



Memorandum

January 10, 2008

TO: Hon. John D. Rockefeller IV
Attention: Jocelyn Moore

FROM: Morton Rosenberg
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SUBJECT: Applicability of the Congressional Review Act to a CMS Guidance Document Regarding Statutory and Regulatory Requirements to be Used in Reviewing State Requests to Extend Eligibility Under SCHIP

On August 17, 2007, the Director of the Center for Medicaid and State Operations of the Centers for Medicare and Medicaid Services (CMS) issued a letter to all state health officials “clarifying” how CMS will apply existing statutory and regulatory requirements in the review of state requests to extend eligibility under the State Children’s Health Insurance Program (SCHIP) to children in families with effective family income levels above 250 percent of the Federal poverty level (FPL).

You inquire whether the CMS “clarification” letter is a rule under the Congressional Review Act (CRA) which should have been reported to the Congress and subjected to review and possible nullification by passage of a joint resolution of disapproval.¹ Our examination of the statutory scheme of the CRA, its legislative history, Government Accountability Office (GAO) opinions interpreting the scope of the coverage of the term “rule” under the Act, and analogous judicial precedents, suggests that a reviewing court is likely to hold that the legal or practical effect of the CMS document is to alter the rights, duties and obligations of non-agency parties subject to the document and that therefore the agency’s action should have been submitted for review under the CRA.

¹ For a broad overview and assessment of the CRA since its passage in 1996, see Morton Rosenberg, CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Update and Assessment of the Congressional Review Act After a Decade*, November 5, 2007 (CRA Report). For an in-depth discussion of procedural issues that may arise during House and Senate consideration of disapproval resolutions, see Richard S. Beth, CRS Report RL31160 *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, October 10, 2001 (Archived).

The CMS Letter

More particularly, the CMS letter explained that its experience and the information gathered in the operation of SCHIP programs indicated that procedures that had been utilized by the states to ensure SCHIP coverage under private group health plans (so called “crowd-out” procedures) were not working effectively and that it had “become clear that the potential for crowd-out is greater for higher income beneficiaries.” As a consequence of this determination, the CMS letter announced that henceforth the five crowd-out “strategies” that over the years had been identified as reasonable crowd-out prevention procedures, any one or more of which could be adopted by a state, as they considered necessary, were now mandatory in their entirety on states that expanded eligibility above the effective level of 250% of the FPL. States would now also have to incorporate three new components as part of these strategies, including requiring state establishment of a one year period of uninsurance for individuals prior to receiving aid. In addition, a state must now make “assurances” that it has enrolled at least 95% of the children in the state below 200 percent of the FPL who are eligible for SCHIP or Medicaid; that the number of children in the target population insured through private employers has not decreased by more than two percentage points over the prior five year period; and that the state is current with all reporting requirements in SCHIP and Medicaid reports relating to crowd-out requirements. The new review requirements apply to SCHIP state plans and section 1115 demonstration waivers that include SCHIP populations. CMS stated it “expected affected States to amend their SCHIP state plan (or 1115 demonstrations) in accordance with this review strategy within 12 months, or CMS will pursue corrective action” to effect compliance with the CMS guidance.

Reaction to the CMS Letter

The CMS letter raised immediate concerns among some Members of Congress, certain states and with child health interest groups that the new conditions imposed would effectively make it difficult if not impossible, for states to cover uninsured children.² Proponents of the CMA action counter that it clarifies existing law, preserves SCHIP for the core population it was intended to serve, deters further erosion of private coverage, and ensures that states are moving forward on meeting the basic goals of the program.³

A SCHIP reauthorization bill, H.R. 976, addressing the source of the concerns raised by the CMS letter, was sent to the President and was vetoed on October 18. A modified version of H.R. 976, H.R. 3963, was sent to the President who again vetoed it on November 12. No action on the second veto has been taken yet.⁴ On September 7, 2007, the Acting Administrator of CMS denied New York State’s state plan amendment (SPA) which would increase the financial eligibility standard for its separate SCHIP program from its current effective family income eligibility level to or below 400 percent of the FPL. The SPA also

² See, e.g. Cindy Mason and Michael Odeh, “Moving Backward: Newly Imposed Limits on States’ Ability to Cover Children,” Center for Children and Families, Georgetown University Health Policy Institute (August 30, 2007) accessible at <http://ccf.georgetown.edu/pdfs/cmsdirective.pdf> (Moving Backward).

