UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASS'N OF PSYCHIATRIC HEALTH SYS., et al.,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 99-2025 (GK)
DONNA E. SHALALA, Secretary, Dep't of Health and Human Servs.,	:	
Defendant.	:	

MEMORANDUM OPINION

Plaintiffs bring this action against Donna E. Shalala, in her official capacity as the Secretary of the Department of Health and Human Services ("HHS"), to challenge an interim final rule which requires a physician or other licensed independent practitioner to evaluate a patient, face-to-face, within one hour after the patient has been placed in restraints or seclusion. This matter is before the Court on Plaintiffs' Motion for Summary Judgment and Application for Permanent Injunction, and Defendant's Motion for Summary Judgment. Upon consideration of the motions, oppositions, replies, the arguments made at the motions hearing, and the entire record herein, for the reasons discussed below, Plaintiffs' Motion for Summary Judgment is **granted in part and denied in part**, Plaintiffs' Application for Permanent Injunction is **denied**, and Defendant's Motion for Summary Judgment is **granted in part and denied in part**.

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I. Background[1]

Plaintiffs bring this case to challenge the interim final rule promulgated by HHS, which requires a physician or other licensed independent practitioner to evaluate a patient, face-to-face, within one hour after the patient has been placed in restraints or in seclusion. 42 C.F.R. § 482.13(f)(3)(ii)(C). This rule will hereafter be referred to as the "one-hour rule."

Plaintiffs are private psychiatric hospitals, and organizations that represent private hospitals, private psychiatric hospitals, and psychiatric units within acute care hospitals. Most of the hospitals represented participate in both the Medicare and Medicaid programs. A few participate in Medicaid but not Medicare.

To participate in Medicare, hospitals must meet certain conditions of participation ("COPs"), which are imposed by statute, regulation, or both. The Medicare statute allows the Secretary to impose additional COPs as necessary to protect the health and safety of Medicare beneficiaries. Hospitals which have received accreditation by a national accreditation body, such as the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"),

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[1] Pursuant to Local Rule 7.1(h), "[i]n determining a motion for summary judgment, the Court may assume that facts identified by the moving party in its statement of material facts are admitted, unless such a fact is controverted in the statement of genuine issues filed in opposition to the motion." The Court thus takes these facts from the parties' statements of material facts not in dispute. Furthermore, since this case is a review of an administrative agency's decision, the Court also relies on facts contained in the administrative record.

are generally deemed to be in compliance with Medicare COPs, except that the Secretary may promulgate standards or requirements higher or more stringent than those prescribed for accreditation by such a national accreditation body. 42 U.S.C. § 1395bb(a), (b).

The Health Care Financing Administration ("HCFA"), which is the agency within HHS responsible for administering the Medicare statute, assesses hospitals' compliance with Medicare COPs through a survey process generally conducted by state agencies. A hospital which has failed to comply with a COP may continue to participate in Medicare by submitting a plan for achieving compliance within a reasonable amount of time. 42 C.F.R. § 488.28(a), (d). If a hospital fails, within a reasonable period of time, to implement this plan or come in compliance with the COPs, the Secretary may terminate or refuse to renew the hospital's provider agreement for participation in the Medicare program. 42 U.S.C. § 1395cc(b)(2)(B); 42 C.F.R. §§ 488.456, 489.53(a)(3).

By notice in the Federal Register on December 19, 1997, HCFA announced a far-ranging proposed rule to revise many different COPs for hospitals participating in Medicare and Medicaid. Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval, 62 Fed. Reg. 66,726 (1997)(this notice of proposed rulemaking shall hereafter be referred to as the "NPRM"). Included in this extensive rulemaking was a HCFA proposal to regulate the circumstances under which hospitals may use

restraints and seclusion.[2] HCFA did not, in the proposed rule, delineate specific requirements for use of restraints and seclusion, but merely offered general guidelines for such use: that they be used "only when absolutely necessary to prevent immediate injury to the patient or others and when no alternative means are sufficient to accomplish this purpose," and that patients should be released from such restraints or seclusion "as soon as they no longer pose an immediate threat of injury to themselves or others." 62 Fed. Reg. at 66,731.

