No. 13-5003

In the U.S. Court of Appeals for the District of Columbia Circuit

AMERICAN PHYSICIANS & SURGEONS, INC. AND
ALLIANCE FOR NATURAL HEALTH USA,
Plaintiffs-Appellants,

vs.

KATHLEEN G. SEBELIUS, SECRETARY OF HEALTH & HUMAN SERVICES,
IN HER OFFICIAL CAPACITY, *ET AL.*,
Defendants-Appellees.

APPEAL FROM U.S. DISTRICT COURT FOR THE
DISTRICT OF COLUMBIA, CIVIL CASE NO. 1:10-cv-00499-ABJ,
HON. AMY BERMAN JACKSON

APPELLANTS' REPLY IN SUPPORT OF EMERGENCY MOTION FOR INTERIM RELIEF ON COUNT IV

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GLOSSARY

AAPS	Association of American Physicians & Surgeons
Add.	Addendum
ANH-USA	Alliance for Natural Health USA
HHS	Department of Health & Human Services
Medicare	Medicare Act, 42 U.S.C. §§1395-1395kkk-l
PECOS	Provider Enrollment, Chain and Ownership System
PPACA	Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Pub. L. No. 111-152, 124 Stat. 1029 (2010)
SAC	Second Amended Complaint

INTRODUCTION

Plaintiffs-appellants Association of American Physicians & Surgeons, Inc. ("AAPS") and Alliance for Natural Health USA ("ANH-USA" and, collectively with AAPS,"Physicians") respectfully submit this reply to the opposition ("Admin. Opp'n") filed by defendants-appellees Kathleen Sebelius, Secretary of the Department of Health & Human Services ("HHS"), *et al.* (collectively, the "Administration") to Physicians' motion to preliminarily enjoin the new HHS requirement that referrers for Medicare services register in the Provider Enrollment, Chain and Ownership System ("PECOS").

The Administration makes six main arguments:

- Physicians needed to seek interim relief in the district court prior to seeking it on appeal. Admin. Opp'n at 8-9.
- Physicians will suffer no irreparable harm absent the injunction, and – assuming *arguendo* that registering in PECOS could constitute irreparable injury for *pro bono* medical directors like Dr. Hammons – the allegedly irreparable harm is too narrow to support a broad injunction that applies to all physicians. *Id.* at 10-11 & n.3.
- "Existing law" bars Physicians from treating Medicare-eligible patients without following Medicare's opt-out safe harbor, 42 U.S.C. §1395a(b), which would generate the HHS-required PECOS registration. *Id.* at 12.

- A final rulemaking from April 2012 moots Physician's challenge to the interim final rule and Medicare change requests challenged in Count IV. *Id.*
- Physicians waived the argument that the enactment of the Patient Protection & Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ("PPACA") violated the Origination Clause because Physicians did not expressly raise that argument in their complaint's specific pleadings, and because neither Physician's general pleading nor supplemental briefing in the district court cured the alleged waiver. *Id.* at 13.
- Due to need to control Medicare's large and growing costs, an injunction would not be in the public interest. *Id.* at 13-14.

The following six sections respond to these Administration arguments.

Before addressing the Administration's specific arguments, however, Physicians first address the Administration's overall failure to support their conclusory contentions with citations to legal authority. Appellate courts typically "require[] that appellees state their contentions and the reasons for them at the risk of abandonment of an argument not presented," *Mironescu v. Costner*, 480 F.3d 664, 677 (4th Cir. 2007), and "[e]ven appellees waive arguments by failing to brief them." *Id.* (quoting *U.S. v. Ford*, 184 F.3d 566, 578 n.3 (6th Cir. 1999)); *Corson & Gruman Co. v. NLRB*, 899 F.2d 47, 50 n.4 (D.C. Cir. 1990) ("Company never raised the issue ... and therefore waived the argument in this case").

I. PHYSICIANS CAN SEEK INTERIM RELIEF FOR THE FIRST TIME ON APPEAL

The Administration cites FED. R. APP. P. 8(a)(1)(C) for the proposition that Physicians needed to seek interim relief in the district court before doing so in this Court. Admin. Opp'n at 8-9. By its terms, Rule 8 provides that "part[ies] must *ordinarily* move first in the district court for … an order … granting an injunction while an appeal is pending." FED. R. APP. P. 8(a)(1)(C) (emphasis added); *see also* FED. R. APP. P. 8(a)(2)(A)(i) (flexibility where "moving first in the district court would be impracticable"). The Administration's cursory opposition on this point makes no effort to distinguish Physicians' factual and legal justifications for seeking appellate interim relief under the particular circumstances presented here, Mot. at 1-2, 3-4 other than to dispute (without citation) that futility qualifies as a basis to avoid moving in the district court. Admin. Opp'n at 8-9.[1] Physicians respectfully submit that this case presents a situation outside Rule 8's "ordinary" situation and that this Court should issue interim relief on appeal. If this Court deems it necessary, however, Physicians can move for interim relief in district