³ See, e.g. Nina Owrharenko, “The Administration’s SCHIP Regulations: A Sound Prescription,” Web Memo No. 1591, August 27, 2007, accessible at www.heritage.org/research/healthcare/wm15911cfm.

⁴ See CRS Report RS22746, “SCHIP: Differences between H.R. 3963 and H.R. 976,” by Evelyn P. Baumrucker, et al.

proposed to implement a six month waiting period of prior uninsurance for children with family incomes above 250 percent of the FPL with certain limited exceptions. The denial is the first to rely on the CMS letter. CMS held that New York had “failed to provide assurances that the state had enrolled at least 95 percent of the children in the core targeted low-income child population, those with family incomes below 200 percent of the FPL. In the absence of such assurances, I cannot conclude that New York is effectively and efficiently using available resources to serve that core population, such that expansion to higher income levels would not divert resources from serving the core population.” The CMS Director also found unreasonable New York procedures for deterring crowd-out by having a six month rather than a one year uninsurance period for populations over 250 percent of the FPL as required by the August 2007 CMS letter.

On October 4, 2007, New York, joined by Illinois, Maryland, and Washington, filed suit in Federal district court in Southern District of New York challenging the validity of the CMS letter on the grounds that it “constituted illegal rulemaking not in conformance with applicable requirements of the Administrative Procedure Act,” and HHS’s published rulemaking policy; that “the requirements it imposed are in excess of the authority vested in the Secretary of HHS under applicable law;” and that “it imposes requirements that are not set forth in statute or codified regulations... .”⁵ Finally, on November 29, 2007, CMS announced that it had approved amendments to Wisconsin’s SCHIP (Badger Care) that would insure children in families of four making up to 250 percent of the FPL. Wisconsin also agreed to abide by CMS letter’s longer uninsurance period.

The New York rejection and its lawsuit, and the apparent compromise by Wisconsin, underline the potentially large direct impact the CMS letter may have. Statistics from the Center for Children and Families of the Georgetown Health Policy Institute indicate that as of August 1, 2007, 19 states (including the District of Columbia) already have income eligibility thresholds above 250 percent of the FPL and that eight states have adopted, but not yet implemented, such eligibility thresholds. Also, four other states have income eligibility thresholds at or slightly below 250 percent of the FPL but apply deductions when computing eligibility.⁶ As a result, these states may see some children lose coverage in order to comply with the CMS letter’s August 2008 deadline.⁷

The number of states that currently exceed the new 250 percent of FPL eligibility threshold is arguably reflective of the policy of flexibility that prevailed since the adoption of the current rulemaking scheme in 2001.⁸ The Statement of Bases and Purpose accompanying and explaining the 2001 final rule makes it clear that many rigid standards in the Notice of Proposed Rulemaking were abandoned after consideration of public comments. The crowd-out procedure language at 42 C.F.R. § 457.805, relied upon by CMS as authority for the more stringent guidance restrictions here in question, simply requires that “[t]he state plan must include a description of reasonable procedures to ensure that health benefits coverage provided under the state plan does not substitute for coverage provided under group

⁵ Complaint, *State of New York et al. v. U.S. Department of Health and Human Services*, Case no. 07-CIV-8621, filed October 4, 2007.

⁶ For instance, by deducting income used to pay for child care expenses.

⁷ See, *Moving Backward*, *supra* n.2.

⁸ See 66 Fed. Reg. 2490, 2493, 2602-2610 (January 11, 2001).

health plans as defined at section 457-10.” The introduction to the 2001 rules’ preamble explains:

Due to a general lack of evidence of the existence of substitution below 200 percent of the FPL and the significant number of comments received on this subject, we have revised the final rule to clarify our policy related to substitution. The preamble to the final rule clarifies that for coverage provided other than through premium assistance programs, we will no longer require a substitution prevention strategy for families with incomes below 250 percent of the FPL. Instead, States will be required to monitor the occurrence of substitution below 200 percent of the FPL. Between 200 and 250 percent of the FPL, we will work with States to develop procedures, in addition to monitoring, to prevent substitution that would be implemented in the event that an unacceptable level of substitution is identified. Above 250 percent of the FPL, States must have a substitution prevention mechanism in place, however we encourage States to use other strategies than waiting periods.

