[NOT YET SCHEDULED FOR ORAL ARGUMENT]

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN PHYSICIANS & SURGEONS, INC., et al., Plaintiffs-Appellants, v. KATHLEEN SEBELIUS, Secretary of Health & Human Services, et al., Defendants-Appellees.	No. 13-5003

RESPONSE TO PLAINTIFFS' EMERGENCY MOTION FOR INTERIM RELIEF ON COUNT IV

INTRODUCTION AND SUMMARY

Medicare Part B provides coverage for a variety of medical items or services, including, for example, wheelchairs or X-rays. *See* 42 U.S.C. §§ 1395k, 1395x(s). These items and services must be ordered by a referring physician, and, since 1992, suppliers of such items have been required to identify the referring physician by name and provider number. *Id.* § 1395*l*(q)(1).

Appellants ask the Court for an emergency injunction that would prohibit the Department of Health and Human Services ("HHS") from "requiring referrers for

Medicare services to register in" a Medicare database that contains information regarding all physicians who enroll in or opt-out of Medicare. *See* Motion 1.

Plaintiffs failed to ask the district court for the emergency relief requested here, as required by Fed. R. App. P. 8(a)(1)(C), and they have not carried their burden with regard to any of the prerequisites for this "extraordinary and drastic remedy." *Davis v. Pension Ben. Guar. Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009).

The Medicare statute has long required physicians who refer patients for items and services covered by Medicare Part B to pursue one of two options. A physician may enroll in Medicare and comply with its requirements and fee limitations. Alternatively, physicians who wish to receive payments higher than those permissible under Medicare must formally opt out of the program. *See United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 967 (D.C. Cir. 1999). The statute has also long required suppliers of Part B items and services to identify the referring physician by name and provider number in order to receive reimbursement. 42 U.S.C. § 1395*l*(q)(1), (2).

The Affordable Care Act of 2010 (ACA) provided additional express authority for these longstanding requirements by explicitly authorizing the Secretary to require that physicians who refer beneficiaries for Part B items and

services be enrolled in Medicare and use a standard provider number.[1] *See* ACA, Pub. L. No. 111-148 § 6405, 142 Stat. 119, 768-69 (2010) (codified at 42 U.S.C. §§ 1395m(a)(11)(B), 1395f(a)(2), 1395n(a)(2), 1395f note). Pursuant to that authority, HHS has issued regulations that expressly require that claims for covered imaging, clinical laboratory services, durable medical equipment, and home healthcare services must contain the name and provider number of the ordering or certifying physician (or other eligible professional, where applicable). 42 C.F.R. § 424.507(a)(1)(iii)(A), (B), 424.507(b)(1)(i), (ii). The physician must either be enrolled in Medicare in approved status or have validly opted out of the Medicare program. *Id*. § 424.507(a)(1)(iii)(C), 424.507(b)(1)(iii).

Plaintiffs lost their claim below, and offer no legal basis on which application of the regulations could properly be enjoined. In district court, plaintiffs asserted a procedural challenge to the interim final rules which, they argued, could not be promulgated without notice and comment. Plaintiffs' motion fails to note that the interim final rules have been superseded by final rules promulgated after notice and comment. *See* 77 Fed. Reg. 25284 (2012). Plaintiffs also assert an origination clause challenge to the Affordable Care Act. But, as the

[1] The relevant provider number is called the National Provider Identifier or NPI. For simplicity, we refer to it as "provider number" throughout this motion.

district court held, plaintiffs waived this argument and, in any event, the regulation at issue here was authorized under prior law.

Plaintiffs fail to identify any irreparable harm to AAPS or its members resulting from the challenged regulations, and their contention that the regulations will harm Medicare beneficiaries is insubstantial. As plaintiffs do not dispute, doctors need not be enrolled in Medicare in order to refer patients for Part B items or services. They need only make clear that they have, in fact, elected to opt out of Medicare. Doing so will have no effect on their patients' Medicare Part B coverage for the ordered and referred items or services.

STATEMENT

1. Medicare Part B is a public health insurance program that provides the disabled and elderly with supplemental medical insurance benefits for certain medical services. It covers "outpatient items and services," including durable medical equipment, certain prescription medications, certain imaging and clinical laboratory services, and home healthcare services. *Hays v. Sebelius*, 589 F.3d 1279, 1280 (D.C. Cir. 2009). Individuals who elect to enroll in Part B must pay insurance premiums. *See* 42 U.S.C. §§ 1395o-1395s; 42 C.F.R. § 407.27.

