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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

STATE OF NEW JERSEY,	
Plaintiff,	Hon. JOEL A. PISANO
v.	Civil Action No. 3:07-cv-04698 (JAP)(JJH)
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	
Defendant.	

REPLY IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS AND OPPOSITION TO PLAINTIFF'S CROSS MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

Defendant, Department of Health and Human Services ("HHS"), demonstrated in its opening brief that the State of New Jersey's challenge to the August 17, 2008 policy guidance issued by the Centers for Medicare and Medicaid Services ("CMS") is not ripe. Issued to inform the states how CMS intends to review state plans – submitted under the State Children's Health Insurance Program ("SCHIP") that seek to expand eligibility to effective family income levels above 250% of the Federal poverty level ("FPL") – the policy guidance is not legally binding, and its precise effect on New Jersey will not be known until it is actually applied to New Jersey's individual circumstances. As CMS recently stated in a letter to state health officials ("SHO"), "[b]ecause State programs (and 1115 demonstrations) vary widely," CMS will "continue to work with affected States and review requests for alternative approaches on a case-by-case basis" to ensure compliance with existing statutory and regulatory requirements. *See* Letter from Herb Kuhn, Deputy Administrator and Acting Director for Center for Medicaid and State Operations to state health officials, dated May 7, 2008 [hereinafter 5/7/08 SHO ltr.], at 1 (attached as Ex. 1).

Judicial review at this stage will unnecessarily intrude into the administrative process and ultimately may be unnecessary. In fact, based on HHS's clarifications in providing technical guidance to the states, many of New Jersey's concerns about the policy guidance's potential effect on its SCHIP population have been proved to be unfounded. It is clear that the policy guidance is not intended to have any effect on the approximately 124,000 children currently enrolled in New Jersey's FamilyCare program, including those with family incomes above 250% of the FPL. Nor need the strategies discussed in the policy guidance be applied to future enrollees with family incomes at or below 250% of the FPL or to unborn children. Until the

Court knows what legal issues it is deciding and what effects its decision will have – which it cannot know absent final agency action applying the policy guidance – it should not entangle itself in abstract disagreements over administrative policy.

In the meantime, New Jersey faces no immediate, significant harm. Although CMS's request for compliance is unequivocal, the law is clear that such a request imposes no legal obligations, is not a final agency action, and causes no cognizable hardship. CMS will not even initiate any investigation of whether any state's activities are consistent with the policy guidance, let alone commence any compliance proceeding until August 2008 at the earliest, and if it does, New Jersey would have an opportunity to defend its position in a full hearing on the record before any sanction may be imposed. Moreover, any sanction that results from a distant, hypothetical determination of non-compliance will be prospective only and will impose no sanction for any prior conduct by New Jersey.

As the Court of Appeals has said, "preenforcement review is the exception rather than the rule." *Artway v. Attorney General*, 81 F.3d 1235, 1247 (3d Cir. 1996). While there may be "certain extraordinary circumstances in which Congress' creation of an exclusive avenue for judicial review of agency action may be bypassed by an action in the district court," *Solar Turbines Inc. v. SEIF*, 879 F.2d 1073, 1077 (3d Cir. 1989), this is not one of them. New Jersey cannot avoid the statutorily established administrative review process concerning compliance determinations by rushing to the district court for an injunction preventing any hypothetical, future action that would set the review process in motion. Whether New Jersey's claims are characterized as facial or purely legal, substantive or procedural, New Jersey will have meaningful review in the Court of Appeals for all of its claims under the SCHIP statutory

scheme, in the event a final administrative determination of noncompliance is made after the administrative review process has been exhausted. The availability of that review precludes this Court's review now under the Administrative Procedure Act ("APA").

ARGUMENT

I. THIS COURT LACKS JURISDICTION OVER PLAINTIFF'S COMPLAINT

A. This Case Is Not Ripe for Judicial Review.

1. New Jersey will not suffer any immediate, significant harm if judicial review is postponed.

In its opening brief, HHS demonstrated that the case is not ripe because New Jersey will suffer no immediate, significant hardship if judicial review is postponed. New Jersey counters that it is faced with the choice of complying with the terms of the policy guidance – which they alleged would be costly and burdensome – or being subjected to "corrective action" and potentially losing all of its SCHIP funding. This "untenable dilemma," New Jersey argues, is directly analogous to that faced by the drug manufacturers in *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967), in which the Supreme Court permitted preenforcement review of certain agency regulations.

Abbott Laboratories, however, is entirely distinguishable. The admittedly substantive, binding regulations in that case – which were "self-operative," *id.* at 148, "made effective immediately upon publication," *id.* at 153, and had "the status of law," *id.* at 152 – forced the drug manufacturers to "risk serious criminal and civil penalties" for any and all noncompliance with the regulations' labeling requirements after the regulations' publication, *id.* at 152-153; *see also id.* at 152 (discussing penalties for unlawful distribution of misbranded drugs under 21

U.S.C. §§ 332-334). Complying with the regulations was extremely costly and there was no opportunity to cure any past noncompliance by subsequent remedial action. *Id.* at 152-53. Also, there were no further administrative proceedings contemplated through which the manufacturers could challenge the regulations. *Id.* at 149.

Here, in contrast, the August 17 policy guidance is not "self-operative," nor does it have the status of law. And, there is a statutorily prescribed administrative process that is yet to take place and that contemplates, in the first instance, informal negotiations between the parties, *see* 42 C.F.R. § 457.204(a)(2). Before CMS may impose any financial sanctions, New Jersey is entitled to notice, a reasonable opportunity for correction, and an opportunity for a hearing. *See* 42 U.S.C. § 1397ff(c), (d); 42 C.F.R. §§ 457.203, 457.204 (compliance action may only be taken if, after hearing, CMS Administrator finds "[t]hat the plan is in substantial noncompliance with the requirements of title XXI of the Act"); *see also* 42 U.S.C. § 1316(a)(2) (before state plan may be disapproved, state is entitled to hearing "on the issue of whether such plan conforms to the requirements for approval under [relevant statutory authority]"). Even then, any sanction will be *prospective* only – *i.e.,* federal funds could be withheld *going forward* from the time of the adverse agency determination and only if a state refuses prospectively to remedy any past non-compliance that has been determined at the administrative level.[1] New Jersey faces no threat of sanction for its present conduct. This alone establishes that the case is not ripe for judicial

[1] As for New Jersey's asserted concern that in case of a noncompliance determination, CMS may cut off New Jersey's SCHIP funding in its entirety, that, too, is highly speculative and implausible. This is particularly so because the policy guidance is intended to affect only *future* enrollees with effective family income levels above 250% of the FPL – which presumably will not be a large percentage of the state's SCHIP program. In fact, New Jersey does not point to any instance in which CMS has cut off a state's SCHIP funding for noncompliance in similar circumstances.

review.

New Jersey's claim of hardship essentially rests on the August 17 SHO letter's unequivocal request that states comply with the policy guidance. But such a request for compliance constitutes no cognizable hardship to justify preenforcement judicial review because it has no legal force. It is settled that even the issuance of a complaint – averring that the agency has reason to believe that the regulated entity is violating the law – does not have the legal force and practical effect on the regulated party necessary to constitute a final agency action under the APA. *See FTC v. Standard Oil Co.*, 449 U.S. 232, 243 (1980) ("Serving only to initiate [compliance] proceedings, the issuance of the complaint averring reason to believe has no legal force comparable to that of the regulation at issue in *Abbott Laboratories* . . . . [which] forced manufacturers to 'risk serious criminal and civil penalties' for non-compliance.").

Here, the August 17 SHO letter asks New Jersey to comply with the policy guidance and advises New Jersey of the *possibility* of future corrective actions if discussions between the agency and New Jersey do not succeed in bringing the plan back into compliance. Like the regulated entity in *Standard Oil*, New Jersey can either take corrective actions or defend its decision not to do so in the adjudicatory process. The risk that New Jersey may not prevail in that process is not a hardship that would entitle New Jersey to by-pass the statutory review scheme. *Cf. National Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 811 (2002) (rejecting argument "that mere uncertainty as to the validity of a legal rule constitutes a hardship for purposes of the ripeness analysis"). It is a cost that New Jersey – a recipient of federal SCHIP funding – "must face as a 'burden of living under government.'" *University of Medicine & Dentistry v. Corrigan,* 347 F.3d 57, 71 (3d Cir. 2003) (quoting *Standard Oil*, 449 U.S. at 244).

