UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN NURSES ASSOCIATION, et al., **Plaintiffs,** **v.** **MICHAEL O. LEAVITT, et al.,** **Defendants.**	**Civil Action 06-01087 (HHK)**

MEMORANDUM OPINION

Plaintiffs, the American Nurses Association, and two of its constituents, the New York State Nurses Association and the Washington State Nurses Association, bring this action against Michael O. Leavitt, Secretary of the United States Department of Health and Human Services and Mark McClellan, Administrator of the Centers for Medicare and Medicaid Services (collectively, "HHS" or the "Secretary") seeking a declaratory judgment. Plaintiffs assert that HHS has unlawfully permitted inadequate staffing of registered nurses at hospitals that participate in the Medicare program. They argue that the Medicare Act, and regulations promulgated by HHS pursuant to it, require HHS to ensure "the immediate availability of a registered nurse for bedside care of any patient." By deeming hospitals in compliance with this requirement if they are accredited by the Joint Commission on Accreditation of Hospitals ("Joint Commission"), a private organization, plaintiffs contend that HHS unlawfully fails to ensure compliance with this requirement and unlawfully delegates its authority to a private party.

Before the court is the motion of the Secretary to dismiss for lack of subject matter jurisdiction and for failure to state a claim upon which relief may be granted [#24] and the

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motion of plaintiffs "for order of jurisdiction or, in the alternative, to permit jurisdictional discovery" [#27]. Upon consideration of the motions, the oppositions thereto, and the record of this case, the court concludes that the Secretary's motion must be granted and the plaintiffs' motion must be denied.

I. BACKGROUND

A. Parties and Claims for Relief

Plaintiffs are nonprofit membership organizations that represent the interests of registered nurses. They promote patient safety, workplace rights, appropriate staffing, workplace and environmental health and safety, and the public health. Plaintiffs allege that inadequate nurse staffing at hospitals accredited by the Joint Commission[1] has led their members to suffer harms, including shifts where they are not able to complete patient care tasks in a manner they believe is necessary and safe or take necessary rest breaks. Among other relief, plaintiffs seek: (1) a declaratory judgment that the failure of HHS to assure that the Joint Commission imposes standards at least equivalent to those promulgated by HHS constitutes action unlawfully withheld and results in the improper participation of hospitals in the Medicare program, and (2) a declaratory judgment that through this failure HHS is engaging in an unlawful delegation of its responsibilities to the Joint Commission. Compl. ¶¶ 60-63.

[1] The Joint Commission is a private non-profit accrediting organization run by the American Medical Association, the American Hospital Association, the American College of Physicians-American Society of Internal Medicine, and the American Dental Association. It receives its funding through fees paid by hospitals to receive accreditation review and consulting services.

B. Statutory and Regulatory Background

In order to participate in the Medicare program, a hospital must meet the statutory definition of a "hospital" found in section 1395x(e) of the Medicare Act, which lists certain conditions of participation. 42 U.S.C. § 1395x(e). The Secretary may refuse to enter into an agreement or may terminate an agreement after determining that a hospital fails substantially to meet these conditions. *Id.* § 1395cc(b)(2)(B). There are nine different conditions. The first eight are substantive and include one condition specifically aimed at nursing requirements: a hospital must "provide[] 24-hour nursing service rendered or supervised by a registered professional nurse, and ha[ve] a licensed practical nurse or registered professional nurse on duty at all times." *Id.* § 1395x(e)(5). The ninth condition requires hospitals to "meet[] such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." *Id.* § 1395x(e)(9).

HHS promulgated a regulation interpreting section 1395x(e) with respect to nursing requirements. *See* 42 C.F.R. § 482.23. The regulation, with respect to nurse staffing, states:

> The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient [hereinafter, the "bedside availability requirement"].

Id.

Under the Medicare Act, if an institution is accredited by the Joint Commission it shall be deemed to meet the requirements of section 1395x(e) with two exceptions. *Id.* § 1395bb(a). Relevant to this case, such accreditation shall not be deemed to meet a requirement promulgated

pursuant to section 1395x(e)(9) if that requirement is higher than the requirements prescribed for accreditation by the Joint Commission unless the Secretary determines the Joint Commission's standard is at least equivalent to that promulgated by the Secretary. *Id*. In addition, notwithstanding any other provision, if the Secretary finds that a hospital has significant deficiencies, the hospital shall be deemed not to meet the conditions the hospital has been treated as meeting pursuant to section 1395bb(a). *Id*. § 1395bb(d).