The Act also provides that the Secretary "shall establish by regulation a process for the enrollment of providers of services and suppliers," including physicians. 42 U.S.C. § 1395cc(j)(1). Pursuant to this directive, HHS has

promulgated regulations requiring that physicians and suppliers who wish to obtain Medicare billing privileges submit an enrollment application. 42 C.F.R. §§ 424.505, 424.510. This application can be submitted either on paper or electronically. Physicians must recertify the accuracy of their enrollment information every five years. *Id.* § 424.515. This enrollment process allows HHS to verify that physicians meet the requirements set out in the Medicare Act. *See* 75 Fed. Reg. at 24443 ("it is necessary that their credentials be verified[,] [and] such verification can occur only as part of the Medicare provider/supplier enrollment process.").

Physicians who are not enrolled in the Medicare program may nevertheless refer patients for Part B items and services if they satisfy statutory and regulatory requirements. A physician who opts out of Medicare may enter into a private contract with a beneficiary for services that will not be subject to Medicare's limitations on actual charges. 42 U.S.C. § 1395a(b)(4). Physicians who wish to refer patients and not be subject to Medicare's limitations on actual charges must notify Medicare that they are opting out of Medicare by submitting an affidavit to Medicare stating that they will not submit any claim to, or receive payment from, Medicare for two years. *Id.*; 42 C.F.R. §§ 405.405, 405.410, 405.420. They must also enter into "private contracts" that meet the requirements described in the statute and regulations. 42 U.S.C. § 1395a(b); 42 C.F.R. § 405.405, 405.415.

These requirements ensure that patients will not be charged amounts greater than those allowable under Medicare absent their clear consent. *See United Seniors Ass'n v. Shalala*, 182 F.3d. 965, 966-67 (D.C. Cir. 1999).

Suppliers of Medicare Part B medical items or services (such as wheelchairs or X-rays) must comply with regulatory requirements to obtain reimbursement. Since 1992, these requirements have included the obligation to identify a referring physician by name and provider number. 42. U.S.C. § 1395*l*(q)(1), (2).

2. In 2009, HHS proposed new means of tracking compliance with these requirements through use of an automated system that would ensure that the referring physician's name and provider number were provided on a claim; that the referring physician's name and provider number match; and that the referring physician (or non-physician professional) is of a specialty eligible to refer. *See* Add. 13-25.

HHS implemented the revised system in two phases. In phase 1, which began in 2009, individuals submitting claims without valid referring physician information were notified that necessary information was missing. Otherwise valid claims were nevertheless still paid. Add. 14, 21. Under phase 2, which is scheduled to go into effect on May 1, 2013, claims will not be paid until the required information is provided. Add. 15, 22, 39.

The Affordable Care Act, which was signed into law in March 2010, endorsed the revised procedures and required HHS to put them into effect as to some referrals by July 1, 2010. *See* ACA § 6405 (codified at 42 U.S.C. §§ 1395m(a)(11)(B), 1395f(a)(2), 1395n(a)(2), 1395f note); 77 Fed. Reg. at 25289. HHS responded by publishing an interim final rule with a 60-day comment period on May 5, 2010. Add. 26.

In April 2012, HHS issued its final rules after receiving and responding to 224 timely comments. 77 Fed. Reg. at 25284. This final rule requires that claims for covered imaging, clinical laboratory services, durable medical equipment, and home healthcare services must contain the name and provider number of the ordering or certifying physician[2] (or other eligible provider, where applicable). 42 C.F.R. § 424.507(a)(1)(iii)(A), (B), 424.507(b)(1)(i), (ii). The physician must either be enrolled in Medicare in approved status or have validly opted out of the Medicare program. *Id.* § 424.507(a)(1)(iii)(C), 424.507(b)(1)(iii).