New Jersey thus faces a similar choice as the one at issue in *Reliable Automatic Sprinkler Co. v. Consumer Product Safety Comm'n*, 324 F.3d 726 (D.C. Cir. 2003). There, a manufacturer of sprinkler heads challenged a letter of the Consumer Product Safety Commission, which stated the agency's intention to make a preliminary determination that the manufacturer's sprinkler heads presented a substantial product hazard. *Id.* at 729. The letter requested the manufacturer to undertake a voluntary corrective action or face enforcement proceedings. *Id.* The court held that the case was unreviewable under the APA because "the agency must still hold a formal, on-the-record adjudication before it can make any determination that is legally binding." *Id.* at 732. As the court reasoned, "the request for voluntary compliance clearly has no legally binding effect," and the burden of responding to an administrative enforcement hearing "'is different in kind and legal effect from the burdens attending what heretofore has been considered to be final agency action.'" *Id.* (quoting *Standard Oil*, 449 U.S. at 242). "So long as [the company] retains the opportunity to convince the agency that it lacks jurisdiction over [its] sprinkler heads," the court concluded, "it makes no sense for a court to intervene." *Id.* at 733.

Third Circuit case law is similarly clear on this point. For example, in *Wyatt, Virgin Islands v. Virgin Islands*, 385 F.3d 801, 807-08 (3d Cir. 2004), the Third Circuit dismissed a preenforcement challenge as unripe despite the agency's two cease-and-desist letters requesting the employer to stop certain employment practice or face fines or imprisonment. And, in *Solar Turbines*, 879 F.2d at 1081, the Third Circuit held that a pre-enforcement challenge to an administrative order of the Environmental Protection Agency ("EPA") requiring plaintiff to cease construction of a certain gas turbine cogeneration facility was not ripe, despite the order's definitiveness and the threat of sanctions against plaintiff. Although the plaintiff characterized

its suit to enjoin the EPA's enforcement action as a challenge to the EPA's *ultra vires* conduct, *see id.* at 1077, the court held that judicial review "would intrude on the procedural sequence created by Congress whereby parties receiving notice of noncompliance are first encouraged to resolve their problems with the states and with EPA in an informal, less costly manner." *Id.* at 1078. "Judicial review becomes appropriate when the EPA, failing efforts at negotiation and compromise, takes steps at enforcement subjecting the facility to sequential penalties." *Id.*

As in *Reliable Automatic Sprinkler* and *Solar Turbines*, New Jersey cannot claim that it faces immediate hardship simply because CMS has requested that New Jersey voluntarily comply with the policy guidance or face corrective action. The procedural sequence contemplated by Congress now is for New Jersey first to work with CMS through informal negotiations, as CMS has begun to do. *See* 42 C.F.R. § 457.204(a)(2) (CMS generally does not hold a hearing until it has made a reasonable effort to resolve the issue through conferences and discussions). Such informal discussions and negotiations generally are very extensive and frequently result in a plan that is acceptable to both parties. *Cf.* S. Rep. No. 404, 89th Cong., 1st sess., reprinted in (1965) U.S.C.C.A.N. 1943, 2090 (recognizing that the review provisions [in 42 U.S.C. § 1316] "are not intended to affect adversely the usual negotiation process between [HHS] and the States which, in nearly all instances, results in the development of a State plan or plan amendment that can be approved by the Secretary"). Should the parties fail to reach a compromise, New Jersey remains free to challenge the policy guidance in the formal enforcement proceeding, with the right to judicial review. In sum, New Jersey faces no immediate, significant hardship now.[2]

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[2] New Jersey's reliance on *Better Government Ass'n v. Dep't of State*, 780 F.2d 86 (D.C. Cir. 1983), in support of its claim of hardship is misplaced. That case involved challenges to (continued...)

2. New Jersey's claims are not fit for judicial review.

a. Further factual development and administrative action are necessary for this Court's resolution of New Jersey's claims.

In any event, even "claims of hardship will rarely overcome the finality and fitness problems inherent in attempts to review tentative decisions." *DRG Funding Corp. v. Sec'y of HUD*, 76 F.3d 1212, 1215 (D.C. Cir. 1996). As HHS has demonstrated in its opening brief, this case is not fit for judicial review because it is still "nebulous and contingent." *Wyatt, Virgin Islands,* 385 F.3d at 806 (quoting *Public Service Commission v. Wycoff Co., Inc*., 344 U.S. 237, 244 (1952)). As HHS has also shown, further factual development and administrative action are necessary before the case can take on "a fixed and final shape so that a court can see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them." *Id.*; *see also Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 736 (1998) ("And, of course, depending upon the agency's future actions to revise the Plan or modify the expected methods of implementation, review now may turn out to have been

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[2](...continued)
Department of Justice-issued guidelines for evaluating fee wavier requests under the Freedom of Information Act ("FOIA"). The defendant agencies had applied the guidelines to deny plaintiffs' fee waiver requests in the past and had asserted that they intended to continue to apply those guidelines in the future, even though the precise fee waiver denial at issue had been resolved in plaintiff's favor by the time of the appeal. *See id.* at 88, 91, 93. The court found that the case was not moot but was ripe because, among other things, the recurring deprivation of statutorily granted fee waivers had a direct impact on the plaintiff organizations, which relied heavily on such fee waivers in carrying out their public interest missions. *Id.* at 95. New Jersey faces no similar harm here. Moreover, while "no further procedural or substantive evolution [was] expected" in *Better Government*, *id.* at 93, much is still to occur here, including a review of New Jersey's operation of its SCHIP program, a determination of whether the state has complied with SCHIP statutory and regulatory requirements, informal processes designed to resolve outstanding issues, and, if necessary, completion of a formal administrative process allowing New Jersey an opportunity to challenge any initial, adverse agency determination.

unnecessary.").

New Jersey maintains, on the other hand, that this case is fit for judicial review because it raises only "facial" or purely legal claims. In effect, New Jersey is asking this Court to render an advisory opinion because even New Jersey's own submissions confirm that there is a great deal of uncertainty regarding how the policy guidance – as a default standard – will be applied to New Jersey and what potential impact it will have on New Jersey's SCHIP population.

In fact, since the filing of this suit, many of New Jersey's asserted concerns have proven to be unfounded. For example, although New Jersey purportedly read the 12-month uninsurance period – one of the strategies discussed in the August 17 SHO letter to prevent substitution of private insurance for SCHIP benefits ("crowd-out") – as conclusively precluding exceptions (and thus potentially causing undue hardship to some new SCHIP enrollees), *see* Compl. ¶¶ 45-50, CMS has explained that the 12-month uninsurance period is the default standard by which states' plans will be evaluated. CMS's Director of the SCHIP Program informed New Jersey in a February 2008 conversation that "[i]n terms of exceptions to the period of uninsurance, we will review any proposed exceptions and justifications [from New Jersey] in making a determination." E-mail from Kathleen Farrell to Ann Clemency Kohler, Feb. 22. 2008, at 2 [2/22/08 Farrell E-mail] (attached as Ex. D to Kohler Aff.).[3] In a recent letter to state health officials in which CMS shared some of the key issues that have arisen during its discussions with states, CMS further explained that it will consider "alternative proposals" to the 12-month period from states as well as "exceptions for categories of individual enrollees" if the state furnishes

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[3] For purposes of determining this Court's jurisdiction, this Court may consider matters outside the pleadings. *See Turicentro, S.A. v. American Airlines Inc.,* 303 F.3d 293, 300 (3d Cir. 2002).

justifications and data demonstrating a low substitution risk. 5/7/08 SHO ltr. at 2.

In addition, the policy guidance will have no effect on the approximately 124,000 children currently enrolled in New Jersey's FamilyCare program. *See* Ltr. from Susan Cuerdon [Acting Director, Family & Children's Health Programs Group, CMS] ("I want to reaffirm that this guidance was specifically designed to apply to new applicants, rather than to individuals currently served by the program.") (attached as Ex. B to Kohler Aff.); 5/7/08 SHO ltr. at 1. CMS has also reiterated that current enrollees with effective family incomes at or above 250% of the FPL can be grandfathered into the state's current coverage and cost sharing levels, as long as they remain continuously enrolled in the program. *See* 5/7/08 SHO ltr. at 1; Testimony of Dennis Smith before the House Energy & Commerce Subcommittee on Health [1/29/08 Smith Testimony] (attached as Ex. C to Kohler Aff.), at 5 ("the guidance is not intended to affect enrollment, procedures, or other terms for [] individuals [with family incomes in excess of 250% of the FPL] currently enrolled in State programs").