For States wishing to utilize premium assistance programs, we have revised the final rule to provide additional flexibility. While we have retained the 6-month waiting period without group health plan coverage, States have flexibility to include a number of exceptions for circumstances such as involuntary loss of coverage, economic hardship, and change to employment that does not offer dependent coverage. We have also removed the requirement for States to demonstrate an employer contribution of at least 60 percent when providing coverage through premium assistance programs. Rather, we have clarified that States must demonstrate cost-effectiveness of their proposals by identifying a minimum contribution level and providing supporting data to show that the level is representative of the employer-sponsored insurance market in their State.

Finally, the final rule provides that the Secretary has discretion to reduce or waive the minimum period without private group health plan coverage.⁹

The Preamble discussions with respect to the need for flexibility and working with the states with respect to individualizing crowd-out procedures fleshes out the introductory remarks:

Our review of States’ March 31, 2000 evaluations indicated that in those States with data on substitution of private coverage with SCHIP coverage, there was little evidence that substitution was as great an issue as initially anticipated. However, because of the current lack of conclusive data around the level of substitution which may be occurring below 200 percent of FPL, we maintain that monitoring of substitution of coverage in SCHIP is critical.

As noted above, we have revised the policy stated in the preamble to the NPRM regarding substitution procedures relating to SCHIP coverage provided outside of programs that offer premium assistance for coverage under group health plans as follows:

- States that provide coverage to children in families at or below 200 percent of FPL must have procedures to monitor the extent of substitution of SCHIP coverage for existing private group health coverage, as was the

⁹ 66 Fed. Reg. at 2493.

policy for such coverage provided to families under 150 percent of FPL proposed in the preamble to the NPRM.

- At a minimum, States that provide coverage to children in families with incomes over 200 percent of FPL should have procedures to evaluate the incidence of substitution of SCHIP coverage for existing private group health coverage. In addition, States offering coverage to children in families over 200 percent of FPL must identify in their State plans specific strategies to limit substitution if monitoring efforts show unacceptable levels of substitution. States must monitor the occurrence of substitution and determine a specific trigger point at which a substitution prevention mechanism would be instituted, as described in the State plan.
- For coverage above 250 percent of the FPL, because evidence shows that there is a greater likelihood of substitution at higher income levels, States must have substitution prevention strategies in place, in addition to monitoring.

Although a period of uninsurance is one possible substitution prevention procedure, we invite States to propose other effective strategies to limit substitution. States may submit amendments to their State plans if they would like to modify their current policies in light of the policies discussed here. We plan to work closely with States to develop appropriate substitution strategies, monitoring tools, and trigger mechanisms. As part of monitoring for substitution of coverage, States should also study the extent to which anti-substitution policies require children who have lost group health coverage through no fault of their own or their employer to wait to be enrolled in SCHIP. To the extent that monitoring finds that such children are forced to go without coverage, States should consider adjustments to their substitution prevention policies that permit exceptions for children who should not be the target of such policies. We will continue to ask States to assess their substitution prevention procedures in their annual reports.

Finally, we note that because the regulatory text at §457.805 required that the State plan include reasonable procedures to prevent substitution and made no distinction for eligibility levels for coverage under State plans, we have not revised the regulation text. It is consistent with our revised policy.¹⁰

* * *

We agree that State's substitution prevention efforts should be considered in the context of the entire State plan with consideration given to a State's particular needs and goals. To this end, we have retained a flexible regulatory requirement regarding substitution and indicated that HCFA will incorporate additional flexibility in its plan review process.¹¹

* * *

As stated above, periods of uninsurance will not be required unless coverage is provided via premium assistance through group health plans, coverage is provided to children with significantly higher income levels, or substitution has been identified as a problem in the State.¹²

* * *

As indicated above, outside of premium assistance programs, States have broad discretion to develop substitution prevention policies that best serve their particular

¹⁰ *Id.* at 2603.

¹¹ *Id.* at 2604.

¹² *Id.*

populations. States that choose to retain or impose periods of uninsurance are encouraged to include exceptions that help prevent the imposition of undue hardship under a range of circumstances, including loss of insurance through no fault of the family, extreme economic hardship, death of a parent, etc.¹³

As is discussed more fully below, substantial departures from these apparent understandings may be seen by a reviewing court as requiring adherence to the notice and comment process required by Section 553 of the Administrative Procedures Act.