[1] Significantly, the Administration does not dispute Physicians' argument that delay alone does not preclude moving for interim relief or that the parties agreed – at the request of the initial judge – to defer any briefing of interim relief until the issues become imminent, which the Administration subsequently relied on dispute that Physicians faced the necessary irreparable harm in district court. Mot. at 1-2. Clearly, if this matter still was in the district court, Physicians could seek interim relief there now. The fact that this matter now is in this Court should not make any difference as to timing.

court under FED. R. CIV. P. 60(b) and 65(a).

II. THE PHYSICIAN GROUPS' MEMBERS AND THEIR PATIENTS WILL SUFFER IRREPARABLE HARM IF THE PECOS CHANGES TAKE EFFECT

The Administration focuses on the lesser aspects of Physicians' filings to argue Physicians have not identified irreparable harm sufficient to justify interim relief. Admin. Opp'n at 10-11. Until a court judgment finally resolves the merits disputes about Medicare opt outs in Physicians' favor, a medical professional who did not wish to treat patients for Medicare reimbursement would need to think hard about entangling his or her practice within Medicare's tentacles. Because Dr. Hammons does not wish to entangle herself, her patients will suffer the loss of necessary medical care, Mot. at 18-19, which is a type of irreparable harm that courts uniformly have recognized. *See id.* (collecting cases). As with its response to so much of Physician's motion, the Administration simply declines to address these issues.

III. THE MEDICARE OPT-OUT SAFE HARBOR DOES NOT QUALIFY AS FEDERAL REGULATION OF NON-MEDICARE PHYSICIANS

The Administration and the district court refuse to engage Physicians on the argument that the safe harbor for Medicare opt outs, 42 U.S.C. §1395a(b), does not impose legal requirements on non-Medicare physicians. Admin. Opp'n at 12; Add. 140. As indicated, the district court was simply mistaken in refusing to assume *arguendo* Physicians' merits views in evaluating Physicians' standing. *See* Mot. at

4-5. The Administration confuses Physicians' jurisdictional argument under Rule 12(b)(1) with asking the district court to accept the Physicians' merits views for purposes of Rule 12(b)(6), Admin. Opp'n at 12, which is simply not what Physicians argued. *See* Mot. at 4-5. The obligation to assume a plaintiff's merits views applies to the jurisdictional analysis, not to failure to state a claim.

That said, the district court at least should have addressed Physicians' merits argument, which neither the district court nor the Administration seek to do. In summary, that merits argument is that Spending Clause programs like Medicare do not give the Administration any authority to regulate state-licensed physicians who do not seek payment from Medicare merely because those physicians treat and bill Medicare-eligible patients. *See* Mot. at 5-6. This issue goes to the substantive merits in Count IV, and it also goes to the arbitrariness and capriciousness of the Administration's various PECOS-related actions.

IV. THE FINAL PECOS RULE DOES NOT MOOT ALL OF THE PHYSICIANS' CLAIMS IN COUNT IV

The Administration argues that its rulemaking on April 27, 2012 (77 Fed. Reg. 25,284) moots Physicians' challenge to the PECOS-related interim final rule and Medicare manual change requests. Admin. Opp'n at 12.[2] While it is certainly

[2] It is disappointing that the Administration did not bring its April 2012 rulemaking to the district court's attention before that court's October 2012 decision, to say nothing of the time and page count that Physicians devoted to those procedural issues in their motion for interim relief.

correct that the rulemaking *changes* the issues raised in Count IV, the Administration is nonetheless wrong that the rulemaking *moots* Count IV. At the outset, Count IV seeks to invalidate HHS actions and obtain declaratory relief on both procedural and substantive grounds, and the rulemaking could potentially moot only the procedural claims. Moreover, to the extent that the new rulemaking itself is procedurally invalid (which Physicians will address in a supplemental pleading[3]), the procedural invalidity of the underlying interim final rule and change requests would remain live questions.

Two substantive issues remain within Count IV, regardless of whether the April 2012 rulemaking cures all of the alleged procedural defects of the prior HHS actions: (1) whether the safe harbor for Medicare opt outs, 42 U.S.C. §1395a(b), imposes legal requirements on non-Medicare physicians, *see* Section III, *supra;* and (2) whether HHS has authority for its PECOS requirements, which both the Administration and Physicians recognize lies in PPACA. With regard to that second substantive question, Physicians proffer the Origination Clause as a basis to invalidate PPACA in its entirety, including the authorization for the PECOS requirements. *See* Section V, *infra.*

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[3] For example, HHS does not appear to have responded to AAPS comments on Medicare opt outs, which could provide a basis to vacate the April 2012 rule.