CMS has also explained that the anti- crowd-out procedures described in that letter – including the 12-month uninsurance period and cost-sharing within one percentage point of family income when compared to the cost of private coverage in the group market or set at the five percent family cap – need not be applied to future enrollees with family incomes at or below 250% of the FPL, or to any unborn children. *See* 5/7/08 SHO ltr. at 1-2.

Furthermore, despite New Jersey's claim that it is impossible to achieve 95% enrollment of children in the state below 200% of the FPL who are eligible for either SCHIP or Medicaid, *see* Compl. ¶ 56, CMS has explained that this 95% enrollment goal is achievable if states use appropriate data. *See* 5/7/08 SHO ltr. at 2. Instead of relying purely on national data such as the

Current Population Survey ("CPS"), which undercounts Medicaid participation and includes children who would not be programmatically eligible, CMS is working with New Jersey to determine an available state-specific survey to refine the CPS data.[4] *See* 2/22/08 Farrell E-mail at 1; 5/7/08 SHO ltr. at 2; 1/29/08 Smith Testimony at 4. Based on conversations with states, CMS believes that many states have already reached the 95% enrollment goal. *See* 5/7/08 SHO ltr. at 2; 1/29/08 Smith Testimony at 4.[5]

Finally, consistent with the August 17 SHO letter, CMS has made it clear that the review strategy set forth in that letter is not intended to be binding by itself. Rather, it is a standard

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[4] Although New Jersey complains that it might have to incur the cost and burden of auditing competing private plans to ensure that the SCHIP cost sharing is not more favorable to the public plans by more than one percent of family income, *see* N.J.'s Br. at 21, this concern is speculative at best. While CMS has encouraged New Jersey to work with the state's insurance commission to locate the appropriate data sources, CMS has also informed New Jersey that it is not prescribing what specific data source New Jersey should use. *See* Kohler Aff., Ex. D. CMS, however, has provided New Jersey technical assistance regarding how to calculate the private sector cost sharing and has shared resources regarding state-specific data of private sector health insurance costs. *Id.*

[5] Connecticut and Massachusetts similarly argue in their *amicus* brief that CMS's 95% enrollment goal "asks the impossible" and is tantamount to "a prohibition" on covering children with family incomes over 250% of the FPL. *Amicus Curiae* Br. of Connecticut and Massachusetts at 15-16. At the same time, the *amici* states also acknowledge that CMS staff has made "occasional oral representations" to them suggesting that their programs might satisfy the 95% enrollment goal. *Id.* at 17 n.15. Because "neither state has [yet] received any official communication from CMS on this point," the *amici*'s argument continues, they are put in the "untenable position of hoping that CMS's informal word prevails while still being held to the requirements of the letter." *Id.* The *amici*'s argument proves precisely why resolution of this case is premature at this stage. As CMS has repeatedly urged, the affected states should work with CMS to ensure compliance with statutory and regulatory requirements in a way that is tailored to the unique circumstances of each state, as Rhode Island has done, *see infra*. And with respect to the 95% enrollment goal, the May 7, 2008 SHO letter also makes clear that CMS will work with states in analyzing the appropriate data to use in order to make that determination. Until that happens, it is simply speculative as to what effect, if any, the policy guidance will have on any particular state's SCHIP population or on the states.

against which CMS will be evaluating state plans on a case-by-case basis, taking into account the unique circumstances of each state. "Because State programs (and 1115 demonstrations) vary widely," CMS stated that it "will continue to work with affected States and review requests for alternative approaches on a case-by-case basis" to ensure compliance with existing statutory and regulatory requirements. 5/7/08 SHO ltr. at 1.

CMS's recent discussions with the State of Rhode Island provide a good illustration. In response to submissions of data and assurances by the state, CMS has informed the state that it believes the state currently is in compliance with SCHIP statutory and regulatory requirements, consistent with the August 17 policy guidance. *See* Ltr. from Herb Kuhn, Acting Director of CMS, to Gray Alexander, Director of Rhode Island's Department of Human Services, dated May 9, 2008 (attached as Ex. 2). Specifically, CMS noted that Rhode Island, using data that refines the CPS data, has provided an assurance that the state is meeting the 95% enrollment goal. *Id.* at 1. In addition, CMS also found Rhode Island to have provided an acceptable alternative to the one year uninsurance period. *Id.*

These clarifications and on-going dialogues confirm that the standards set forth in the August 17 SHO letter are not immutable and that it is premature to address New Jersey's challenge to the policy guidance now. As CMS continues to provide technical assistance to the states to "ensure that compliance with statutory and regulatory requirements in a way that is tailored to the unique circumstances of each State," *id.*, it is unclear what, if any, effect the policy guidance will ultimately have on New Jersey's SCHIP population. *See Philadelphia Fed'n of Teachers v. Ridge*, 150 F.3d 319, 324 (3d Cir. 1998) (challenge to statutory amendment to the state's workers' compensation act unripe because there was "a great deal of uncertainty regarding

how the statute will operate against plaintiffs' members"); *Wyatt, Virgin Islands*, 385 F.3d at 807-08 (pre-enforcement action unripe because "the Commissioner's decision on how he would follow up the initial [cease-and-desist] letters" is "inconclusive" and the employer "did not give the Commissioner the chance to proceed on its own grounds" or to reduce the "general policies" into a "concrete order").

Until CMS reviews New Jersey's operation of its SCHIP program and considers – but rejects – any alternatives that may be proposed and justified by New Jersey, judicial review is squarely precluded by the ripeness doctrine, which is designed precisely "to protect the agencies from judicial interference until an administrative decision has been formalized and *its effects felt in a concrete way* by the challenging parties." *Felmeister v. Office of Attorney Ethics*, 856 F.2d 529, 535 (3d Cir. 1988); *see also American Trucking Ass'ns, Inc. v. ICC*, 747 F.2d 787, 790 (D.C. Cir. 1984) (challenge to agency policy statement dismissed as unripe because "concrete results" of adjudications made pursuant to the policy statement "are highly pertinent if not utterly indispensable to resolution of the question" before the court).

b. Review of New Jersey's APA claims is impossible without an administrative record.

The above discussion also makes clear that judicial review is impossible without an administrative record, and contrary to New Jersey's argument, a review of the "historical record" will not suffice. As the Court of Appeals has said, the "principal consideration" in deciding whether an issue is fit for review is "whether the record is factually adequate to enable the court to make the necessary legal determinations." *Artway*, 81 F.3d at 1246-47. New Jersey's APA claims cannot be assessed in the abstract without the context in which the policy guidance was

issued or is applied. To be sure, a review of the SCHIP statute would reveal the indisputable statutory mandate that state plans must ensure that SCHIP coverage extends to only targeted low income children and that SCHIP coverage does not substitute for private insurance. A review of CMS's promulgation of the SCHIP regulations would also reflect that CMS previously had provided only broad guidelines regarding how states can achieve these statutory mandates. *See, e.g.*, 62 Fed. Reg. at 2,493 (for children in families with income above 250% of the FPL, states must have a substitution prevention mechanism in place). Although CMS previously has stated that if monitoring indicated unacceptable levels of substitution CMS "may reconsider the requirements intended to prevent substitution," *id.* at 2,604, without an administrative record, this Court does not have before it a full and formal explanation of the agency's rationale (and supporting data and evidence) for issuing the policy guidance.

For example, the policy guidance was issued because of the trend of states extending SCHIP coverage to an increasingly higher income population, thus crowding out private insurance coverage. *See* Statement of Dennis Smith before Senate Committee on Finance Subcommittee on Health Care, April 9, 2008 ["4/9/08 Smith Testimony"] at 11 (*available at* http://www.senate.gov/~finance/hearings/testimony/2008test/040908dstest.pdf.); 1/29/08 Smith Testimony at 7-8. As a CMS official recently testified in Congress, concerns about substitution were substantiated last year by the Congressional Budget Office ("CBO"), which, after reviewing the volume of research on crowd-out, observed that for every 100 uninsured children covered as a result of SCHIP, there is a corresponding reduction in private coverage of 25 to 50 children. *See* 4/9/08 Smith Testimony at 6 (citing COB, *The State Children's Health Insurance Program*, May 2007 at VIII-IX); *see also* 1/29/08 Smith Testimony at 7 (noting data regarding decline of

children covered by private insurance). The policy guidance discussed strategies developed in the course of ten years of SCHIP operations, which CMS believes should be included when expanding eligibility to effective family income levels above 250% of the FPL. *See* 5/7/08 SHO ltr. at 1; 8/17/07 SHO ltr. at 1.