The Medicare Act requires the Secretary to enter into agreements with states to determine whether institutions in that state qualify as hospitals within the meaning of the Act, and to the extent the Secretary finds it appropriate, she may treat an institution certified by the state as a hospital. *Id*. § 1395aa(a). The Secretary may also enter into an agreement with any state to survey hospitals deemed to meet the conditions of participation under section 1395bb(a) (i.e. to meet the requirements because they have been accredited by the Joint Commission) on a selective sample basis or on the basis of substantial allegations. *Id*. § 1395aa(c).

HHS has promulgated regulations further specifying how it will enforce the conditions of participation at accredited hospitals. *See* 42 C.F.R. § 488.7. Under these regulations, HHS, through the relevant state agency, may require a survey of an accredited provider to validate a hospital's accreditation on a representative sample basis or in response to substantial allegations of noncompliance. *Id*.; *see also id*. § 488.10 (describing the Secretary's authority under 42 U.S.C. § 1395aa and bb). For non-accredited hospitals, HHS will determine on the basis of a state survey whether the hospital is eligible to participate in the Medicare program. *Id*. § 488.12. Determinations by HHS that a hospital is in compliance with the conditions of participation are made as often as HHS deems necessary. *Id*. § 488.20.

II. ANALYSIS

HHS moves to dismiss this action under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). HHS contends that the court does not have subject matter jurisdiction under Rule 12(b)(1) because plaintiffs do not have standing to sue either as organizations or on behalf of their member nurses. HHS further contends that this court does not have subject matter jurisdiction because review of plaintiffs' claims is not available under the Administrative Procedures Act. Finally, HHS asserts that plaintiffs fail to state a claim upon which relief may be granted under Rule 12(b)(6) because they lose on the merits.

A. Plaintiffs Have Standing in Their Capacity as Representatives of Their Member Nurses.

HHS argues that plaintiffs lack both standing in their own right and representational standing to assert the putative rights of their member nurses. While the court agrees with HHS that plaintiffs lack standing in their own right, it agrees with plaintiffs that they have standing to prosecute this action in a representional capacity on behalf of their members.[2]

When an organization brings suit in a representational capacity, the organization must demonstrate that at least one of its members "would have standing to sue in [her] own right, [that] the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires individual members' participation in the lawsuit."

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[2] Organizational standing is only proper where the challenged conduct has directly harmed an organization's ability to provide services. *Nat'l Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1433 (D.C. Cir. 1995). Frustration of an organization's objectives alone "is the type of abstract concern that does not impart standing." *Id.* Plaintiffs allege that they have had to spend resources to monitor staffing levels because of the alleged violation. HHS rightly points out, however, that having to juggle limited resources is a challenge faced by all organizations, and the alleged violation does not affect plaintiffs' ability to conduct such monitoring. Thus, the court rejects plaintiffs' assertion that they have organizational standing.

Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., 528 U.S. 167, 169 (2000); *see also Int'l Cntr. for Tech. Assessment v. Johanns*, 473 F. Supp. 2d 9, 14 (D.D.C. 2007).

For an organization's member to have standing in her own right, she "must demonstrate an 'actual or immediate' 'injury-in-fact' that is 'fairly traceable' to the challenged conduct and 'likely' to be 'redressed by a favorable decision.'" *Tozzi v. U.S. Dep't of Health and Human Servs.*, 271 F.3d 301, 307 (D.C. Cir. 2001) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992)). Where the plaintiff seeks review under the Administrative Procedures Act of an agency's failure to comply with a statute, the judiciary has imposed an additional limit which requires the plaintiff to show that its alleged injury falls within the "zone of interests" sought to be protected by the statutory provision whose violation forms the legal basis for her complaint. *See Clarke v. Secs. Indus. Assn.*, 479 U.S. 388, 395-96 (1987).

HHS contends that the member nurses lack standing. In particular, HHS contends that member nurses cannot establish that their injuries are traceable to HHS's alleged violation or that their injuries are likely to be redressed by a favorable court decision. HHS also asserts that the injuries allegedly suffered by the member nurses are not within the zone of interests protected by the Medicare Act and therefore that the member nurses do not have prudential standing. HHS's arguments are without merit.

1. The member nurses' injuries are fairly traceable to the alleged violation and likely to be redressed by a favorable action of the court.