3. Plaintiffs are the American Association of Physicians and Surgeons and the Alliance for Natural Health USA. Their amended complaint sought to enjoin

[2] The interim final rule spoke in terms of referring physicians. However, under the final rule, the changes will not apply to physicians referring patients to other physicians. The changes apply only to physicians ordering covered imaging, clinical laboratory services, durable medical equipment, and home healthcare services and physicians certifying that home healthcare services are needed. 77 Fed. Reg. at 25290.

the Medicare manual changes, the interim final rule, and the provisions of the ACA that required "federal criteria for acceptable health insurance policies for private individuals or businesses" or "any mandate that individuals or businesses purchase or carry health insurance." Add. 78-79.

After the government filed a motion to dismiss, the case was stayed pending challenges to the constitutionality of the ACA that were being considered by this Court and by the Supreme Court. After the Supreme Court issued its decision in *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012), the district court granted the government's motion. As to the manual changes and interim final rule at issue in this motion, the court held that that HHS had authority to make the changes under both pre-existing law and under the ACA. Add. 143-44. The court also held that notice and comment was not required because the manual changes were "'rules of agency organization, procedure, or practice,'" Add. 144 (quoting 5 U.S.C. § 554(b)(3)(A)), and the regulation merely reasserts preexisting requirements, Add. 145. On March 1, 2013, HHS announced that it was moving forward with the second phase of this process and would begin denying claims that did not fulfill the requirements effective May 1, 2013.

ARGUMENT

A. As an initial matter, plaintiffs have improperly sought an injunction pending appeal in this Court without first seeking that relief in district court as

required by Fed. R. App. P. 8(a)(1)(C). Plaintiffs cannot excuse their failure to comply with the requirements of Rule 8 on the ground that it would be "futile" to request an injunction from the district court because the district court has dismissed the action. Motion at 3. Rule 8 contemplates that litigants will move for relief pending appeal in the court that has declined to grant them relief. Plaintiffs' argument would render the requirement a nullity.

B. In determining whether to grant the "extraordinary remedy" of an injunction, a party must make a "clear showing" that (1) it "is likely to succeed on the merits"; (2) it "is likely to suffer irreparable harm" without such relief; (3) "the balance of equities tips in [its] favor"; and (4) "an injunction is in the public interest." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20, 22 (2008)) (internal quotation marks omitted). Before *Winter*, this Court considered those factors on a sliding scale – i.e., "a strong showing on one factor could make up for a weaker showing on another." *Sherley*, 644 F.3d at 392. This Court has read *Winter* as suggesting that "'a likelihood of success is an independent, free-standing requirement'" that must always be satisfied for an injunction. *Id*. at 393 (quoting *Davis v. Pension Benefit Guaranty Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh, J., concurring)). As in *Sherley* and *Davis*, an injunction pending appeal is not warranted here, regardless of how the four factors are analyzed, because plaintiffs

have failed to show that any factor weighs in their favor.

1. Plaintiffs' motion identifies no irreparable harm that will befall their members absent an injunction. Their claim that Medicare beneficiaries will be deprived of medical services is without basis. *See* Motion 18-19. As in the past, physicians need not participate in Medicare in order to treat Medicare patients or order covered services. Also as in the past, they need only notify Medicare that they have opted out of Medicare.

Plaintiffs submit two declarations, both from 2011. One is from a physician who asserts that he does "not see Medicare-eligible patients." Add. 85 (Smith Decl.). As such, he is not affected by the challenged requirements, which apply only to physicians who elect to treat Medicare-eligible patients.

The second declarant asserts that she treats Medicare patients but "would prefer not to enroll in PECOS," a Medicare database that contains information regarding all physicians who enroll in or opt-out of Medicare. Add. 80-81 (Hammons Decl.). This assertion falls far short of the type of irreparable injury required for a preliminary injunction. Declarant asserts that registering with PECOS will create "an unwarranted risk of unauthorized disclosure of information about me and my practice, and an economic risk that the Medicare system will erroneously debit my business banking account." Add. 80-81. But physicians who wish to enroll in Medicare only to order Medicare services and do not wish to bill

Medicare are "not . . . required to submit financial information." 77 Fed. Reg. 25284, 25292 (April 27, 2012). The declarant provides no basis for her highly speculative concerns, let alone reason to think that an injunction is needed to prevent irreparable injury.