Moreover, the policy guidance is also intended to address the concern that expansion of SCHIP eligibility to higher income levels could interfere with the overall effective and efficient provision of coverage, coordinated with other sources of health benefit coverage, to core SCHIP populations. *See* 5/7/08 SHO ltr. at 1; 8/17/07 SHO ltr. at 1. Thus, the policy guidance asks the states to ensure that they have reached the core targeted low income population before extending SCHIP coverage to children in higher income levels not foreseen by Congress. *See* 4/9/08 Smith Testimony at 11.

No formal documentation of these policy considerations or the relevant practical experience CMS has gained in administering the SCHIP program are before this Court. There is no administrative record to set forth more fully the agency's reasons for issuing the policy guidance or, more importantly, how the guidance is to be applied to New Jersey's unique circumstances; instead, that remains to be worked out between New Jersey and CMS. *Cf. Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 163-164 (1967) (rejecting as unripe challenge to a regulation based on statutory authority to promote "efficient enforcement," given that such a challenge "will depend not merely on an inquiry into statutory purpose," but on an understanding of "what types of enforcement problems are encountered" under the statute). There are only "abstract disagreements over administrative policies." *Abbott Labs.*, 387 U.S. at 148-49. Given that "[t]he focal point for judicial review" in APA actions is "the administrative record already in

existence, *not some new record made initially in the reviewing court*," *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (emphasis added); *accord NVE, Inc. v. HHS*, 436 F.3d 182, 189 (3d Cir. 2006); *Horizons Int'l, Inc. v. Baldrige*, 811 F.2d 154, 162 (3d Cir. 1987), this Court would face the practical problem of deciding in a vacuum whether the policy guidance is arbitrary and capricious and contrary to the statutory scheme, and whether, contrary to HHS's explicit statements, the agency intends to use the guidance as a series of binding, substantive requirements, as New Jersey claims.[6]

The cases on which New Jersey relies primarily are cases in which the agency had concededly issued orders or regulations following notice and comment and had compiled an administrative record for the orders and regulations themselves which was available for judicial review. *See, e.g.,* N.J. Br. at 26 (citing *Mountain States Tel. & Tel. Co. v. FCC*, 939 F.2d 1035

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[6] New Jersey acknowledges that in determining whether any agency action is contrary to law, or arbitrary or capricious under the APA, the court must determine whether "'the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" N.J. Br. at 25 (quoting *Motor Vehicle Mfr. Ass'n v. State Farm Ins.*, 463 U.S. 29, 44 (1983)). As New Jersey also recognizes, the reviewing court "may not supply 'a reasoned basis' for the agency's action that the agency itself has not given." N.J. Br. at 25 (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43). Moreover, this Court must uphold an agency decision "of less than ideal clarity if the agency's path may reasonably be discerned" from the administrative record. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. Finally, even if the agency action represents a departure from past practice, as New Jersey claims that the policy guidance does, this Court similarly must uphold the agency action "so long as [the agency] can justify its change with a 'reasoned analysis.'" *Time Warner Telecom., Inc. v. FCC*, 507 F.3d 205, 221 (3d Cir. 2007). In the absence of an administrative record, none of these analyses is possible now. Nor most crucially, is it possible to discern how the agency will use the policy guidance in evaluating New Jersey's (and other states') compliance with SCHIP statutory and regulatory requirements. The only thing that is clear (from both the August 17, 2007 and May 7, 2008 SHO letters) is that the agency does not intend to use the guidance in the August 17 letter as establishing bedrock requirements with no individual state explanation or variation of conduct allowed.

(D.C. Cir. 1991) (reviewing orders which "[were] the product of four years of consideration and study by the FCC through extensive notice and comment rulemaking proceedings, and the FCC [had] not suggested in the rulings themselves, or even in its effort to avoid [the court's] review, that its views on these subjects [were] open to modification")).

For example, *National Ass'n of Home Builders v. Army Corps of Eng'rs*, 417 F.3d 1272, 1276 (D.C. Cir. 2005), upon which New Jersey relies heavily, involved challenges to the agency's issuance, following notice and comment, of nationwide permits that were designed to minimize delays and paperwork for projects with minimal environmental impact. Although a regulated entity could pursue an individual permit free of the restrictions in the general permit, *id.* at 1279, the court found the case ripe because "[t]he administrative process has run its course," *id.* 1283, and "[a]ll of the facts necessary for judicial review were before the Corps when it issued the permits." *Id.* at 1282. "[O]n APA review, [the agency's] action necessarily stands or falls on that administrative record and its statutory permitting authority under the [governing statute]." *Id.*

Similarly, in *Fox Television Stations v. FCC*, 280 F.3d 1027, 1035 (D.C. Cir. 2002), another case New Jersey cited, the agency rules on ownership under challenge had been subjected to a Notice of Inquiry seeking comments on all ownership rules. Congress had also directed that the agency complete all reply comments within a certain time frame and issue a report to explain its actions should it decide to retain any of the rules under review. *Id.* at 1036. The agency ultimately issued such a report. *Id.* at 1038. The court held that the agency decision to retain certain rules constituted a final agency action, and based on administrative record before it, the court was able to decide whether the FCC's determination was arbitrary and capricious and

whether the challenged rules violated the First Amendment. *Id.* at 1039.

Of course, even when there is an administrative record for review and the issues are purely legal, the fitness inquiry is far from over. Two cases upon which New Jersey relied for the proposition that its claims are purely legal illustrate this point. In *Atlantic States Legal Found. v. EPA*, the court held that challenges to the regulations implementing a pilot program were not ripe, even if purely legal, because many potential developments would likely assist the court in deciding the case, and "we need to wait for a rule to be applied to see what its effect will be." 325 F.2d 281, 285 (D.C. Cir. 2002). Similarly, in *Ohio Forestry Ass'n, Inc. v. Sierra Club*, the Supreme Court held that immediate judicial review of a Forest Service management plan was unripe, in part because judicial review "could hinder agency efforts to refine its policies: (a) through revision of the Plan, *e.g.,* in response to an appropriate proposed site-specific action that is inconsistent with the Plan, or (b) through application of the Plan in practice, *e.g.,* in the form of site-specific proposals, which are subject to review by a court applying purely legal criteria." 523 U.S. 726, 735 (1998).

In any event, because CMS has chosen to apply the policy guidance in the adjudicatory process on a case-by-case basis, as it is within its discretion to do,[7] there is no administrative

[7] "[I]t is a basic tenet of administrative law that agencies have some discretion to choose between adjudication and rulemaking when interpreting statutes and regulations committed to their authority." *Beazer East, Inc. v. EPA*, 963 F.2d 603, 609 (3d Cir. 1992); *SEC v. Chenery Corp*, 332 U.S. 194, 202-03 (1947) (recognizing that the choice "lies primarily in the informed discretion of the administrative agency"); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 292-94 (1974) (same); *see also W. Va. v. Thompson*, 475 F.3d 204, 210 (4th Cir. 2007) (recognizing agency's authority to choose adjudication rather than rulemaking in context of CMS administrator's review of Medicaid state plan amendment); *Alaska Dep't of Health & Social Servc. v. CMS*, 424 F.3d 931, 939 (9th Cir. 2005) (same). This is so because a contrary rule would "stultify the administrative process, ignoring the benefits of adjudicatory development that

(continued...)

record for this court's review now. The practical result of CMS's choice to proceed by adjudication here is that "[w]hen the agency applies the policy in a particular situation, it must be prepared to defend it, and cannot claim that the matter is foreclosed by the prior policy statement." *Matter of Seidman*, 37 F.3d 911, 931 (3d Cir. 1994). Assuming any statutory or regulatory compliance issues (if they ever arise) are not resolved informally during the administrative process, both CMS and New Jersey would be entitled to present evidence in support of their positions, ultimately yielding a final agency decision that is grounded in a complete evidentiary record suitable for judicial review. *See* 42 U.S.C. § 1316(a)(3) (contemplating judicial review of plan-conformity decisions based on "the record of the proceedings on which [the HHS Secretary] based his determination"); 42 C.F.R. § 457.208(b)(2) (requiring CMS Administrator to file such record where his determination is appealed).