HCFA did note, however, that it had considered adding further detail to these general guidelines, and requested comments on whether additional prescriptive requirements were necessary. Id. In the preamble of the NPRM, HCFA listed a number of prescriptive requirements as examples of the types of standards it had considered adopting, including requiring physicians to conduct face-to-face assessments of restrained or secluded persons, requiring orders of restraint or seclusion to be signed by a physician and be specific and time-limited, requiring that restrained and secluded patients be constantly monitored for comfort, health, and safety, and limiting the time that a patient may be kept in restraints or

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[2] Although not discussed in the NPRM, the Interim Final Rule noted that restraints referred to physical restraints (use of physical force and/or mechanical devices such as ankle cuffs or straitjackets), as well as chemical restraints (medication for controlling behavior or restricting movement). Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights, 64 Fed. Reg. 36,070, at 36,089 (1999).

seclusion. Id.

The entire record developed in response to all the COP proposals contained in the NPRM includes 200 pages of studies and articles, as well as over 1,000 pages of public comments. As to the one-hour rule, the studies and articles document the link between improper use of restraints and injury or death. Injuries include the psychological (aggression, withdrawal, morbidity, loss of self-esteem, etc.) as well as the physical (burns, pressure sores, limb injury, circulatory obstruction, nerve compression, etc.). The record revealed that restraints are a common intervention, estimating that they are applied hundreds of thousands times a day in the United States, but that restraint-related deaths and injuries (estimated at over 100 per year) often go unreported. The comments received in response to the NPRM stressed the need for frequent monitoring and rapid assessment of persons in restraints or seclusion, and stressed that restraints and seclusion should only be used in emergencies. HCFA received approximately 60,000 public comments in response to all the COP proposals, and a number of them discussed the face-to-face assessment requirement that HCFA had considered when it published the NPRM. A.R. at 295, 519-20, 569, 602, 1217, 1278.

On July 2, 1999, HCFA promulgated the patient-rights COP as an

Interim Final Rule.[3] Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights, 64 Fed. Reg. 36,070 (1999). In the Interim Final Rule, HCFA stressed that restraints and seclusion should be used only in emergencies, and stressed the need for rapid assessment and continuous monitoring of patients in restraints or seclusion. The Interim Final Rule listed more specific requirements, which tracked many of the guidelines established by the JCAHO, including the requirement of face-to-face evaluation prior to the renewal of an order for restraints or seclusion. 42 C.F.R. § 482.13(f)(3)(ii)(D). To ensure more involvement by physicians or licensed independent practitioners, HCFA added the additional requirement (which went beyond the JCAHO guidelines) of a face-to-face assessment of the patient by a physician or licensed independent practitioner within one hour of the application of restraints or use of seclusion. 42 C.F.R. § 482.13(f)(3)(ii)(C). It is this final requirement that is at issue in this case.

II. Standard of Review

Initially, it must be remembered that the Court is bound by a highly deferential standard of review for agency action. Under the Administrative Procedure Act ("APA"), an agency's action may be set aside only if it is "arbitrary, capricious, an abuse of discretion,

[3] The Interim Final Rule was enforceable immediately, but the Secretary continued to receive public comments on it.

or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In making this finding, the Court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The Court may not substitute its judgment for that of the agency. Id. If the "agency's reasons and policy choices . . . conform to 'certain minimal standards of rationality' . . . the rule is reasonable and must be upheld," Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 521 (D.C. Cir. 1983)(citation omitted), even though the Court itself might have made different choices. This standard presumes the validity of agency action. Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir. 1976)(en banc), cert. denied, 426 U.S. 941 (1976).