Congressional Review of Agency Rules

The congressional review mechanism, codified at 5 U.S.C. §§ 801-808, and popularly known as the Congressional Review Act (CRA), requires that all agencies promulgating a covered rule must submit a report to each House of Congress and to the Comptroller General (CG) that contains a copy of the rule, a concise general statement describing the rule (including whether it is deemed to be a major rule), and the proposed effective date of the rule. A covered rule cannot take effect if the report is not submitted.¹⁴ Each House must send a copy of the report to the chairman and ranking minority member of each jurisdictional committee.¹⁵ In addition, the promulgating agency must submit to the CG (1) a complete copy of any cost-benefit analysis; (2) a description of the agency's actions pursuant to the requirements of the Regulatory Flexibility Act and the Unfunded Mandates Reform Act of 1995; and (3) any other relevant information required under any other act or executive order. Such information must also be made "available" to each House.¹⁶

Section 804(3) adopts the definition of "rule" found at 5 U.S.C. § 551(4) which provides that the term rule "means the whole or part of an agency statement of general . . . applicability and future effect designed to implement, interpret, or prescribe law or policy."¹⁷ The legislative history of Section 551(4) indicates that the term is to be broadly construed: "The definition of rule is not limited to substantive rules, but embraces interpretive, organizational and procedural rules as well."¹⁸ The courts have recognized the breadth of the term, indicating that it encompasses "virtually every statement an agency may make,"¹⁹ including interpretive and substantive rules, guidelines, formal and informal statements, policy proclamations, employee manuals and memoranda of understanding, among other

¹³ *Id.*

¹⁴ 5 U.S.C. § 801(a)(1)(A).

¹⁵ 5 U.S.C. § 801(a)(1)(C).

¹⁶ 5 U.S.C. § 801(a)(1)(B).

¹⁷ 5 U.S.C. § 804(3) excludes from the definition "(A) any rule of particular applicability, including a rule that approves or prescribes for the future rates, wages, prices, services, or allowance therefore, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (B) any rule relating to agency management or personnel; or (C) any rule of agency organization, or practice that does not substantially affect the rights or obligations on non-agency parties."

¹⁸ Attorney General's Manual on the Administrative Procedure Act 13 (1948).

¹⁹ *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897 (5th Cir. 1983).

types of actions.²⁰ Thus a broad range of agency action is potentially subject to congressional review.

The drafters of the congressional review provision arguably adopted the broadest possible definition of the term “rule” when they incorporated § 551(4) of the APA. As just indicated, the legislative history of § 551(4) and the case law interpreting it make clear that it was meant to encompass all substantive rulemaking documents — which may include policy statements, guidances, manuals, circulars, memoranda, bulletins and the like — which as a legal or practical matter an agency wishes to make binding on the affected public.

The legislative history of the CRA²¹ emphasizes that by adoption of the § 551 (4) definition of the term “rule”, the review process would not be limited only to coverage of rules required to comply with the notice and comment provisions of the APA or any other statutorily required variations of notice and comment procedures, but would rather encompass a wider spectrum of agency activities characterized by their effect on the regulated public: “The committee’s intent in these subsections is . . . to include matters that substantially affect the rights or obligations of outside parties. The essential focus of this inquiry is not on the type of rule but on its effect on the rights and obligations of non-agency parties.”²² The drafters of the legislation indicated their awareness of the practice of agencies avoiding the notification and public participation requirements of APA notice-and-comment rulemaking by utilizing the issuance of other documents as a means of binding the public, either legally or practically,²³ and noted that it was the intent of the legislation to subject just such documents to congressional scrutiny:

The committees are concerned that some agencies have attempted to circumvent notice-and-comment requirements by trying to give legal effect to general statements of policy, “guidelines,” and agency policy and procedure manuals. The committees admonish the agencies that the APA’s broad definition of “rule” was adopted by the authors of this legislation to discourage circumvention of the requirements of chapter 8.²⁴

During floor consideration of the CRA, Representative McIntosh, a principal sponsor of the legislation, emphasized the importance that the effect on private parties was to have in determining what is a covered rule:

²⁰ See, e.g., *Chem Service, Inc. v. EPA*, 12 F.3d 1256 (3d Cir. 1993)(memorandum of understanding); *Caudill v. Blue Cross and Blue Shield of North Carolina*, 999 F.2d 74 (4th Cir. 1993)(interpretative rules); *National Treasury Employees Union v. Reagan*, 685 F.Supp 1346 (E.D. La 1988)(federal personnel manual letter issued by OPM); *New York City Employment Retirement Board v. SEC*, 45 F.3d 7 (2d Cir. 1995)(affirming lower court’s ruling that SEC “no action” letter was a rule within § 551(4)).