The parties agree that the alleged injury stems from the understaffing of registered nurses in accredited hospitals. The court finds that the injuries complained of, namely loss of breaks

and poor working conditions, are legally cognizable.[3] Because HHS's arguments that the member nurses' injuries are not fairly traceable to HHS's alleged violation and are not likely to be redressed by a favorable action of the court are founded on the same basic premise, the court addresses the causation and redressibility requirements together.

HHS contends that plaintiffs have not shown any causal connection between the alleged understaffing of nurses and HHS's decision that the beside availability standard falls under section 1395x(e)(5) (and therefore a hospital accredited by the Joint Commission may be deemed to be in compliance with it). In particular, HHS argues that the "deeming" requirement is only provisional and so the only difference between being an (e)(5) requirement and an (e)(9) requirement is how the condition of participation is enforced. The only difference between enforcement of provisions that fall under (e)(5) and (e)(9), according to HHS, is that under (e)(5), states monitor hospitals on a representative sample basis or in response to substantial allegations of noncompliance, while under (e)(9), states monitor hospitals on a periodic basis. Likewise, HHS contends that the only action the court may take is to direct it to enforce the bedside availability requirement under (e)(9) and thus by periodic monitoring. The member nurses' injuries are unlikely to be redressed, according to HHS, because plaintiffs cannot show that if HHS enforced the bedside availability provision under (e)(9) there would be better staffing because they cannot show that periodic monitoring is superior to sample-based and allegation-driven monitoring.

[3] Some of the other injuries alleged by the member nurses, such as inability to perform to the standards of their profession, are not legally cognizable. Nor have plaintiffs alleged with sufficient particularity that their members are injured as Medicare recipients.

Further, HHS contends that the hospitals, and not HHS, are responsible for the staffing of nurses and that this makes it even harder for plaintiffs to show that HHS's action or inaction causes the understaffing or would redress it. Finally, HHS argues that there is no substantive difference between its bedside availability requirement and the Joint Commission's requirement that hospitals provide nursing services twenty-four hours a day, seven days a week with at least one on-premise registered nurse furnishing or supervising the service, and therefore plaintiffs cannot show that deeming accredited hospitals in compliance with the bedside availability requirement causes unlawful understaffing. Nor could they show, according to HHS, that a favorable judgment would not simply lead to HHS determining that the Joint Commission's standard is equivalent to the bedside availability standard leaving the member nurses' alleged injuries unredressed.

Plaintiffs rejoin that the understaffing of registered nurses in accredited hospitals can be attributed to HHS's failure to categorize the bedside availability requirement under (e)(9) and associated failure to ensure that hospitals meet this higher standard by deeming accredited hospitals in compliance with it. Plaintiffs argue that the Joint Commission's standards are not the same as the HHS regulations in this regard because around the clock coverage by one registered nurse is not the same as having enough staff to provide the immediate availability of a registered nurse to give bedside care whenever needed. Moreover, plaintiffs contend that establishing traceability does not require them to prove that periodic surveying is superior to sample-based and allegation-driven monitoring because this would require them to prove another case – that there are deficiencies in the periodic surveys. Finally, plaintiffs contend that their

injuries would be redressed by a favorable court decision requiring HHS to establish a system to ensure that the Joint Commission standards are at least equivalent to those established by HHS.

The question presented is whether plaintiffs can demonstrate that the understaffing they allege causes their injuries is fairly traceable to the government's categorizing the bedside availability requirement under (e)(5) instead of (e)(9) and would likely be redressed by a declaratory judgment from this court that the government must categorize the bedside availability requirement under (e)(9). When a plaintiff's "asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*," it is particularly difficult to demonstrate causation and redressability. *Lujan*, 504 U.S. at 562. Where the challenged government action allows conduct that would otherwise be unlawful, however, standing exists. *Renal Physicians Ass'n v. U.S. Dep't of Health and Human Servs.*, 489 F.3d 1267, 1275 (D.C. Cir. 2007).

Section 1395bb deems that a hospital accredited by the Joint Commission has met the requirements of section 1395x(e)(5); it does not do so with respect to the requirements of section 1395x(e)(9) that are higher than the Joint Commission requirements unless the Secretary determines that the Joint Commission's standard is at least equivalent to that promulgated by HHS. 42 U.S.C. § 1395bb(a). Once a hospital is deemed accredited, HHS may only revoke its status as a "hospital" if it finds "significant deficiencies," *id.* § 1395bb(d), or determines that the hospital "fails substantially to meet the applicable provisions of section 1395x," *id*. § 1395cc(b)(2); *see also* Defs.' Mot. at 36 ("A hospital deemed to meet these requirements by receiving Joint Commission accreditation . . . can be terminated [from its ability to participate in the Medicare program] only if that enforcement mechanism reveals 'significant' deficiencies.").