Courts also give a high degree of deference to agency actions based on an evaluation of complex scientific data within the agency's technical expertise. See Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983); NRDC v. EPA, 824 F.2d 1211, 1216 (D.C. Cir. 1987)(citing NRDC v. EPA, 812 F.2d 721, 725 (D.C. Cir. 1987))("[I]t is not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence."). Where the agency decision turns on issues requiring the exercise of technical or scientific judgment, it is essential for judges to "look at the decision not as the chemist, biologist, or statistician that we are

qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality." Ethyl Corp., 541 F.2d at 36.

III. Analysis

The four issues before the Court are whether this Court has subject matter jurisdiction over this action, whether Defendant violated the notice-and-comment requirement of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(b), whether Defendant's promulgation of the Interim Final Rule was arbitrary and capricious, and whether Defendant violated the Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601 et seq.

A. Does the Court Have Subject Matter Jurisdiction?

Our Court of Appeals has long held that "[a] federal court's subject-matter jurisdiction, constitutionally limited by article III, extends only so far as Congress provides by statute." Commodity Futures Trading Comm'n v. Nahas, 738 F.2d 487, 492 (D.C. Cir. 1984). Therefore, "the court must scrupulously preserve the precise jurisdictional limits prescribed by Congress." Id. at 492 n.9 (citations omitted).

In 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, Congress expressly precluded federal question jurisdiction over claims "arising under" the Medicare Act. That statute provides that "[n]o action against . . . the [Secretary] or

any officer or employee thereof shall be brought under Section 1331 . . . of title 28 to recover on any claim arising under this subchapter [i.e., the Medicare Act]." The Supreme Court has held that a "[p]etitioner's claim 'arises under' the Medicare Act within the meaning of this provision [when] both the standing and the substantive basis for . . . the claim are the Medicare Act." Your Home Visiting Nurse Servs., Inc. v. Shalala, 119 S. Ct. 930, 935 (1999) (internal quotations and citations omitted).

This one section of an incredibly complex, not to say Byzantine, statute has spawned an enormous amount of litigation. Just six months ago, the Supreme Court revisited the issue of the federal courts' subject matter jurisdiction over claims arising under the Medicare Act in Shalala v. Illinois Council on Long Term Care, 120 S. Ct. 1084 (2000). In that case, the Supreme Court reviewed a facial challenge, by an association of nursing homes, to a set of regulations imposing a schedule of penalties and sanctions for violation of substantive Medicare Act standards. Plaintiff invoked federal question jurisdiction under 28 U.S.C. § 1331.

The Supreme Court held that § 405(h) precluded judicial review under § 1331, and required channeling virtually all legal challenges through the agency's administrative process before such challenges could be heard in federal court. Id. at 1093-94. In reaching this conclusion, the Court relied heavily on the Secretary's representations that "a nursing home with deficiencies can

test the lawfulness of her regulations simply by refusing to submit a [corrective] plan and incurring a minor penalty. Minor penalties, she says, are the norm, for 'terminations from the program are rare and generally reserved for the most egregious recidivist institutions.'" Id. at 1098.

The Plaintiff in Illinois Council had argued that it fell squarely within the exception created by Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667, 681 n.12 (1986), for cases where the application of § 405(h) would not lead to a channeling of review through the agency, but would mean no review at all. Significantly, even though the Supreme Court refused to apply the Bowen exception to the plaintiff in Illinois Council, because of the Secretary's description of the agency's general practice, it declined the opportunity to overrule Bowen. Rather, the Court explicitly left open for another day the issue of "whether a general agency practice that forced [hospitals] to abandon legitimate challenges to agency regulations could amount to the 'practical equivalent of a total denial of judicial review,'" Id. (quoting McNary v. Haitian Refugee Center, Inc., 498 U.S. 479, 497 (1991)).