²¹ Joint Explanatory Statement of House and Senate Sponsors, 142 Cong. Rec. E 571 (daily ed. April 19, 1996; 142 Cong. Rec. S 3681 (daily ed. April 18, 1996).

²² Joint Explanatory Statement of House and Senate sponsors, *supra* n.21, at E 579, S 3687.

²³ This practice has been long recognized and criticized in administrative law commentaries. See, e.g., Robert A. Anthony, Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like — Should Federal Agencies Use Them To Bind The Public? 41 Duke L.J. 1311 (1992). See also, General Accounting Office, Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules, GAO/GGD-98-126 (August 1998).

²⁴ Joint Explanatory Statement of House and Senate sponsors, *supra* n.21, at E 578, S 3687.

Pursuant to section [804(3)(C)], a rule of agency organization, procedure, or practice, is only excluded if it “does not substantially affect the rights or obligations of nonagency parties.” The focus of the test is not on the type of rule but on its effect on the rights or obligations of nonagency parties. A statement of agency procedures or practice with a truly minor, incidental effect on nonagency parties is excluded from the definition of the rule. Any other effect, whether direct or indirect, on the rights and obligations of nonagency parties is a substantial effect within the meaning of the exception. Thus, the exception should be read narrowly and resolved in favor of nonagency parties who can demonstrate that the rule will have a non-trivial effect on their rights and obligations.²⁵

Representative McIntosh also pointed out that rules subject to congressional review are not the same as those subject to APA notice and comment requirements:

All too often, agencies have attempted to circumvent the notice and comment requirements of the Administrative Procedure Act by trying to give legal effect to general policy statements, guidelines, and agency policy and procedure manual. Although agency interpretative rules, general statements of policy, guideline documents, and agency and procedure manual may not be subject to the notice and comment provisions of section 553(c) of title 5, United States Code, these types of documents are covered under the congressional review provisions of the new chapter 8 of title 5.

Under section 801(a), covered rules, with very few exceptions, may not go into effect until the relevant agency submits a copy of the rule and an accompanying report to both Houses of Congress. Interpretive rules, general statements of policy, and analogous agency policy guidelines are covered without qualification because they meet the definition of a “rule” borrowed from section 551 of Title 5, and are not excluded from the definition of rule.²⁶

To date, at least eight agency failures to report agency actions have come to the attention of committee chairmen and Members and were referred to the Comptroller General for determinations whether they were covered rules. In five of the eight cases the Comptroller General determined the action documents to be reportable rules.²⁷ Two are pertinent to the instant matter.

In Opinion Number B-281575 (January 20, 1999), GAO advised that an “Interim Guidance for Investigating Title VI Administrative Complaints Challenging Permits” issued by the Environmental Protection Agency (EPA) was a reportable rule. EPA had argued that the rule fell within the exception of 5 U.S.C. § 804 (3)(C) as a “rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.” The GAO General Counsel noted that “it is the substance of what EPA has purported to do and has done which is decisive.” Here, the General Counsel found that the Interim Guidance established procedures that departed from existing rules, giving the recipients of a complaint rights they did not have under those rules, and held “they clearly alter the existing regulation and give significant rights they did not previously possess for obtaining dismissal of a complaint. In this respect these new steps meet the elements of a

²⁵ 142 Cong. Rec. H3005 (daily ed. March 28, 1996).

²⁶ *Id.*

²⁷ See CRA Report, *supra* n. 1, at 25-26.

substantive rule: they affect the rights and duties of the recipient, the complainant, and the affected populations; they will have future effect and they change the existing regulation.”