Therefore, if the bedside availability requirement is a section 1395x(e)(9) "other requirement," HHS may require compliance in the first instance, whereas if it is a section 1395x(e)(5) requirement, HHS must initially deem a hospital in compliance and may require compliance only if it determines that the hospital has significant deficiencies or fails substantially to meet the conditions of participation. If the bedside availability requirement is more stringent than the Joint Commission's registered nursing requirement,[4] then if a hospital is unlawfully deemed to meet that standard because it is accredited, it unlawfully will be able to participate in the Medicare program, so long as the Secretary does not find significant deficiencies or substantial failure, by meeting a lower standard than if it were not so deemed. *See Renal Physicians Ass'n*, 489 F.3d at 1275. Meeting this lower standard would presumably require a lower registered nurse to patient ratio thus being fairly traceable to the injuries of which the member nurses complain – fewer breaks and poor working conditions.

Likewise, if the court were to rule that HHS may not deem hospitals in compliance with the beside availability requirement based on their accreditation without a finding of equivalency, then if the Joint Commission standard is lower than the bedside availability standard, hospitals whose participation is based on their accreditation could be required to meet the higher standard without a finding of significant deficiencies or substantial failure. It appears likely to the court that a hospital that desired to maintain its participation in the Medicare program would then have greater incentive to ensure that it complied with the bedside availability requirement and therefore, notwithstanding the fact that the hospitals are a third party, a "favorable decision

[4] The court does not reach the question of whether the standards are equivalent, but finds that plaintiffs have sufficiently alleged that they are not.

would create 'a significant increase in the likelihood that the plaintiff would obtain relief . . . .'" *See Klamath Water Users Ass'n v. FERC*, 534 F.3d 735, 739 (D.C. Cir. 2008) (quoting *Utah v. Evans*, 536 U.S. 452, 464 (2002)).

Moreover, the language of the statute is not as clear as HHS contends with respect to whether the "deeming" itself is provisional. HHS points to three provisions of the Medicare Act for the proposition that the "deeming" is provisional. First, it points to section 1395aa(c) which authorizes HHS to enter into an agreement with a state to survey hospitals that have been deemed to meet the conditions of section 1395x(e). The statutory language, however, does not require the Secretary to do so and does not clearly override section 1395bb(a)'s directive that accredited hospitals "shall be deemed" to meet the requirements of section 1395x(e). *See* 42 U.S.C. § 1395aa(c).

Second, HHS points to section 1395bb(d) which provides that an accredited hospital found to have "significant deficiencies" shall "be deemed not to meet the requirements" of section 1395x(e). *Id*. § 1395bb(d). But, as discussed above, surely this *significant* deficiencies standard creates a higher bar for removing deemed status than were a hospital not so deemed in the first instance. Third, HHS points to the section 1395bb(a), which forbids the granting of deemed status with respect to Joint Commission standards that are less stringent than HHS's requirements under section 1395x(e)(9). This provision, however, merely makes plaintiffs' point – that (e)(9) provisions are treated differently than other provisions. If the "deeming" is not provisional, a favorable ruling could result in a higher substantive standard being required of hospitals in order to participate in the Medicare program, and the elements of causation and redressibility would be met.

2. The member nurses' alleged injuries are within the zone of interests protected by the Medicare Act.

In addition to demonstrating injury, causation, and redressibility to meet the requirements of Article III, plaintiffs must also demonstrate that the alleged injuries of their member nurses are within the zone of interests sought to be protected by the Medicare Act. HHS argues that the member nurses cannot do this because nurse satisfaction is not within the zone of interests protected or regulated by the Medicare Act; rather the conditions of participation at issue in this case are for the benefit of patients. Plaintiffs rejoin that the zone of interests test is not particularly demanding and does not require an indication of congressional purpose to benefit the would-be plaintiff. Instead, according to plaintiffs, it is enough that their interests converge with those of the patients.[5]