That is precisely the issue presented in this case. Plaintiff argues that in order to contest the validity of the one-hour rule a hospital must violate a condition of participation, or face the

draconian sanction of termination from the Medicare program.[4] See 42 C.F.R. §488.28 (a), (d); 42 U.S.C. § 1395cc(b)(2)(B); 42 C.F.R. § 488.456, 489.53(a)(3). Unlike the nursing homes in Illinois Council, Plaintiff's members, as a practical matter, do not have the option of incurring a minor penalty and receiving an administrative hearing before proceeding to federal court.[5]

Thus, the facts in this case, as opposed to those presented in Illinois Council, do fall squarely within the Bowen exception. Application of § 405(h) would amount to the "practical equivalent of a total denial of judicial review" because "what appears to be simply a channeling requirement [turns] into complete preclusion of judicial review". Id. For that reason, the Court concludes that § 405(h) is not applicable and that the Court has federal question jurisdiction under 28 U.S.C. § 1331.

B. Did Defendant Violate the Notice-and-Comment Requirement of the APA?

Under the rulemaking provisions of the APA, an agency must provide the public with notice of any proposed rule it wishes to

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[4]Plaintiffs point out that, in addition to facing "economic suicide" by termination from Medicare, many hospitals would also lose their certificates of need from their state or local health planning agency during the period of time in which they were litigating termination before the agency and the federal courts.

[5] Defendant does not contest the accuracy of this description, and at oral argument defense counsel admitted that there were circumstances in which termination was mandatory.

promulgate (through publication in the Federal Register), and must afford the public an opportunity to comment on that proposed rule before it becomes final. 5 U.S.C. § 553(b). The agency, however, is not required to include every possible version of a proposed rule in its notice of proposed rulemaking; instead, the agency may include only a description of the subjects and issues involved. Id. Agencies are also not limited to adopting final rules identical to the proposed rules. National Mining Ass'n v. Mine Safety and Health Admin., 116 F.3d 520, 531 (D.C. Cir. 1997). The relevant inquiry is "whether the notice given affords exposure to diverse public comment, fairness to affected parties, and an opportunity to develop evidence in the record." Id. (internal citations and quotations omitted); see also BASF Wyandotte Corp. v. Costle, 598 F.2d 637, 642 (1st Cir. 1979), cert. denied sub nom., Eli Lilly & Co. v. Costle, 441 U.S. 1096 (1096).

If the regulation is a "logical outgrowth" of the proposed rule, notice is said to be adequate. National Mining Ass'n, 116 F.3d at 531. A final rule is considered the "logical outgrowth" of the proposed rule if at least the "germ" of the outcome is found in the original proposal. Natural Resources Defense Council v. Thomas, 838 F.2d 1224, 1242 (D.C. Cir. 1988). The question, however, "always requires careful consideration on a case-by-case basis." BASF Wyandotte Corp., 598 F.2d at 642.

While our Circuit Court of Appeals has addressed the issue of

what constitutes a "logical outgrowth" of a proposed rule in many, many cases, it is fair to say that it is hard to discern a clear rationale differentiating the holdings of those cases. Cf. National Mining Ass'n, 116 F.3d at 532 (holding notice inadequate when final rule changed requirement for examinations of mines, but proposed rule did not indicate that agency had considered changing the requirement); American Water Works Ass'n v. EPA, 40 F.3d 1266 (D.C. Cir. 1994)(holding notice inadequate when final rule adopted broader definition of the word "control", in reference to manner in which public water systems must take responsibility for controlling water quality under Safe Drinking Water Act, than had been foreshadowed in proposed rule); Horsehead Resource Development Co. v. Browner, 16 F.3d 1246 (D.C. Cir. 1994)(holding notice was inadequate when proposed rule did not sufficiently foreshadow agency's intent to regulate not only emissions of either carbon monoxide or total hydrocarbons, but also combined emissions of those two pollutants); with Natural Resources Defense Council v. Thomas, 838 F.2d 1224 (D.C. Cir. 1988)(holding notice adequate where proposed rule outlined plan where emissions requirements would depend on varying criteria, but final rule adopted uniform criteria for emissions); United Steelworkers v. Marshall, 647 F.2d 1189 (D.C. Cir. 1980), cert. denied, 435 U.S. 913 (1981)(holding notice adequate even when final rule setting standard for allowable exposure of airborne lead in workplace was twice as stringent as