V. THE PHYSICIANS DID NOT WAIVE THE RIGHT TO ARGUE THAT PPACA VIOLATED THE ORIGINATION CLAUSE

The Administration argues that – notwithstanding that Physicians raised the Origination Clause in response to the district court's request for supplemental briefing and notwithstanding the general pleading in Physicians' complaint and the authorities cited to this Court on general pleadings, Mot. at 11-12 – that Physicians waived arguments based on the Origination Clause. Admin. Opp'n at 13 (*citing* App 131). Significantly, the district court did not hold that Physicians waived the right to argue that Origination Clause to invalidate the PECOS provisions; rather the district court held that Physicians waived the Origination Clause only with respect to PPACA's individual insurance mandate. App. 131.

The waiver argument is particularly inappropriate because the district court *invited* supplemental briefing on the impact of the Supreme Court's decision on PPACA, and Physicians' supplemental brief qualifies as raising the issue sufficiently for purposes of establishing the Administration's implied consent under FED. R. CIV. P. 15(b). *See, e.g., City of Green Cove Springs v. Donaldson*, 348 F.2d 197, 202 (5th Cir. 1965); *Strategic Outsourcing, Inc. v. Continental Cas. Co.*, 274 Fed.Appx. 228, 233 (4th Cir. 2008). In any event, the Supreme Court has rejected requiring waiver on facts far less sympathetic to plaintiffs than the facts here. *U.S. Nat. Bank of Oregon v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 445-48 (1993):

> Respondents did not challenge the validity of section 92 before the District Court; they did not do so in their opening brief in the Court of Appeals or, despite the court's invitation, at oral argument. Not until the Court of Appeals ordered supplemental briefing on the status of section 92 did respondents even urge the court to resolve the issue, while still taking no position on the merits.

Id. at 445. Even under those circumstances, the Supreme Court allowed the plaintiff to challenge section 92 as part of the plaintiff's overall case. *Id.* at 446-47.

Here, by contrast, Physicians raised the issue during the briefing of the Administration's motion to dismiss via supplemental briefing requested by the district court. While it would have been inconceivable for Congress to have enacted PPACA as a sizable income-tax increase on middle-income families, Second Am. Compl. ¶67 (App. 67), that is the implication of Chief Justice Roberts' decision that the individual mandate was not a tax for statutory purposes but was a tax for constitutional purposes. That sea change would have justified amending or supplementing the complaint under Rule 15(a) or (c) if the supplemental briefing had not taken place. *See* Mot. at 11-12.

The Administration notes that the parties filed their supplemental briefs simultaneously, depriving the Administration of an opportunity to respond. *Id.* at 13 n.4. To avoid Rule 15(b), however, the Administration needed to object. *Banks v. Dretke*, 540 U.S. 668, 704 (2004). Had the Administration done so, Physicians could have moved to amend and supplement their complaint, and the district court

would have had to grant leave. *Caribbean Broad. Sys., Ltd. v. Cable & Wireless P.L.C.*, 148 F.3d 1080, 1083-85 (D.C. Cir. 1998). The Administration's waiver argument is specious.

VI. AN INJUNCTION WOULD SERVE THE PUBLIC INTEREST

Of the other two injunction factors, the Administration questions only the public interest. Admin. Opp'n at. 13-14. Here again, the Administration offers no citations to rebut the authorities cited by Physicians. Insofar as it is therefore undisputed that the public interest collapses into the merits in cases such as this, 11A CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FED. PRAC. & PROC. Civ.2d §2948.4, the parties' wide dispute on the likelihood of Physicians' prevailing (which the Court will address in any event) makes it relatively easy to resolve the public interest: whichever side wins the likelihood of prevailing will have a leg up on the public interest.

But even if the Court cannot or does not resolve the merits in either party's favor, the Court still could grant interim relief only for AAPS and ANH-USA members as a way of addressing the Administration's systemic concerns about a "broad injunction applying to all physicians." Admin. Opp'n at 11 n.3. In fact, Physicians closed their motion with a request for interim relief "[a]t least with respect to AAPS and ANH-USA members." Mot. at 20.

CONCLUSION

At least with respect to AAPS and ANH-USA members, the PECOS changes should be preliminarily enjoined pending final judgment.

Dated: April 8, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of April 2013, I have caused the foregoing document, together with its addendum, to be served on the following counsel via the Court's CM/ECF System:

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