Prudential standing encompasses "the requirement that a plaintiff's complaint fall within the zone of interests protected by the law invoked." *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 12 (2004) (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)). The court need not, however, "inquire whether there has been a congressional intent to benefit the would-be plaintiff;" instead it must inquire whether the plaintiff's interests affected by the agency action in question are among those interests "arguably . . . to be protected" by the statutory provision. *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 489 (1998). The zone of interests test is not "especially demanding," *Am. Chiropractic Ass'n, Inc. v. Leavitt*, 431 F.3d 812, 815 (D.C. Cir. 2005) (quoting *Clarke*, 479 U.S. at 399-400), and is intended to "exclude

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[5] HHS also argues that Congress clearly meant to exclude nurses from using the Medicare statutes and regulations as a forum to air their grievances against hospitals, pointing to the legislative history. As discussed *post* at note 8, however, the court does not read the legislative history as indicating an intent to preclude this suit.

only those whose interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit," *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1287 (D.C. Cir. 2005) (quoting *Clarke*, 479 U.S. at 399).

Here, the member nurses' injuries fall within the zone of interests arguably to be protected by the Act. The Act seeks to provide quality medical care to its beneficiaries and therefore imposes conditions, including requirements related to necessary nursing capabilities, upon hospitals in order to participate in the program. Understaffing of nurses, the injury complained of, arguably leads to lower quality care and therefore the interests of the member nurses are "sufficiently congruent" with the congressional purpose. *See Citizens Exposing Truth about Casinos v. Kempthorne*, 492 F.3d 460, 464 (D.C. Cir. 2007). Moreover, where nursing conditions are poor due to a lack of registered nurses, the interests of plaintiffs and the patients converge. *See Am. Chiropractic Ass'n, Inc.*, 431 F.3d at 816. Plaintiffs have standing to sue on behalf of their member nurses.[6]

B. Some of Plaintiffs' Claims Are Reviewable Under the Administrative Procedures Act.

HHS also challenges the court's subject matter jurisdiction to hear plaintiffs' claims under the Administrative Procedures Act. Section 701 of the Administrative Procedures Act, authorizing judicial review of agency action, states: "This chapter applies . . . except to the

[6] The other requirements for associational standing, that the interests at stake are germane to the organization's purpose and that neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit, are easily met. Plaintiffs' purpose is to represent the interests of registered nurses, including appropriate staffing, and no individual nurse is necessary to adjudicate whether HHS has complied with the Medicare Act or to issue a declaratory judgment so determining.

extent that – (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). HHS challenges the court's jurisdiction under both of these exceptions.

As an initial matter, the court agrees with HHS that, to the extent plaintiffs allege, in a generalized sense, that the Secretary "is not using enough vigor to enforce compliance with conditions of participation related to hospital staffing of registered nurses," Defs.' Mot. at 32, review of that allegation is precluded by section 701 of the Administrative Procedures Act as action "committed to agency discretion by law." The "committed to agency discretion by law" exception is "very narrow," *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 410 (1971), but an agency's decision not to take enforcement action is presumed to lie within this exception, *Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985). In particular, the Medicare Act grants the Secretary a great deal of latitude in determining how it will enforce the conditions of participation. *See* 42 U.S.C. § 1395cc(b)(2) ("The Secretary *may* refuse to enter into an agreement . . . [or] *may* refuse to renew or *may* terminate such agreement after the Secretary – . . . has determined that the provider fails substantially to meet the applicable provisions of section 1395x . . . .") (emphasis added).

HHS also challenges the court's jurisdiction under section 701(a)(1) as precluded by statute. Citing *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340 (1984), HHS argues that this provision precludes judicial review of plaintiffs' claims because the statutory scheme gives administrative and judicial remedies to certain regulated entities, but not to the public or other interested parties. Plaintiffs rejoin that *Block* is inapplicable and instead argue that the court should look to *Bowen v. Mich. Acad. of Family Phsyicians*, 476 U.S. 667 (1986), because they do

not challenge any determination by the Secretary that a provider is ineligible or has substantially failed to meet the standard, but instead the *method* by which such determinations are made. Plaintiffs are correct.

The Administrative Procedures Act confers a general cause of action for those adversely affected within the meaning of a statute, but withdraws it to the extent the relevant statute precludes judicial review. 5 U.S.C. § 701(a)(1). "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block*, 467 U.S. at 345. "The mere fact that some acts are made reviewable," however, "should not suffice to support an implication of exclusion as to others." *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967).