proposed rule); and District of Columbia v. Train, 521 F.2d 971 (D.C. Cir. 1954)(holding notice adequate when proposed rule discussed EPA regulations for transportation control and mentioned alternate forms of transportation, but final rule created network of 60 miles of bicycle lanes and imposed requirements of bicycle storage facilities in certain parking lots).

Since it is clear that the inquiry must be undertaken on a case-by-case basis, and since our circuit has provided "no precise definition of what counts as a 'logical outgrowth,'" National Mining Ass'n, 116 F.3d at 531, this Court must look to the specific facts of this case in determining whether the Secretary's final rule was the logical outgrowth of the one proposed.

In the present case, Plaintiffs argue that notice was inadequate because (1) the final rule departed from the JCAHO standards that had been proposed in the NPRM, (2) the JCAHO standard upon which the one-hour rule was based required face-to-face assessment only prior to renewing a restraint order, not subsequent to signing the initial restraint order, and (3) none of the comments in the record suggested or advocated requiring a face-to-face assessment of a patient so shortly after the signing of an initial order of restraint or seclusion by a physician. Plaintiffs argue that the generalized reference to face-to-face assessment in the preamble of the NPRM is insufficient to provide notice of the agency's final rule because it related to the JCAHO standards,

which require such an assessment only upon renewal of the restraint order.

Defendant, on the other hand, argues that the mention in the preamble that the Secretary was considering a requirement of a face-to-face assessment was sufficient to put the public on notice that she might adopt such a requirement. Defendant also points out that she can promulgate regulations that are stricter than those required for accreditation by the JCAHO. Finally, Defendant notes that some commentators did comment on the face-to-face assessment requirement, but that in any event, the adequacy of notice cannot be judged by the number and type of comments in response to the NPRM.

This Court finds that the final rule was in fact the logical outgrowth of the proposed rule. Defendant put the commenters on notice that her overriding concern was for the patient's health and safety, that she sought to minimize the use of restraints and seclusion, and she noted that restraints and seclusion have the potential to produce serious psychological and physical harm to the patient. 62 Fed. Reg. at 66,731.

Defendant offered a list of prescriptive examples as possible requirements that she might impose on the use of restraints and seclusion, and stated that it was an open question as to whether further, more stringent, requirements should be adopted. Id. One of these examples was the face-to-face evaluation by a physician of

a restrained or secluded person prior to the renewal of an order of restraint or seclusion. Id. Further examples of prescriptive requirements being considered included frequent checking of the patient for comfort and safety, frequent documentation of the patient's condition, an outside time limit on orders of restraint or seclusion, requiring physicians to place time limits on such orders (and noting that time-limited orders may be terminated early if the patient demonstrates a change in the behavior that led to being placed in restraints or seclusion), and requiring such orders to be specific as to date, time, reason, and method of restraint or seclusion. Id. It is clear that the Secretary's goals were to ensure that restraints and seclusion not be overused or improperly used, that patients be frequently monitored while in restraints or seclusion, and that patients be removed from them as soon as possible.

The one-hour requirement imposed in the final rule is a logical outgrowth of the proposed rule, as it specifically addressed those goals; an early face-to-face evaluation of a patient placed in restraints or seclusion would ensure that such restraints or seclusion were being properly used, that the patient's health and safety were not being endangered, and that the restraints or seclusion continued to be necessary. The commenters had fair notice that the Secretary wished to address these concerns in her final rule, and their failure to anticipate the exact

contours of the Secretary's final rule does not compel the conclusion that the final rule is not a logical outgrowth of the proposed rule. "They cannot now complain because they misread the regulatory waters, incorrectly anticipated how [the agency] would react to their criticisms, and, consequently, submitted comments that left some things unsaid." BASF Wyandotte Corp., 598 F.2d at 643.