In Opinion Number B-286338 (October 17, 2000) the issue involved the Farm Credit Administration’s (FCA) establishment of a National Charter Initiative which would accept applications for national charters that would remove regulatory geographic barriers imposed on Farm Credit System banks. Geographic jurisdiction limitations had been a historic policy of the FCA which it attempted to alter in a 1998 notice-and-comment rulemaking. The proposal was dropped from the final rule but FCA attempted to accomplish this purpose through its so-called National Charter Initiative. The GAO General Counsel rejected the claim that the application process set up by the Initiative was adjudicatory in nature, finding that since the express purpose of the Initiative was to change the geographic limitation policy, it was unrelated to any particular institution’s application. Rather, the General Counsel found, it was of general applicability, future effect, and prescribed a change in policy that would have a substantial effect on non-agency parties and thus was a reportable rule.

In an analogous manner, the courts have looked behind the label an agency has given a particular action document to ascertain the practical effect it has had on non-agency parties. Where the courts have discerned that the agency document has substantively changed the rights, duties and obligations of regulated persons, they have held the agency action invalid for failure to comply with the APA’s notice and comment requirements. For example, in *Appalachian Power Co. v. EPA*,²⁸ the appeals court dealt with a claim by electrical power companies and trade associations that a “guidance” document allegedly imposed unauthorized requirements on states in connection with their operating permit purposes. The court found that the document was a final binding decision of the agency subject to judicial review, the guidance broadened the underlying agency rule and that its promulgation was impermissible absent notice and comment rulemaking procedures. The court held that: “If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe it will declare permits invalid unless they comply with the terms of the document, then the agency’s document is for all practical purposes ‘binding.’”

Similarly, in *Chamber of Commerce of the U.S. v. Department of Labor*,²⁹ OSHA had issued a directive stating that employees in certain industries that participated in a “cooperative compliance program” would have significantly reduced risk of being subject to an inspection. The cooperative program included some requirements that “exceed[ed] those required by law.” The appeals court concluded that: “In practical terms, the [DOL] Directive places the burden upon those employers that fail to join [the program], and will have a substantial impact upon all employers within its purview--including those that acquiesce in the agency’s use of ‘leverage’ against them.”³⁰

²⁸ 208 F.3d 1015, 1020-23 (D.C. Cir. 2000).

²⁹ 174 F.3d 206, 211-13 (D.C. Cir. 1999).

³⁰ See also, *National Family Planning and Reproductive Health Assoc. v. Sullivan*, 979 F. 2d 227, 229 (“The new ‘Directives’ neither clarify nor explain the previous regulation, which was adopted by notice and comment rulemaking, but instead effectively amend the 1988 regulations to
(continued...)”)

Conclusion

Our analysis of the statutory scheme of the CRA, its legislative history, and opinions of the General Counsel of GAO, indicates that the framers of the congressional review provision were concerned with then prevalent agency actions that had the practical effect of imposing binding norms on non-agency parties without being promulgated in conformance with requirements of notice and comment rulemaking, and therefore adopted a broad definition of the term “rule” that would capture such actions for congressional review. The rulings of numerous appellate courts recognizing the invalidity of such actions supports the CRA’s history and the GAO interpretations. The courts have also indicated that the past practice of an agency in implementing a rulemaking may be looked at for insight as to the understanding and reliance regulated parties and beneficiaries have placed on such past agency practices. In such instances, the courts have held that an abrupt change of course requires a rulemaking to substantively alter those practices and relied upon interpretations. In this instance, CMS practice under the 2001 crowd-out rules arguably has become a “binding norm,” and that changing such practice is an action that is covered by the CRA that may not be effectuated until it is reported to Congress and the Comptroller General.

³⁰ (...continued)

significantly alter its meaning, as previously interpreted and enforced by HHS and upheld by the Supreme Court in *Rust v. Sullivan* [500 U.S. 173(1991)].”). See also, *Davidson v. Glickman*, 169 F.3d 996 (5th Cir. 1999); *Snyder Intl. v. Shalala*, 127 F.,3d. 90 (D.C. Cir. 1997); *Paralyzed Veterans of America v. D.C. Area L.P.*, 117 F. 3d 579, 587 (D.C. Cir. 1997); *Hoctor v. U.S. Department of Agriculture*, 82 F.3d. 165 (7th Cir. 1996). See severally, Jeffrey S. Lubbers, “A Guide to Federal Agency Rulemaking,” pp.73-104 (4th Ed. 2006).