The court finds that judicial review of plaintiffs' claims is not barred by the statute because the statute speaks only to the mandated review procedure for institutions or agencies dissatisfied with a determination by the Secretary "that it is not a provider of services" or that it "fails substantially to meet" the conditions of 1395x(e). *See* 42 U.S.C. § 1395cc(h)(1)(A). Plaintiffs seek to challenge the method by which these determinations are made, i.e. whether a hospital may be deemed in compliance with the bedside availability requirement through accreditation. This is very different from the determination of which the statute speaks, that a specific facility is not in compliance with the conditions of participation.[7]

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[7] HHS's citation to the legislative history is unavailing. In its report, the Senate Finance Committee described the various methods of appeal under the Medicare Act, including the provision for hospitals to appeal a determination that they are ineligible, and then states, "[i]t is intended that the remedies provided by these review procedures shall be exclusive." S. Rep. 89-404 at 1995 (1965). There is nothing to suggest, however, that the Committee meant any more

This case is quite similar to *Bowen*, in which the Court held that a provision of the Medicare Act specifying and limiting judicial review of the Secretary's determination as to the amount of payment to be made or amount of benefits to be covered "simply does not speak to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves." 476 U.S. at 675. It is quite different from *Block*, in which the plaintiffs wanted to challenge the same determination for which judicial review had been specified and limited in the statute, namely to challenge the milk orders on the basis that they made reconstituted milk uneconomical for handlers to process. *Block*, 467 U.S. at 344. And, unlike in *Block*, the persons for whom judicial review is specified in the Medicare Act, namely the hospitals dissatisfied with the Secretary's determination that they are ineligible or fail to substantially meet the conditions of participation, cannot circumvent the specified administrative and judicial process to challenge the same determination. They could only challenge the method by which it is made.

An additional consideration weighing in favor of permitting judicial review is that ruling otherwise would result in a lack of a forum in which this aspect of the Secretary's actions could be reviewed. *See id.* at 352. The agencies and institutions authorized to bring suit to challenge the Secretary's determination that they are ineligible for the program would not have the incentive to challenge whether the bedside availability requirement is more stringent than the equivalent Joint Commission standard. *See id.* at 351-52.

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than that for a hospital wishing to challenge a determination of ineligibility, the provisions for administrative and judicial review in the Act are exclusive. The Committee simply did not address challenges by other parties to other determinations.

C. Plaintiffs Fail to State a Claim Upon Which Relief May Be Granted.

HHS also moves to dismiss plaintiffs' claims under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. To survive a 12(b)(6) motion, a plaintiff must allege a plausible entitlement to relief by setting forth "any set of facts consistent with the allegations." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, ---,127 S. Ct. 1955, 1969 (2007); *Kowal v. MCI Communs. Corp.*, 16 F.3d 1271, 1276 (D .C. Cir. 1994). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations . . . a plaintiff's obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions . . . . Factual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp.*, 127 S. Ct. at 1964-65 (citations and internal quotation marks omitted). Thus, the court need not "accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint. Nor must the court accept legal conclusions cast in the form of factual allegations." *Kowal*, 16 F.3d at 1276.

Plaintiffs' complaint contains three allegations: (1) that "the 'deemed' status of hospitals participating in Medicare is assumed by HHS notwithstanding the higher requirements of HHS regarding nurse staffing" resulting in inadequate staffing, Compl. ¶¶ 40, 58; (2) that "due to the official neglect of HHS, [some] hospitals have consistently failed to provide sufficient registered nurse staffing to make a registered nurse immediately available when needed, yet those hospitals participate in and receive funds from the Medicare program," Comp. ¶ 41; and (3) that "[t]hrough its failure to require [the Joint Commission] to have an equivalent registered nurse staffing standard . . . HHS has unlawfully delegated its authority to" the Joint Commission, Compl. ¶ 59.

The court addresses each to assess whether plaintiffs have set forth any set of facts consistent with these allegations plausibly entitling them to relief.

1. Classifying bedside availability as an (e)(5) standard instead of an (e)(9) standard.

Plaintiffs allege that HHS has unlawfully treated the bedside availability requirement as a section 1395x(e)(5), instead of a section 1395x(e)(9), requirement and have therefore unlawfully deemed accredited hospitals to be in compliance with it. They write, "Upon information and belief, the 'deemed' status of hospitals participating in Medicare is assumed by HHS notwithstanding the higher requirements of HHS regarding nurse staffing," Compl. ¶ 40, and "HHS . . . ha[s] failed to implement statutory and regulatory requirements that [the Joint Commission] standards be at least equivalent to requirements established by the Secretary of HHS as a prerequisite to having [Joint Commission] accreditation be deemed approval to participate in the Medicare Program," Compl. ¶ 58.