C. Is the Interim Final Rule Arbitrary and Capricious?

In reviewing an agency's decision under the APA, the Court cannot set aside that decision unless it is arbitrary, capricious, an abuse of discretion, or otherwise contrary to law. 5 U.S.C. § 706(2)(A). In making this finding, the Court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park, 401 U.S. at 416. The Court may not substitute its judgment for that of the agency, but must uphold a decision that is reasonable and conforms to minimal standards of rationality. Additionally, a high degree of deference is owed to agency actions based on an evaluation of complex scientific data within the agency's technical expertise. Baltimore Gas & Elec. Co., 462 U.S. at 103.

Plaintiffs make two arguments for why the final rule adopted by the Secretary is arbitrary and capricious. First, Plaintiffs argue that the Secretary failed to justify the adoption of the

rule, and that there is no adequate basis in the record to support the decision. Plaintiffs maintain that the Secretary's mere three-sentence justification of the rule is insufficient, especially in light of the fact that none of the studies, articles, or comments directly discussed or addressed the need for a face-to-face assessment of a restrained or secluded patient within a short period of time after that patient is placed in restraints or seclusion.

Plaintiffs' perspective for evaluating the rule is too narrow. Both the need and justification for it are to be found in the extensive commentary regarding the need for rapid assessment and constant monitoring of the patient's condition. The Secretary was concerned that improper use of restraints and seclusion were jeopardizing patients' health and safety, psychologically as well as physically, and wanted to provide clear guidelines within which physicians must operate when ordering the use of restraints or seclusion. The Secretary considered the various studies, articles, and comments that discussed the harms that can befall patients when restraints or seclusion are improperly initiated or continued in coming to her decision to promulgate the final rule. Thus, it appears that the Secretary considered all relevant factors in reaching her decision, and her decision requiring maximum patient protection is a reasonable one.

Plaintiffs' second argument is that the evidence in the record

does not support the final rule, but instead leads to the opposite conclusion. Plaintiffs argue that the one-hour rule interferes with a physician's diagnosis or treatment of a patient, by requiring a face-to-face assessment that may be unnecessary or, in some instances, may even be counterproductive. For example, Plaintiffs argue that if the patient is removed from restraints or seclusion in less than an hour, or if the patient is asleep or extremely agitated, a face-to-face assessment may not be in the patient's best interest, and only the patient's physician should make that assessment. Plaintiffs also argue that requiring a physician to make a face-to-face evaluation in every case within one hour of the restraint order is unnecessary, and that a highly trained psychiatric nurse could brief the physician who would then make any necessary decisions regarding the patient's safety and health and need for an in-person evaluation.

Plaintiffs may be correct that a somewhat more narrowly crafted rule could have been formulated from the available evidence, but that is not the standard by which this Court reviews agency decisions under the APA. Where the agency decision turns on issues requiring the exercise of technical or scientific judgment, it is essential for judges to "look at the decision not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain

minimal standards of rationality." Ethyl Corp., 541 F.2d at 36. The Secretary's decision certainly conforms to far more than "minimal" standards of rationality, and is supported by the record.