Deciding this case before either the informal review or the formal adjudicatory process has taken place would expose this Court to "two equally unattractive alternatives" – *i.e.*, to either "review the [policy guidance] in a vacuum" or to consider the impact of the challenged August 17 policy guidance "upon all the possible factual situations which could develop." *See American Iron & Steel Institute v. EPA*, 543 F.2d 521, 528 (3d Cir. 1976) (declining review until regulations were applied in a permit proceeding). This Court should – and under controlling authority must – decline to pursue either option.[8]

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[7](...continued)
have led courts to recognize a very definite place for the case-by-case evolution of statutory standards." *W. Va. v. Thompson*, 475 F.3d at 210.

[8] And, as noted, here New Jersey is seeking review of a letter (rather than regulations), which it claims, in the absence of any application or context, will inevitably yield certain results.

3. **New Jersey's rulemaking claim is not ripe**.

HHS recognizes that its own characterization of the policy guidance is not necessarily dispositive on the question of whether the policy guidance should have been subjected to the APA's notice and comment requirements. Also, in appropriate circumstances, a reviewing court may be able to assess a procedural rulemaking claim based purely on the language of the interpretative rule under challenge. But as the D.C. Circuit has said, "often . . . an early procedural challenge to a purported policy statement on the ground that it is actually a legislative rule is not ripe because it is not yet demonstrable that the agency intends to treat it as having the characteristics of a rule." *Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 215 n.5 (D.C. Cir. 2007) (*quoting Hudson v. FAA*, 192 F.3d 1031, 1034-35 (D.C. Cir. 1999)).

Here, New Jersey's rulemaking challenge – which depends on whether the policy guidance is legally binding – at a minimum is not ripe but must await further development. CMS's statement that it would consider alternatives to the review strategy set forth in the policy guidance on a case-by-case basis, as the CMS Administrator undoubtedly is entitled to do, 42 C.F.R. § 457.150(c), confirms that the policy guidance has no binding effect. *See* 5/7/08 SHO ltr. Even if there is any doubt, only the agency's concrete applications will tell whether the policy guidance is treated to have the force of law. *See Pub Citizen v. U.S. Nuclear Regulatory Comm'n*, 940 F.2d 679, 683 (D.C. Cir. 1991) ("Where . . . the agency's practical application of a statement would be important, we have found the issue [whether notice and comment was required to promulgate the statement] not ripe. The judicial process would clearly gain by waiting for a concrete application.") (citations omitted); *National Ass'n of Regulatory Util. Comm'rs v. Dep't of Energy*, 851 F.2d 1424, 1430 (D.C. Cir. 1988) (finding notice-and-comment

challenge unripe where effect of statement "may well be clarified" in upcoming agency action).

In any case, the ripeness analysis includes more than simply whether New Jersey's rulemaking claim is purely legal. Here, among other problems of premature review, judicial review of the claim now would lead to inefficient use of judicial resources through piecemeal litigation, *McGee v. United States*, 402 U.S. 479, 484 (1971); *McKart v. United States*, 395 U.S. 185, 195 (1969), and may in the end turn out to have been entirely unnecessarily, *see Ohio Forestry Ass'n*, 523 U.S. at 732-33 (case not ripe because "depending upon the agency's future actions to revise the Plan or modify the expected methods of implementation, review now may turn out to have been unnecessary").

Thus, for example, in *National Ass'n of Regulatory Utility Com'rs v. Dep't of Energy*, the court found a rulemaking challenge to the agency's cost allocation methodology announced in an agency notice not ripe because the effect of the methodology was "open to doubt and may well be clarified" when a certain government report issues. 851 F.2d 1424, 1430 (D.C. Cir. 1988). Specifically, the court had found the plaintiff's substantive challenge not ripe because the agency had not applied the challenged cost allocation method in a way that would allow the court "to consider, by examining its 'concrete effects and implications,' whether it is consistent with the Act." *Id.* at 1429. There was therefore "a genuine interest in postponing review of petitioners' procedural claim, too." *Id.* at 1430. As the Court found, "judicial economy favors considering all challenges to the Department's methodology, both substantive and procedural, in one proceeding." *Id.* Similarly here, even if New Jersey's rulemaking claim is deemed purely legal, this Court should postpone review of that procedural challenge until there is concrete application of the policy guidance and until the effect of the policy guidance is known.

Cement Kiln Recycling Coalition, 493 F.3d at 215, cited by New Jersey, is inapposite. There the plaintiffs made several substantive and procedural challenges to a guidance document issued by the EPA, including (1) that the guidance did not spell out the information that will be required in a permit application contrary to the requirement under the Resource Conservation and Recovery Act ("RCRA") that permit applications shall contain such information as may be required under regulations promulgated by the EPA; (2) that contrary to RCRA, the guidance failed to define with sufficient specificity when a site-specific risk assessment would be required; and (3) that the guidance should have been, but was not, promulgated pursuant to the APA's notice-and comment requirements. *See id.* at 214-15. The court found preenforcement review appropriate because the challenge to the guidance could be determined on the face of the document and would not depend on the way in which the document will be applied. *See id.* at 215; *see also id.* at 216 ("Where we believed the agency's practical application of a statement would be important, we have found the issue not fit for judicial determination.").

The same is not true here. The issues in *Cement Kiln* were on their face purely legal. Also, under the RCRA, Congress had specifically authorized preenforcement view of "action of the EPA in promulgating any regulation or requirement under [RCRA]." *Id.* at 214 and 215 n.3.[9] A showing of hardship or actual application was thus unnecessary, and the plaintiff Coalition thus had specifically disavowed its intention to rely on how the guidance has been or will be

[9] *Cf. Ohio Forestry Ass'n*, 523 U.S. at 737 (finding that a challenge to a Forest Service management plan was unripe, in part because "Congress has not provided for preimplementation judicial review of forest plans" under the National Forest Management Act, in contrast to other statutes, like RCRA). As discussed in HHS's opening brief (at 33 n.7), when Congress intends to authorize pre-enforcement review, it does so explicitly. The RCRA is one of many examples HHS cited in its opening brief.

applied to particular facilities – an option that was available under the statutory scheme, even if it "create[d] a significant obstacle to the success of the Coalition's challenge." *Id.* at 216.

New Jersey does not have that option here. It is seeking to enjoin the very application of the policy guidance to New Jersey and its claims are not purely legal. Moreover, as discussed *infra*, the SCHIP statutory scheme does not permit preenforcement review of potential plan conformity disputes. In sum, New Jersey's claims are not ripe and this Court should dismiss the action.

B. Judicial Review Under the APA Is Improper Because Review Under the SCHIP Statutory Scheme Constitutes An "Adequate Remedy In A Court" and Such Review Is Exclusive

In its opening brief, HHS demonstrated that even if the policy guidance is deemed a "final agency action" – which, under the Supreme Court's decision in *Standard Oil*, 449 U.S. 232, it clearly is not – New Jersey is not entitled to judicial review under the APA because New Jersey has an "adequate remedy in a court." 5 U.S.C. § 704. The SCHIP statute specifically allows New Jersey to seek judicial review in the regional court of appeals if the Administrator finds New Jersey's plan to be in substantial noncompliance with federal requirements. *See* 42 U.S.C. § 1316(a); *see also* 42 C.F.R. § 457.208(a). Moreover, as HHS has also demonstrated, under the Supreme Court's controlling precedent, *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207-09 (1994), New Jersey cannot avoid the statutorily mandated administrative and judicial review process by rushing to the district court for an injunction to prevent that review process from occurring.

In response, New Jersey argues that judicial review under the SCHIP statute is inadequate because of "the timing of review" – it requires New Jersey to first pursue the administrative

process, potentially exposing New Jersey to the "loss of all of the state's SCHIP funding." N.J.'s Br. at 37. Again characterizing its claims as "facial challenges," New Jersey further argues that judicial review under the SCHIP statute is not intended to address such challenges but is limited to plan conformity disputes.