The question of whether the bedside availability standard is an (e)(5) or (e)(9) standard and therefore whether HHS unlawfully deemed hospitals in compliance with it is a pure question of law. Pointing to the preamble to the regulation promulgating the bedside availability requirement, HHS argues that it is clear that the Secretary promulgated this requirement, along with the other nursing standards, under (e)(5), and that the Secretary's construction of her own regulations is entitled to substantial deference. Further, HHS argues that the Secretary's construction is reasonable because it reasonably interprets the (e)(5) requirement that a hospital have "24-hour nursing services rendered or supervised by a registered professional nurse."

Plaintiffs rejoin that the regulatory history reveals that section 1395x(e)(9) was the foundation for the bedside availability requirement, pointing to the 1966 Federal Register Notice promulgating the initial set of standards which differentiated between the "specific [statutory] requirements" and other requirements considered necessary. They argue that it would be quite possible to comply with the statutory nursing requirement of twenty-four hour nursing services rendered or supervised by a registered nurse without ensuring the regulatory requirement of availability of a registered nurse at the bedside when needed, and therefore assert that the bedside availability requirement must be an additional requirement. Plaintiffs contend that this reading is reinforced by the regulatory history, pointing to a 1997 Notice of Proposed Rulemaking which they argue also juxtaposes the (e)(1)-(8) requirements with the (e)(9) requirements set forth in 42 C.F.R. § 482 (which contains the nursing standards).

The court "affords great deference to an agency's interpretation of its own regulation: under well-recognized precedent, [it] can reject the Secretary's interpretation only if it is plainly erroneous or inconsistent with the regulation." *Sec'y of Labor v. Twentymile Coal Co.*, 411 F.3d 256, 260 (D.C. Cir. 2005); *see also Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). Here, HHS's interpretation of its own regulation is not plainly erroneous or inconsistent with the regulation.

The regulation at issue in this case is found at 42 C.F.R. § 482.23, entitled "Conditions of participation: Nursing services." It essentially states the statutory requirement at the outset: "The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse." It then lays out three standards – one for organization, one for staffing and delivery of care, and one for

preparation and administration of drugs. *Id*. The bedside availability requirement is found in the subsection addressing staffing and delivery of care. There is nothing in the regulation to suggest that it was promulgated under the Secretary's (e)(9) authority or that it does anything other than elaborate upon the meaning of the statutory standard stated at the outset. The preamble contained in the Federal Register explaining the regulation's nursing services provisions lends further support to the Secretary's interpretation. That preamble refers specifically to "Section 1861(e)(5) of the Social Security Act" (codified at 42 U.S.C. § 1395x(e)(5)) and the regulations that implement "this statutory requirement." 51 Fed. Reg. 22010, 22018 (June 17, 1986).

Moreover, the Secretary's interpretation is reasonable. The statutory prescription, "24-hour nursing services rendered or supervised by a registered professional nurse," 42 U.S.C. § 1395x(e)(5), is ambiguous and can reasonably be interpreted to incorporate the bedside availability requirement. *See Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 740-41 (1996) ("Congress, when it left ambiguity in a statute meant for implementation by an agency, understood the ambiguity would be resolved, first and foremost, by the agency.").[8] Therefore, plaintiffs fail to state a claim upon which relief may plausibly be granted with respect to their allegation that HHS has improperly categorized the bedside availability standard as an section 1395x(e)(5) standard.

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[8] Plaintiffs' citations to the regulatory history do not demonstrate that the Secretary's interpretation is plainly erroneous or inconsistent with the regulation. All that the 1966 Federal Register notice establishes is that there are both specific statutory requirements and other requirements considered necessary. It does not do anything to indicate under which the bedside availability requirement falls. *See* 31 Fed. Reg. 13,421, 13,424 (Oct. 18, 1966). The same is true of the 1997 Notice of Proposed Rulemaking. When it states "Under this authority" the Secretary has promulgated the regulations at 42 C.F.R. Part 482, it does not specify whether it means only (e)(9) or all of the conditions of participation. *See* 62 Fed. Reg. 66,726, 66,727 (Dec. 19, 1997).