The declarant also asserts that she considers registering in PECOS to be an "administrative burden." Add. 80. The complaint likewise alleges that enrolling in Medicare "require[s] up-front and ongoing paperwork and monitoring." Add. 58. But if an individual does not want to enroll in Medicare, she need only provide a valid opt-out affidavit to Medicare and private contracts to her patients in order to continue ordering Medicare services for her patients. *See* 42 U.S.C. § 1395a(b); 42 C.F.R. § 424.507(a)(1)(iii)(C), 424.507(b)(1)(iii). If the practitioner would prefer to enroll, HHS has made a simplified enrollment form available. 77 Fed. Reg. 25284, 25292 (April 27, 2012). Plaintiffs do not even attempt to show that enrolling in or opting out of Medicare would cause them irreparable harm.[3]

Plaintiffs also asserted in their complaint that their members will be at a competitive disadvantage in attracting Medicare-eligible patients if they cannot

[3] In any event, as the district court explained, "under pre-existing regulations, it is inevitable" that any physician who treats Medicare patients for payment will be required to obtain a PECOS record. Add. 141. Thus, even if a PECOS entry could be considered irreparable harm as to those physicians, like Hammons, who treat Medicare-eligible patients only on a volunteer basis, it could provide no possible basis for the broad injunction applying to all physicians that plaintiffs request.

order Medicare services for those patients without enrolling in or opting out of Medicare. Add. 57. Under pre-existing law, however, physicians are already barred from treating Medicare patients for compensation unless they enroll or opt out of Medicare. 42 U.S.C. § 1395a(b). The district court was not, as plaintiffs mistakenly suggest (*see* Motion at 4-5), required to accept as true their allegation that Medicare does not contain any such requirement. *See Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009).

2. Plaintiffs have demonstrated no possibility of success on the merits. The interim final rule has been superseded by a final rule promulgated after notice and comment. Their challenge to the interim final rule is thus "quite obviously moot." *American Federation of Government Employees, AFL–CIO v. Office of Personnel Management*, 821 F.2d 761, 766 n.4 (D.C. Cir. 1987). In any event, the district court correctly held that the requirements of which plaintiffs complain were not the products of the challenged interim final rule or the manual change requests, which merely provided improved means of tracking compliance with requirements already imposed by law.

Plaintiffs devote most of their motion to arguing that the enactment of the ACA violated the origination clause. As plaintiffs are compelled to acknowledge, this claim was not included in their complaint. *See* Motion at 11. Nor did they ever seek to amend their complaint to add it, or even mention it in response to the

government's motion to dismiss. Indeed, their contention was raised for the first time in supplemental briefing more than two years after the suit was filed. The district court correctly concluded that the argument was waived.[4] Add. 131.

Plaintiffs erroneously suggest that they were unable to advance this argument until the Supreme Court held that the minimum coverage provision of the ACA was a constitutional exercise of the taxing power. Indeed, plaintiffs argued in their complaint that the minimum coverage provision was a direct tax. Add. 77.

Plaintiffs similarly err in arguing that they were entitled to raise an origination claim at any time because their complaint requested "[s]uch other relief as may be just and proper." *See* Add. 79; Motion at 11. This general request for relief based on the claims presented in the complaint does not permit a litigant to raise constitutional claims at any point in the litigation.

3. Granting an injunction would be contrary to the public interest. In light of the large and growing costs of Medicare, "it is imperative to establish accountability measures to ensure compliance with the ordering and referring provisions." 77 Fed. Reg. at 25309. An unwarranted delay in implementing these

[4] Plaintiffs note that the government did not argue in district court that the origination clause argument was waived after plaintiffs raised it in their supplemental briefs. Per the district court's order of July 13, 2012, the government and plaintiffs filed their supplemental briefs simultaneously.

provisions would undermine HHS's "efforts to reduce and eliminate fraud and abuse in the Medicare and Medicaid programs." 77 Fed. Reg. at 25289. Plaintiffs note that these changes have been in the process of implementation for some time. Indeed, HHS delayed the final implementation step until it could ensure that "all eligible suppliers . . . have been given the opportunity to enroll or revalidate enrollment for the purpose of meeting the ordering and certifying requirement." 77 Fed. Reg. at 25298. That the agency proceeded by notice and comment and afforded affected parties ample opportunity to comply with the regulations provides no basis for an injunction.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2013, I electronically filed the foregoing with the Clerk of the Court by using the appellate CM/ECF system.

I certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/Dana Kaersvang
DANA KAERSVANG