cannot rely on RFRA and the assurance process—upon whom this Court could base Article III jurisdiction.

Question 3. Whether the court may consider the new rule in assessing the likelihood that any of appellants' members face a credible threat of an enforcement action, and if so, whether the new rule reduces such risk.

The Court cannot consider the new rule as relevant to standing, because "Supreme Court and Sixth Circuit caselaw have consistently held that the court must determine whether standing exists at the time of the filing of the complaint only." *Graveline v. Benson*, 992 F.3d 524, 532 (6th Cir. 2021) (quotation marks omitted); *Barber*, 31 F.4th at 390 ("When assessing standing, courts look only to the facts existing when the complaint is filed." (quotation marks omitted)). But the Court can consider the new Final Rule for purposes of assessing both mootness and ripeness. The likelihood that any of plaintiffs' identified members face a credible threat of being subject to an enforcement action is relevant to both inquiries. As explained above, *supra* pp. 5-12, the case will soon become moot in light of the Final Rule's treatment of RFRA protections and the assurance process in § 92.302. The Final Rule also confirms that plaintiffs' claims are unripe.

As the Supreme Court has recognized, "ripeness is peculiarly a question of timing, and it is the situation now rather than the situation at the time of the decision under review that must govern." *Anderson v. Green*, 513 U.S. 557, 559 (1995) (per

curiam) (alteration and quotation marks omitted); see also, e.g., Church of Our Lord & Savior Jesus Christ v. City of Markham, 913 F.3d 670, 677 (7th Cir. 2019). Accordingly, "[r]ipeness should be decided on the basis of all the information available to the court. Intervening events that occur after decision in lower courts should be included, just as must be done with questions of mootness." 13B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure Jurisdiction § 3532.7, Westlaw (3d ed. database updated Apr. 2023) (footnote omitted).

Cases that were ripe at the time the complaint was filed or the district court decision issued can thus become unripe on appeal due to intervening developments. See Trump v. New York, 592 U.S. 125, 131 (2020) (per curiam) (holding that case was unripe after "any chilling effect" had "dissipated" on appeal); Walmart Inc. v. U.S. Dep't of Justice, 21 F.4th 300, 313 (5th Cir. 2021) ("The bringing of the Delaware suit proves that, when this case was filed, enforcement was indeed impending. When considered from the standpoint of the present, however, the suit's existence also suggests that future enforcement is unlikely." (emphasis omitted)).

In order to satisfy ripeness, a case must "concern a dispute that is likely to come to pass" and not "turn[] on contingent future events that may not occur as anticipated, or indeed may not occur at all." *OverDrive Inc. v. Open E-Book Forum*, 986 F.3d 954, 957-58 (6th Cir. 2021) (alteration and quotation marks omitted). For preenforcement actions, this inquiry involves determining whether a plaintiff faces a

credible threat of enforcement and thus a sufficiently imminent future injury. See, e.g., Kiser v. Reitz, 765 F.3d 601, 607, 609 (6th Cir. 2014).

As discussed, *supra* pp. 7-11, the Final Rule's process for seeking an assurance of religious exemption under § 92.302 underscores the lack of likelihood that there will ever be an enforcement against plaintiffs' identified individual members. The members would only be subject to an enforcement action if an unlikely chain of events were to transpire: if they face an OCR investigation, and when they raise a RFRA exemption under the § 92.302 assurance process (either before any investigation or after it begins), if OCR denies the assurance request, and—assuming the member does not voluntarily forgo its appeal rights—if an HHS hearing adjudicator then upholds the denial. "If and when do not a ripe controversy make." OverDrive, 986 F.3d at 958. Where, as here, intervening events make clear that the threat of enforcement is remote, a pre-enforcement challenge must be dismissed for lack of ripeness. See Salvation Army v. Department of Cmty. Affairs of N.J., 919 F.2d 183, 192 (3d Cir. 1990) (finding suit nonjusticiable because "intervening event[s]" had "remove[d] [the] conditions" for an Article III controversy because any "real and immediate" enforcement threat had dissipated).

In addition to making abundantly clear that plaintiffs' members do not face a credible threat of enforcement, the Final Rule clarifies that the members will not suffer any hardship by waiting to raise their legal claims until the unlikely event that they ever do face an enforcement action. *See Ammex, Inc. v. Cox*, 351 F.3d 697, 706,

709-10 (6th Cir. 2003) (considering intervening event in assessing the hardship prong of ripeness, *i.e.*, the "hardship [plaintiff] incurs by waiting for enforcement" to raise its claims).

The Final Rule provides multiple layers of protection for plaintiffs' members that ensure they will not suffer from uncertainty or discomfort arising from the possibility of some future enforcement action. The Final Rule expressly states that providers "may rely on applicable Federal protections for religious freedom" like RFRA, and instructs that providers "shall not be required" to follow "particular provision(s) of this part" with respect to "specific contexts, procedures, or health care services ... where such protections apply." 45 C.F.R. § 92.302(a) (89 Fed. Reg. at 37,701-02). In the preamble discussion, HHS clarified that a provider "does not violate section 1557 if it so relies" on applicable RFRA protections under § 92.302(a). 89 Fed. Reg. at 37,659. HHS further explained that "[w]hen a recipient acts based upon its good faith reliance that it is exempt from providing a particular medical service due to the application of relevant religious freedom and conscience protections (e.g., RFRA), OCR will not seek backward-looking relief against that recipient even if the recipient had not affirmatively sought assurance of an exemption under § 92.302(b)." *Id.* at 37,657. Nor do members need to experience uncertainty regarding whether they could validly invoke religious protections in the event of any potential future agency investigation: the Final Rule enables them to eliminate the uncertainty by seeking an assurance from OCR of their RFRA exemptions and a

permanent exemption from administrative investigation and enforcement, even before any investigation is initiated. 45 C.F.R. § 92.302(b), (d) (89 Fed. Reg. at 37,702).

Plaintiffs have consistently represented that their members "will follow their convictions and decline to participate in the objectionable practices." Reply Br. 16. Consistent with this concession that they have never been chilled from adhering to their religious beliefs, the Final Rule makes clear that providers with valid RFRA protections may rely on RFRA as a safe harbor for their religiously motivated conduct, and will face no repercussions for doing so in good faith.

After the Final Rule becomes effective, the Court can thus affirm the district court's dismissal of plaintiffs' action for lack of ripeness.

#### **CONCLUSION**

For the foregoing reasons, and the reasons set out in our principal brief, the judgment of the district court should be affirmed.

Respectfully submitted,

BRIAN M. BOYNTON

Principal Deputy Assistant Attorney General

CHARLES W. SCARBOROUGH

s/ McKaye L. Neumeister

McKaye L. Neumeister

Attorneys, Appellate Staff

Civil Division, Room 7231

U.S. Department of Justice

950 Pennsylvania Avenue NW

Washington, DC 20530

(202) 514-8100

McKaye.L.Neumeister@usdoj.gov

May 2024

## CERTIFICATE OF COMPLIANCE

This brief complies with this Court's May 8, 2024 order because it is no more than 25 pages in length. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

s/ McKaye L. Neumeister
McKaye L. Neumeister

## **CERTIFICATE OF SERVICE**

I hereby certify that on May 29, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the appellate CM/ECF system.

s/ McKaye L. Neumeister

McKaye L. Neumeister