New Jersey is wrong on both counts. The mere possibility that New Jersey might not prevail in the administrative proceeding and that sanctions might be imposed before it can obtain judicial review in the Court of Appeals does not render the available statutory review scheme inadequate. Were it otherwise, parties would always be able to evade administrative exhaustion requirements by calling their unripe challenges to agency action "facial challenges." As HHS has already demonstrated in its opening brief, for purposes of determining whether APA review is appropriate, it is well established that the opportunity for judicial review at the conclusion of a statutorily prescribed review process constitutes an "adequate remedy in a court" barring judicial review under the APA. The same is true even if the SCHIP statutory review scheme is deemed not as effective as review under the APA or is procedurally inconvenient for New Jersey. *American Disabled for Attendant Programs Today v. HUD*, 170 F.3d 381, 390 (3d Cir. 1999) ("section 704 does not require an equally effective remedy, only an adequate one"); *Turner v. Secretary of HUD,* 449 F.3d 536, 541 (3d Cir. 2006) ("A legal remedy is not inadequate for purposes of the APA because it is procedurally inconvenient for a given plaintiff . . .").

In the event that CMS finds New Jersey to be noncompliant after all negotiations are concluded, New Jersey will be able to raise in the Court of Appeals the same challenges to the policy guidance it attempts to raise here; *i.e.,* that the policy guidance was used as a substantive rule which should have been promulgated through notice and comment rulemaking, and that the

guidance is arbitrary, capricious and contrary to the SCHIP statute and implementing regulations.[10] In fact, the Court of Appeals would also review the adverse agency action under essentially the same standard of review in an APA action, and may similarly remand the case to the Administrator to take further evidence. *See* 42 U.S.C. § 1316(a)(4) (requiring appeals court to accept the agency's findings of fact if supported by "substantial evidence"); *Memorial Hosp./Adair County Health Ctr., Inc. v. Bowen*, 829 F.2d 111, 117 (D.C. Cir. 1987) (explaining that "substantial evidence" test entails same level of scrutiny as "arbitrary and capricious" test); 5 U.S.C. § 706(2)(A), (E).

New Jersey argues that "[n]owhere does Section 1316(a) state that it is the 'exclusive' method for challenging HHS rules and regulations," N.J. Br. at 38, noting in particular that in two of the cases HHS cited – *FCC v. ITT World Commc'ns, Inc.*, 466 U.S. 463, 468 (1984), and *Yi v. Maugans,* 24 F.3d 500, 507 (3d Cir. 1994) – Congress specified that the statutory review scheme at issue was exclusive. However, the law is clear that "[if] Congress specifically designates a forum for judicial review of administrative action, such a forum is exclusive, and this result does not depend on the use of the word 'exclusive' in the statute providing a forum for judicial review." *Getty Oil Co. v. Ruckelshaus*, 467 F.2d 349, 356 (3d Cir. 1972); *see also United States v. Troup,* 821 F.2d 194, 198 (3d Cir. 1987); *Cost Control Mktg. & Mgmt., Inc. v. Pierce*, 848 F.2d 47, 49 (3d Cir. 1988).

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[10] New Jersey argues that the two cases HHS cited in support of this proposition – *W. Va. v. Thompson*, 475 F.3d 204, 210 (4th Cir. 2007), and *Pennsylvania v. HHS*, 723 F.2d 1114, 1118 (3d Cir. 1984) – did not address the question of whether facial challenges can be brought in the district court under the APA. *See* NJ's Br. at 36 n.4. While that may be true, it is irrelevant to the proposition for which HHS cited them, which is that New Jersey will be able to raise in the Court of Appeals its procedural, rulemaking challenge – as did the plaintiff in *W. Va. v. Thompson* – and its substantive challenge – as did the plaintiff in *Pennsylvania v. HHS*.

Moreover, when there *is* a specific statutory grant of jurisdiction to the court of appeals, the presumption is in favor of court of appeals review. *See Natural Resources Defense Council v. Abraham*, 355 F.3d 179, 193 (2d Cir. 2004); *National Parks & Conservation Ass'n v. FAA,* 998 F.2d 1523, 1529 (10th Cir. 1993) ("[i]f there is any ambiguity as to whether jurisdiction lies with a district court or with a court of appeals we must resolve that ambiguity in favor of review by a court of appeals"); *Gen. Elec. Uranium Mgmt. Corp. v. Dep't of Energy,* 764 F.2d 896, 903 (D.C. Cir. 1985) (same); *Ind. & Mich. Elec. Co. v. EPA,* 733 F.2d 489, 491 (7th Cir. 1984) (invoking "the judge-made presumption in favor of court of appeals review in doubtful cases"); *see also TRAC v. FCC*, 750 F.2d 70, 78-79 (D.C. Cir. 1984) (request for relief in district court that might affect Court of Appeals' future, exclusive jurisdiction is subject to the exclusive review of the court of appeals).

In *Thunder Basin*, the Supreme Court was similarly confronted with a statutory scheme (the Mine Act) that permitted court of appeals review but did not say that the review scheme was exclusive. The plaintiff there brought a preenforcement challenge to an agency regulation in the district court seeking to enjoin the agency from enforcing the regulation against it. Like New Jersey here, the plaintiff claimed that it would be irreparably harmed if it complied with the regulation and would face stiff civil penalties if it did not. 510 U.S. at 205-207. The Supreme Court held that the district court lacked subject matter jurisdiction to entertain the plaintiff's challenge. *Id*. at 209. As the Court explained:

> Petitioner's claims are "pre-enforcement" only because the company sued before a citation was issued, and its claims turn on a question of statutory interpretation that can be meaningfully reviewed under the Mine Act. Had petitioner persisted in its refusal to [comply with the regulation at issue], the Secretary

> would have been required to issue a citation and commence enforcement proceedings. Nothing in the language and structure of the Act or its legislative history suggests that Congress intended to allow mine operators to evade the statutory-review process by enjoining the Secretary from commencing enforcement proceedings, as petitioner sought to do here. To uphold the District Court's jurisdiction in these circumstances would be inimical to the structure and the purposes of the Mine Act.

Id. at 216. As in *Thunder Basin*, New Jersey cannot avoid the review scheme provided in the SCHIP statute. In fact, New Jersey's claim is even weaker here than the claim in *Thunder Basin* because HHS does not assert that the challenged SHO letter has the effect of a regulation – a claim not disputed even in *Thunder Basin*.

To allow New Jersey to proceed in this Court would also potentially create two tracks of judicial review – one under the APA in the district court and the other under Section § 1316 in the court of appeals. Besides the risk of inconsistent results, that would be contrary to Congress' provision of a comprehensive administrative and judicial review under the SCHIP statute. *Cf. Great Plains Coop v. Commodity Futures Trading Comm'n,* 205 F.3d 353, 355 (8th Cir. 2000) (plaintiff's preenforcement challenge "is an impermissible attempt to make an 'end run' around the statutory scheme" and "would create two avenues of judicial review and would allow the plaintiff to short-circuit the administrative review process and the development of a detailed factual record by the agency").

In other words, artful characterization of unripe challenges does not suffice to short-circuit the statutory review scheme. In *Solar Turbines Inc.,* 879 F.2d at 1077, the plaintiff sought to enjoin preenforcement an EPA administrative order that, if ripe, would be reviewable under the Clean Air Act. The plaintiff contended that the statutory review scheme was not applicable

because it was "seeking to enjoin plainly ultra vires EPA action under constitutional, [APA], and common law principles." The Third Circuit held that despite plaintiff's "attempt to characterize its claims otherwise, it [was] evident that [the plaintiff's] district court action in fact [sought] to challenge the merits of EPA's position under the Clean Air Act." *Id.* at 1077.

The same is true here. New Jersey's claims, at bottom, are about whether CMS has the statutory authority to apply the policy guidance to New Jersey in an enforcement proceeding; in fact, New Jersey seeks to enjoin that very enforcement proceeding – and even the preliminary steps that might lead to an enforcement proceeding – from occurring. And, as the Third Circuit has noted, "[t]he limited legislative history confirms that section 1316(a) review [in the regional court of appeals] should be available to resolve disputes over whether a federal agency action is consistent with the intent of the federal statute." *Pennsylvania v. HHS*, 723 F.2d 1114, 1118 (3d Cir. 1984) (citing 111 Cong. Rec. 3067-68 (1965) (remarks of Sen. Javits). New Jersey cannot bypass that review scheme simply by casting its claims differently. *Cf. Massieu v. Reno*, 91 F.3d 416, 424 (3d Cir. 1996) (alien challenging the constitutionality of the statute under which his deportation was being sought must first exhaust his administrative remedies and then petition for review in the Court of Appeals; "[a]lthough plaintiff would prefer to have his claim heard by this court now rather than after the conclusion of the administrative process, we cannot upset the scheme created by Congress to provide plaintiff with a faster decision").