2. Failing to enforce the bedside availability standard.

Plaintiffs also allege that "due to the official neglect of HHS, [some] hospitals have consistently failed to provide sufficient registered nurse staffing to make a registered nurse immediately available when needed, yet those hospitals participate in and receive funds from the Medicare program." Comp. ¶ 41. The court agrees with HHS that this allegation is essentially that the Secretary "is not using enough vigor to enforce compliance with the conditions of participation related to hospital staffing of registered nurses," Defs.' Mot. at 32, and therefore the court lacks jurisdiction over this allegation under section 701(a)(2) of the Administrative Procedures Act. *See supra* Part IIB.

3. Unlawfully delegating its authority to the Joint Commission.

Plaintiffs' third allegation is that "[t]hrough its failure to require [the Joint Commission] to have an equivalent registered nurse staffing standard . . . HHS has unlawfully delegated its authority to" the Joint Commission. Compl. ¶ 59. HHS argues that plaintiffs fail to state a claim for which relief may be granted because while the legislature cannot delegate its power to make law, it can make a law to delegate a power to determine some fact upon which the law makes its own action depend. Here, HHS contends, the Secretary merely takes notice of the fact of whether the Joint Commission has accredited a hospital when she decides how to enforce the conditions of section 1395x(e) as required by statute. Plaintiffs rejoin that a federal agency may not delegate to a private entity the agency's statutory obligations absent an affirmative showing of congressional authorization. They argue that HHS unlawfully does this when it allows the Joint Commission to determine that its nursing standards are at least equivalent to the HHS bedside availability standard. HHS is correct.

Once again, the court is faced with a purely legal issue. Because the court holds that HHS lawfully interpreted the bedside availability standard as stemming from its section 1395x(e)(5) authority, there is no need for the Secretary to determine equivalency with the Joint Commission standard and therefore the Secretary has not delegated this authority, lawfully or unlawfully, to the Joint Commission. To the extent plaintiffs make this allegation more broadly, HHS is correct that the Secretary's determination that an accredited hospital is deemed to meet the requirements of section 1395x(e)(5) is not only authorized by Congress, *see United States v. Widdowson*, 916 F.2d 587, 592 (10th Cir. 1990) ("The relevant inquiry in any subdelegation challenge is whether Congress intended to permit the delagatee to delegate the authority conferred by Congress") (citing *United States v. Giordano*, 416 U.S. 505, 512-23 (1974)), but delegates to the Joint Commission only a finding of fact, i.e. whether or not a hospital meets the Joint Commission's standards, and not a delegation of the power to make law, *see United States v. Grimaud*, 220 U.S. 506, 520 (1911) ("The legislature cannot delegate its power to make a law, but it can make a law to delegate a power to determine some fact or state of things upon which the law makes or intends to make its own action depend.") (internal citation omitted). Plaintiffs have therefore failed to state a claim upon which relief may be granted with regard to their allegation of improper delegation.

D. Plaintiffs' Motion for Order of Jurisdiction or To Permit Jurisdictional Discovery is Denied.

The court has determined that it has subject matter jurisdiction over plaintiffs' allegations that HHS has improperly categorized the bedside availability standard and improperly delegated its authority to the Joint Commission. It has determined that it does not have jurisdiction with

respect to plaintiffs' allegation that HHS has failed to enforce the conditions required to be a hospital. Because the court has determined its jurisdiction, it need not address plaintiffs' motion for an order of jurisdiction, which motion relies on plaintiffs' complaint and briefing on HHS's motion to dismiss. Plaintiffs also request to be permitted to conduct jurisdictional discovery should the court determine that it does not have subject matter jurisdiction over their claims. When requesting jurisdictional discovery a plaintiff must make a "detailed showing of what discovery it wishes to conduct or what results it thinks such discovery would produce." *United States v. Philip Morris Inc.*, 116 F. Supp. 2d 116, 130 n.16 (D.D.C. 2000). Because plaintiffs have failed to argue with any specificity what evidence they believe they could find to supplement their current allegations, their request for jurisdictional discovery is denied.

III. CONCLUSION

For the foregoing reasons, HHS's motion to dismiss is GRANTED and plaintiffs' motion for order of jurisdiction, or, in the alternative, to permit jurisdictional discovery is DENIED. An appropriate order accompanies this memorandum opinion.

Henry H. Kennedy, Jr.
United States District Judge