D. Did Defendants Violate the Regulatory Flexibility Act?

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 601 et seq., requires agencies to assess the negative impact of their rules on small businesses. An agency must perform an initial regulatory flexibility analysis ("IRFA") in its notice of proposed rulemaking, 5 U.S.C. § 603(a), unless the head of the agency certifies that the rule will not "have a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b). The agency must also perform a final regulatory flexibility analysis ("FRFA") in its final rule, 5 U.S.C. § 604(a), unless it again makes the requisite certification. 5 U.S.C. § 605(b). The adequacy of the FRFA is subject to APA review, 5 U.S.C. § 611(a)(1) and (2). The agency needn't present its FRFA in any "particular mode of presentation," as long as the FRFA "compiles a meaningful, easily understood analysis that covers each requisite component dictated by the statute and makes the end product-whatever form it reasonably may take-readily available to the public." Associated Fisheries of Maine, Inc. v. Daley, 127 F.3d 104, 115 (1st Cir. 1997). The requisite components of a FRFA, as set forth in 5 U.S.C. § 604(a), are:

> (1) a succinct statement of the need for, and objectives of, the rule;

(2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

In the NPRM, the Secretary made a certification of no significant economic impact, and thus did not perform an IRFA. 62 F.R. at 66,753. Plaintiffs do not challenge this certification, but argue that because the final rule was so dramatically different from the proposed rule, the Secretary was required to perform an adequate FRFA or certify that the rule would have no significant impact. Plaintiffs argue that the Secretary did neither, but instead made the brief, conclusory, and erroneous statement that she did not "anticipate . . . a substantial economic impact on most Medicare-participating hospitals." 64 Fed. Reg. at 36,085. Plaintiffs specifically argue that the Secretary completely failed

to address the second, fourth, and fifth components of FRFAs, as contained in 5 U.S.C. § 604(a)(quoted above).

The second component of a FRFA requires the agency to summarize the significant issues raised by the public comments in response to the IRFA, and to summarize the agency's assessment of those issues. 5 U.S.C. § 604(a)(2). Plaintiffs argue that Defendant could not have complied with this component, since she never presented the one-hour rule in the NPRM for public comment. Defendant correctly points out that since an IRFA was not needed because she certified that there would be no significant impact to small businesses (a certification which Plaintiffs do not dispute), there were no IRFA-related issues that the Secretary could have discussed in her FRFA.

The fourth component of a FRFA requires the agency to describe what reporting, recordkeeping, or other compliance requirements the rule would likely produce, and to estimate the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of those compliance requirements. 5 U.S.C. § 604(a)(4). Plaintiffs argue that the Secretary made no effort whatsoever to comply with this component, and argue that there is nothing in the final rule discussing reporting or recordkeeping requirements, to ensure the rule is complied with. Defendant is again correct in noting that she has complied with this component: as stated in the FRFA, the only new

recordkeeping requirement imposed by the rule is a telephone call to HCFA regional offices to report deaths from restraint or seclusion. 64 Fed. Reg. at 36,086.[6]

The fifth component of a FRFA requires the agency to describe the steps the agency took to minimize the significant economic impact on small businesses, and to include a "statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected." 5 U.S.C. § 604(a)(5).

As to this requirement, the Secretary's analysis is severely lacking, and the Court cannot find that she has made a "reasonable, good-faith effort to canvass major options and weigh their probable effects." Associated Fisheries of Maine, 127 F.3d at 116. The Secretary did not obtain data or analyze available data on the impact of the final rule on small entities, nor did she properly assess the impact the final rule would have on small entities. Plaintiffs point out that in promulgating a restraint and seclusion rule that would apply to nursing homes, the Secretary estimated the economic impact of that rule would be $35 million,[7] but that she

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[6] Defendant also points out that no new recordkeeping requirements are created by this rule because hospitals are already subject to preexisting recordkeeping requirements, as specified in 42 C.F.R. § 482.24.

[7] Proposed Rule, Medicare and Medicaid Programs; Omnibus Nursing Home Requirements, 57 Fed. Reg. 4516 (1992).

performed no such estimate or analysis with respect to this rule. The Secretary also failed to consider other significant alterna tives to the rule before settling on the one-hour rule.[8] There is no discussion of what, if any, steps the agency took to minimize the significant economic impact on small businesses. There is no "statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule." There is no discussion of what other significant alternatives which affect the impact on small entities were considered (if any in fact were considered), and why those alternatives were rejected. Defendant protests that her FRFA need not exhibit mathematical exactitude, and need take no special form of presentation, as long as each component is covered somewhere in the final rule. The Secretary is not being held to this high a standard. The fact of the matter is that she has totally failed to comply with section (5) of § 604(a) of the FRFA.