By the same token, New Jersey cannot separate its procedural challenge – that the policy guidance should have been subjected to the APA's notice-and-comment requirements – from its substantive challenges in order to obtain faster review. *Heckler v. Ringer*, 466 U.S. 602, 614 (1984), is illustrative of this point. In that case, the Supreme Court held that the plaintiffs there –

who were challenging the Secretary's alleged failure to comply with the rulemaking requirements of the APA in issuing certain Medicare instructions and a rule – could not separate their claims into "substantive" and "procedural elements" in order avoid statutory exhaustion requirements because their claims, at bottom, were that they should be paid for the medical procedure at issue.

In sum, New Jersey's various claims – substantive or procedural, facial or otherwise – must be brought pursuant to the statutorily mandated review scheme. This Court cannot look elsewhere (*e.g.,* to the APA) to find authority for its intervention now.

II. CMS'S POLICY GUIDANCE IS NOT SUBJECT TO THE NOTICE AND COMMENT PROCESS

In its opening brief, HHS demonstrated that even if this Court has jurisdiction to review New Jersey's procedural challenge to the August 17 policy guidance, New Jersey cannot succeed because the policy guidance is merely an interpretative rule or a general statement of policy, not subject to the APA's notice and comment requirements. 5 U.S.C. § 553(b). As noted before, the policy guidance is an interpretative rule because it advises the states as to how CMS intends to review state plans in the future to ensure compliance with existing SCHIP statutory and regulatory requirements, including the requirement that state plans contain "reasonable procedures" to prevent crowd out. *See Central Texas Tel. Co-op, Inc. v. FCC*, 402 F.3d 205, 214 (D.C. Cir. 2005) ("an agency may use an interpretive rule to transform a vague statutory duty or right into a sharply delineated duty or right"). The policy guidance also includes strategies developed in the course of ten years of SCHIP operation, *see* 5/7/08 SHO Ltr. at 1, which is what an interpretative rule is designed to do, *see Sekula v. FDIC*, 39 F.3d 448, 457 (3d Cir. 1994) ("Interpretative rules constitute a body of experience and informed judgment to which courts and

litigants may properly resort for guidance.").

New Jersey has cross-moved for partial summary judgment on this issue,[11] arguing that the policy guidance effected a "fundamental modification" of an existing interpretation such that the agency was required to go through the notice and comment process. Indeed, the Supreme Court has held that if an interpretative rule "adopted a new position inconsistent with any of the Secretary's existing regulations," then the APA's rulemaking process would be required. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995) . But there is no such fundamental change, nor is the policy guidance inconsistent with existing regulations. As HHS demonstrated in its opening brief, all that the August 17 SHO letter does is to expand on CMS's prior policy guidance regarding the requirement in 42 C.F.R. § 457.805 that a state plan must include "reasonable procedures" to prevent crowd out. Previously, CMS said that if a state expands SCHIP coverage above 250% of the FPL, it "must have a substitution prevent mechanism in place." 62 Fed. Reg. at 2,493. Now the August 17 SHO letter advises the states what specific crowd-out strategies CMS expects to see in the state plan for those future enrollees with family

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[11] In support of its cross motion, New Jersey has submitted a statement of material facts as to which no genuine issue exists. In an APA case, the Court generally does not determine whether facts are undisputed to rule on summary judgment; rather, it reviews the material facts set forth in the administrative record to ascertain whether as a matter of law the evidence permits the agency to make its decision. *See NVE*, 436 F.3d at 189 (recognizing that "APA's rule that judicial review of administrative action is limited to the administrative record"); *Horizons Int'l, Inc.,* 811 F.2d at 162 (describing review of the existing administrative record as one of "the traditional limits of judicial review applied under section 10 of the APA"). New Jersey's submission of a statement of material facts, therefore, cannot substitute for the lack of an administrative record, much less any final agency action for this Court to review. In any event, as defendant stated in response to plaintiff's statement of material facts not in dispute, the "materials facts" listed by plaintiff are either characterizations or selected quotations from statutes, regulations, or the August 17, 2007 SHO letter itself. Rather than "material facts," they are immaterial to the legal issues the Court must decide and/or are disputed.

incomes above 250% of the FPL. And there can be no dispute that "[a] rule does not . . . become an amendment because it supplies crisper and more detailed lines than the authority being interpreted." *American Mining Cong. v. Mine Safety & Health Admin.,* 995 F.2d 1106, 1112 (D.C. Cir. 1993).

That CMS previously has approved state plans containing different crowd-out procedures simply means that CMS's sub-regulatory practice regarding crowd-out strategies has changed. That is insufficient to trigger the APA's notice and comment process. For example, in *SBC v. FCC*, 414 F.3d 486, 499 (3d Cir. 2005), the Third Circuit held that the FCC's elimination of a "functional equivalence" test for a competitive carrier to recover certain tandem interconnection rate was not a legislative rule, even though the FCC's prior guidance had used the test and some state commissions have so interpreted that prior guidance. As the court noted, the only regulation on the question "says nothing about requiring the other carrier to satisfy a functional equivalency test." *Id.* Similarly here, CMS's August 17 SHO letter is simply providing fuller guidance of the term "reasonable procedures."

New Jersey also argues that not only is the language of the policy guidance binding on its face, but CMS's subsequent course of conduct allegedly indicates CMS's intent to treat the policy guidance as having the force of law. New Jersey points to the following information: (1) a follow-up letter from CMS indicating CMS's intention to work with New Jersey to implement appropriate procedures to ensure compliance with the policy guidance and asking that the state contact the Director of the Division of State Children's Health Insurance, Kathleen Farrell, to set up a telephone conference; (2) Farrell's e-mail confirming the parties' discussions during that telephone conference; and (3) the former CMS Director's congressional testimony in which he

stated that "the 95 percent goal is not only achievable, but should be expected and demanded." Kohler Aff. ¶¶ 39-47, and Ex. B, C, and D. New Jersey argues that "at no point, outside the context of this litigation, has CMS indicated that the requirements of the Letter . . . might be modified." N.J. Br. at 30. Thus, according to New Jersey, the policy guidance forecloses alternative courses of action and conclusively affects the rights of all parties. *Id.* at 43. New Jersey is wrong.

In determining whether an agency statement is a substantive rule or a policy statement, "the ultimate issue is 'the agency's intent to be bound.'" *Public Citizen, Inc. v. U.S. Nuclear Regulatory Comm'n*, 940 F.2d 679, 682 (D.C. Cir. 1991) (quoting *Vietnam Veterans v. Secretary of the Navy*, 843 F.2d 528, 538 (D.C. Cir. 1988). In this regard, the Third Circuit has instructed that the agency's characterization of its rule as an interpretative rule "in itself is entitled to a significant degree of deference." *SBC*, 414 F.3d at 495; *see also New Jersey v. HHS*, 670 F.2d 1282 (3d Cir. 1981); *Cerro Metal Products v. Marshall*, 620 F.2d 964, 981 (3d Cir. 1980).

Here, not only does the policy guidance itself suggest that it is merely a "review strategy" whose effect and scope will depend on future applications, but CMS has so confirmed since the policy guidance was issued. New Jersey's submissions in this case support that CMS is working with New Jersey to determine the policy guidance's appropriate application to New Jersey's individual circumstances. Consistently, CMS also stated in its May 7, 2008 SHO letter that it is "working with States to ensure compliance with statutory and regulatory requirements "in a way that is tailored to the unique circumstances of each state." 5/7/08 SHO ltr. at 1. More importantly, "[b]ecause State programs (and 1115 demonstrations) vary widely," CMS noted that it "will continue to work with affected States and review requests for alternative approaches on a

case-by-case basis to ensure compliance with these existing requirements of law." *Id.* at 2. In other words, while the policy guidance "may change the way in which the parties present themselves to the agency," *SBC, Inc.*, 414 F.3d at 497, it does not "foreclose alternate courses of action or conclusively affect rights of private parties." *FLRA v. Dep't of Navy*, 966 F.2d 747, 762 -763 n.14 (3d Cir. 1992) (*en banc*). As such, it has no present effect and is a non-binding action not subject to the APA's notice and comment requirements.

CONCLUSION

For all the foregoing reasons, this Court should grant HHS's motion to dismiss and deny plaintiff's cross motion for partial summary judgment.

Dated: May 9, 2008

Respectfully submitted,

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EXHIBIT 1

CMSDEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

MAY 07 2008

SHO #08-003

Dear State Health Official:

In our August 17, 2007 letter to State Health Officials, we discussed our review strategy for ensuring compliance with existing requirements under the State Children's Health Insurance Program (SCHIP) established under title XXI of the Social Security Act (Act) for the effective and efficient provision of child health assistance coordinated with other sources of health benefits coverage. In working with States to ensure compliance with statutory and regulatory requirements in a way that is tailored to the unique circumstances of each State, we have learned that some States were unclear about our approach. This letter addresses some of the key issues that have arisen during those discussions.

In the August 17 letter, we discussed the need to minimize the substitution of SCHIP coverage for private coverage ("crowd-out") at higher income levels in accordance with existing statutory and regulatory requirements. We discussed our review strategy for evaluating State compliance with requirements under 2102(b)(3)(C) of the Act and with regulations at 42 C.F.R. 457.805 for reasonable crowd-out procedures when States expand eligibility to effective family income levels above 250 percent of the Federal poverty level (FPL) to include some strategies developed in the course of ten years of SCHIP operation. We also set forth our concern that expansion to higher income levels could interfere with the overall effective and efficient provision of coverage, coordinated with other sources of health benefits coverage, to core SCHIP populations. We indicated that we would ask States to make assurances related to this concern, based on data concerning coverage of lower income children.

In our prior letter, we stated that we would "not expect any effect on current enrollees" from the review strategy announced in the letter. Nevertheless, a number of States who currently provide coverage to children above 250 percent of the FPL and are working to comply with the letter have expressed concern about the effect on current enrollees. We reiterate that any changes made to a State's crowd-out procedures in response to the August 17 letter need not be applied to prior enrollees. These children can be grandfathered into the State's current coverage and cost sharing levels, as long as they remain continuously enrolled in the program.

Some affected States have asked whether the crowd-out procedures described in our prior letter – in particular, the 12-month uninsurance period and cost-sharing within one percentage point of family income when compared to the cost of private coverage in the group market or set at the five percent family cap–should be applied to all enrollees or only those enrollees with effective family incomes above 250 percent of the FPL. Because our heightened concern about increased substitution risk applies to higher income levels, such crowd-out procedures need not be applied

to enrollees with effective family incomes at or below 250 percent of the FPL. However, States do have the option to apply these crowd-out procedures to enrollees with family incomes at or below 250 percent of FPL as part of efforts to ensure that SCHIP coverage does not substitute for private coverage. States do not have to use crowd out procedures when covering children at any level of income solely with their own funds.

In our prior letter, we did not address the special circumstance of unborn children. Because of the unique importance of timely prenatal care, we would not expect States to apply crowd-out procedures to SCHIP coverage for unborn children.

The 12-month period of uninsurance is the standard by which States will be evaluated. However, CMS will review alternative proposals from States, and the justifications for them. We will also consider exceptions for categories of individual enrollees (based on particular circumstances) if the State furnishes justifications and data demonstrating a low substitution risk.

The assurance that at least 95 percent of children in the State with family incomes below 200 percent of the FPL have coverage can be supported by data demonstrating Medicaid, SCHIP or private coverage. This is an achievable goal and based on conversations with States, we are convinced that a number of States have already reached this goal. We will continue to work individually with affected States on different approaches to document this assurance, including the use of state-specific survey data or other data sources to refine the underlying Current Population Survey (CPS) data.

The purpose of the crowd-out procedures and assurances discussed in the August 17th letter is to ensure compliance with existing regulatory requirements by reasonably protecting against crowd-out and otherwise ensuring the effective and efficient operation of the SCHIP program in serving the most vulnerable low-income populations, when coverage is extended to populations with higher income levels. Because State programs (and 1115 demonstrations) vary widely, we will continue to work with affected States and review requests for alternative approaches on a case-by-case basis to ensure compliance with these existing requirements of law.

If you have any questions regarding this guidance, please contact Ms. Kathleen Farrell, Acting Director, Family and Children's Health Programs Group, who may be reached at (410) 786-1236.

Sincerely,

Herb B. Kuhn
Deputy Administrator
Acting Director, Center for Medicaid and State Operations

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
Division of Medicaid and Children's Health

Barbara Edwards
NASMD Interim Director
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Debra Miller
Director for Health Policy
Council of State Governments

Christie Raniszewski Herrera
Director, Health and Human Services Task Force
American Legislative Exchange Council

Barbara Levine
Director of Policy and Programs
Association of State and Territorial Health Officials

EXHIBIT 2

DDEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

MAY - 9 2008

Mr. Gary D. Alexander
Director
Department of Human Services
600 New London Avenue
Cranston, RI 02920

Dear Mr. Alexander:

Thank you for submitting information and data supporting Rhode Island's compliance with existing requirements under the State Children's Health Insurance Program (SCHIP) for the effective and efficient provision of child health assistance coordinated with other sources of health benefits coverage. The August 17, 2007 State Health Official (SHO) letter discussed the Center for Medicare & Medicaid Services' (CMS) review strategy for evaluating State compliance with requirements under 2102(b)(3)(C) of the Act and with regulations at 42 CFR § 457.805 for reasonable crowd-out procedures when States expand eligibility to effective family income levels above 250 percent of the Federal poverty level (FPL).

Rhode Island has provided an assurance that 95 percent of the children at or below 200 percent of the FPL in the State have health insurance coverage. Rhode Island's supporting data was based on refining the Current Population Survey (CPS) data to exclude children who would not be programmatically eligible for Medicaid or SCHIP coverage. Our evaluation of the methodology and resulting rate of coverage concluded that Rhode Island can support this assurance.

In addition, Rhode Island has provided an assurance that the number of children with family incomes below 200 percent of the FPL in the State who are insured through private employers has not decreased by more than two percentage points over the prior five-year period. And the CPS data submitted for the most recent five-year period available (2002-2006) not only supports Rhode Island's assurance, but shows an increase of 4.29 percent in private coverage for this population, from 37.86 percent in 2002 to 42.15 percent in 2006.

Rhode Island is also current with all reporting requirements in SCHIP and Medicaid and, when the instrument and process is established, the State has provided an assurance that it will report data related to crowd-out on a monthly basis.

The cost sharing component of the SHO letter reflects that cost sharing under the State's public program, when compared to cost sharing required by competing private plans, should not be more favorable to the public plan by more than one percentage point, unless the public plan's cost sharing is set at the five percent family cap. Cost sharing under Rhode Island's SCHIP program for children with effective family income levels above 250 percent FPL is set at

3.9 percent of family income. When compared to the publicly available data of the Medical Expenditure Panel Survey, which estimates cost sharing required by competing private plans at 2.2 percent of family income, cost sharing under Rhode Island's SCHIP program is consistent with the cost-sharing guidelines provided in the SHO letter.

Rhode Island proposed an alternative strategy to the minimum of one-year period of uninsurance referenced in the SHO letter. The State proposes that mandatory enrollment in RIte Share, the State's premium assistance program, if the SCHIP or Medicaid eligible individual has access to Department of Human Services (DHS)-approved employer-sponsored insurance, is an effective strategy to prevent substitution of private coverage. The program employs data tape matches with commercial insurers and State laws require employers to provide information about their health insurance benefits to DHS. The State has publicly reported that for every 1,000 persons enrolled in RIte Share, the State saves more than $1million. RIte Share eliminates the need for a waiting period, as it captures cost-effective employer insurance for Medicaid eligible persons and requires mandatory enrollment in employer-sponsored insurance if available. CMS has determined that this is an acceptable alternative to the one-year period of uninsurance.

Rhode Island monitors and verifies the existence of coverage through non-custodial parents by means of tape matches with commercial insurers and information gathered on the RIte Care application and renewal. Rhode Island ensures that children identified as having private insurance coverage through non-custodial parents receive only wrap-around services through Medicaid. This systematic process uses information from external sources including tape matching with commercial insurers, RIte Care applications, and the Rhode Island Child Support Enforcement division. The information is then evaluated to identify necessary requirements and follows the RIte Share process for enrollment into the commercial insurance. This comprehensive process is consistent with the crowd-out prevention guidance outlined in the SHO letter regarding monitoring and verification of coverage through non-custodial parents.

We appreciate Rhode Island's efforts to minimize the substitution of SCHIP coverage for private coverage and share your goal of providing health care to eligible, low-income children through the Medicaid and SCHIP programs.

Sincerely,

Herb B. Kuhn
Deputy Administrator
Acting Director, Center for Medicaid and State Operations