E. Should A Permanent Injunction Be Granted?

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[8] For example, Plaintiffs argue that the Secretary failed to consider the obvious and less burdensome alternatives of extending the time between the order of restraint and the face-to-face evaluation, or permitting a trained mental health clinician (such as a psychiatric nurse) to telephonically provide a physician with any information necessary to allow the physician to make an informed clinical decision with respect to the patient.

It is important to note the similarities between the RFA and the National Environmental Policy Act, 42 U.S.C. § 4321 et seq. The objective of both acts is to require the agency to analyze the adverse effects (whether economic or environmental) of its decisions before those decisions are implemented, and to consider less harmful alternatives. See Associated Fisheries of Maine, 127 F.3d at 114.

Plaintiffs ask the Court to permanently enjoin enforcement of the one-hour rule because of Defendant's violation of the RFA. The well-settled requirements for a permanent injunction are adopted from the requirements for a preliminary injunction, as stated in Wisconsin Gas Co. v. FERC, 758 F.2d 669, 673-74 (D.C. Cir. 1985) and Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841, 843 (D.C. Cir. 1977): (1) success on the merits; (2) irreparable harm absent the injunction; (3) the balance of hardship tips in favor of the plaintiff if an injunction is not granted; and (4) the public interest lies in granting an injunction. See also National Mining Ass'n v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1409-10 (D.C. Cir. 1998)(applying preliminary injunction standard to request for permanent injunction).

It should be noted that although the statute gives the Court the option of deferring enforcement of the Rule against small entities until completion of a compliant FRFA, the statute also permits continued enforcement of the Rule if the Court finds that continued enforcement is in the public interest. 5 U.S.C. § 611(a)(4). Consequently, an injunction should issue only if Plaintiffs can show irreparable harm, and that the public interest would best be served by issuance of an injunction.

First, Plaintiffs have failed to show what, if any, irreparable harm would befall them should the Court refuse to enter an injunction. Plaintiffs argue that they will suffer irreparable

harm from the enforcement of the rule, because it will allegedly cost them $100 million to come into compliance with this new requirement. Plaintiffs, however, offer no concrete, reliable evidence to support their contentions of irreparable harm.[9]

Second, and more importantly, Defendant has clearly established that the public interest would best be served by continued enforcement of the Rule. The Rule was promulgated to protect patients against the unnecessary and excessive use of restraints or seclusion. Delaying enforcement would create the likelihood that injuries or death could result if the restraints or seclusion continued to be used inappropriately, because restraints and seclusion are dangerous interventions. Given the severe psychological and physical injuries that can and do result from inappropriate use of restraints and seclusion, and the fact that many of these injuries go unreported, the public interest lies in continued enforcement of the Rule.

Consequently, the case will be remanded to the agency for completion of a compliant FRFA, without enjoining continued enforcement of the rule while the agency completes a new FRFA.

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[9] Most of the evidence offered by Plaintiffs is contained in the two declarations of Covall and King. Both are based solely on hearsay. Moreover, despite the fact that this Rule has been in effect for more than a year, Plaintiffs offer no economic data as to what, if any, adverse effects they or their clients have suffered.

IV. Conclusion

For the reasons discussed above, Plaintiffs' Motion for Summary Judgment is **granted in part and denied in part**, Plaintiffs' Application for a Preliminary Injunction is **denied**, and Defendant's Motion for Summary Judgment is **granted in part and denied in part**. An Order will issue with this Opinion.

Sept. 14, 2000
Date

GLADYS KESSLER
United States District Judge