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April 17, 2008

The Honorable John D. Rockefeller, IV
Chairman
Subcommittee on Health Care
Committee on Finance
United States Senate

The Honorable Olympia Snowe
Committee on Finance
United States Senate

Subject: *Applicability of the Congressional Review Act to Letter on State Children's Health Insurance Program*

By letter of February 13, 2008, you asked whether an August 17, 2007 letter issued by the Centers for Medicare & Medicaid Services (CMS) to state health officials concerning the State Children's Health Insurance Program is a rule for the purpose of section 251 of the Contract with America Advancement Act of 1996,[1] commonly referred to as the Congressional Review Act (the Review Act). The Review Act is intended to keep Congress informed of the rulemaking activities of federal agencies and provides that before a rule can take effect, the agency must submit the rule to each House of Congress and the Comptroller General.[2] For the reasons discussed below and more fully explained in the enclosure, we conclude that the August 17, 2007 letter is a rule under the Review Act. Therefore, it must be submitted to Congress and the Comptroller General before it can take effect.

BACKGROUND

The State Children's Health Insurance Program (SCHIP) finances health care to low-income, uninsured children whose family incomes exceed the eligibility limits under their state's Medicaid program, but who cannot afford other health insurance coverage.[3] To participate in SCHIP, a state must submit a plan that describes how its program meets applicable requirements and must receive approval of the plan from

[1] Pub. L. No. 104-121, § 251, 110 Stat. 847, 868 74, *codified at* 5 U.S.C. §§ 801-808.

[2] 5 U.S.C. § 801(a)(1).

[3] *See* 42 U.S.C. § 1397aa.

CMS.[4] States are required to amend their plans to reflect changes in federal law, regulation, or policy, and changes in the operation of their programs, including, for example, changes in eligibility criteria or benefits.[5]

As required by law, a state plan must describe the procedures used to ensure that coverage under the plan does not substitute for coverage under group health plans, generally referred to as "crowd out."[6] Regulations promulgated by CMS require states to adopt "reasonable procedures" to prevent crowd out.[7] Since CMS promulgated the regulations in 2001, states have adopted a number of different measures to prevent crowd out, which CMS has approved.

In its August 17 letter, CMS purports to clarify the statutory and regulatory requirements concerning prevention of crowd out for states wishing to provide SCHIP coverage to children with effective family incomes in excess of 250 percent of the federal poverty level (FPL) and identifies a number of particular measures that these states should adopt. The letter indicates that CMS will apply the measures to states' proposals to cover such children, as well as to states that already cover them. According to the letter, CMS may take corrective action against states that fail to adopt the identified measures within 12 months.

SUMMARY OF ANALYSIS

The definition of "rule" in the Review Act incorporates by reference the definition of "rule" in the Administrative Procedure Act (APA), with some exceptions. Our analysis of whether the August 17 letter is a rule under the Review Act thus entails determining whether the letter is a rule under the APA and whether it falls within any of the exceptions contained in the Review Act.[8] The APA definition of rule has been said to

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[4] 42 U.S.C. § 1397aa(b). The authority vested in the Secretary of Health and Human Services to approve and disapprove SCHIP state plans and plan amendments has been delegated to the Administrator of CMS. *State Child Health; Implementing Regulations for the State Children's Health Insurance Program*, 64 Fed. Reg. 60882, 60895 (Nov. 8, 1999) (proposed rule).

[5] 42 C.F.R. § 457.60.

[6] 42 U.S.C. § 1397bb(b)(3)(C).

[7] 42 C.F.R. § 457.805.

[8] The Review Act excepts the following from its definition of rule: (1) rules of particular applicability, including a rule that approves or prescribes for future application rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. § 804(3). As discussed below, the letter is not a statement of particular applicability; rather, it substantially affects all states that seek to cover children with effective family incomes in excess of 250 percent of the FPL, as well as those states that already cover these children. The letter does not relate to agency management or personnel, and it does not relate to "agency organization, procedure, or practice" with no substantial effect on non-agency parties. Accordingly, we do not believe that any of these three exceptions applies to the August 17 letter.

include "nearly every statement an agency may make."[9] It includes three elements that are relevant here: an agency statement is a rule if it is of general applicability; of future effect; and designed to implement, interpret, or prescribe law or policy.

On its face, the August 17 letter meets these criteria. The letter is of general, rather than particular, applicability since it extends to all states that seek to enroll children with effective family incomes exceeding 250 percent of the FPL in their SCHIP programs, as well as to all states that have already enrolled such children.[10] In addition, it is prospective in nature since it is concerned with policy considerations for the future rather than the evaluation of past or present conduct.[11] Finally, it purports to clarify and explain the manner in which CMS applies statutory and regulatory requirements to states that want to extend coverage under their SCHIP programs to children with effective family incomes above 250 percent of the FPL and seeks to promote the implementation of statutory requirements applicable to state plans. Accordingly, it is designed to implement, interpret, or prescribe law or policy.[12]

The history of the regulatory provision regarding substitution of coverage discussed in the letter lends support to our view that the letter is a rule. In the preamble to the proposed rule to implement SCHIP, CMS indicated that it could not require states to adopt any particular measures as part of the effort to prevent substitution of coverage, stating that it did not have a statutory or empirical basis for doing so.[13] CMS confirmed this interpretation in a final rule.[14] In its August 17 letter, however, CMS states that its experience and information derived from the operation of SCHIP programs have made it clear that the potential for substitution is greater at higher income levels, and states seeking to expand their SCHIP populations should implement specific strategies as "reasonable procedures" to prevent substitution of coverage (for example, a minimum

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[9] *Batterton v. Marshall*, 648 F.2d 694, 700 (D.C. Cir. 1980) (*citing* 5 U.S.C. § 551(4)). Section 551(4) of title 5, United States Code, defines the term "rule" in relevant part as "[t]he whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . . ."

[10] *Cf. U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* 13 (1947) (the term "rule" includes statements of particular applicability applying either to a class or to a single person).

[11] *See Bowen v. Georgetown University Hospital*, 488 U.S. 204, 216 (1988) (Scalia, J., concurring) ("future effect" means that agency statement will have legal consequences for the future); *see also U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* at 14 (rulemaking regulates the future conduct of either groups of persons or a single person and is essentially legislative in nature because it operates in the future and is primarily concerned with policy considerations, while adjudication is concerned with the determination of past and present rights and liabilities).

[12] *See A.D. Transport Express, Inc. v. United States*, 290 F.3d 761, 768 (6th Cir. 2002) (order explaining agency regulation is an interpretative rule under the APA); *Guardian Federal Savings and Loan Ass'n v. Federal Savings and Loan Insurance Corp.*, 589 F.2d 658, 664 (D.C. Cir. 1978) (agency statements that clarify laws or regulations are rules under the APA).

[13] 64 Fed. Reg. at 60921-22.

[14] *See State Child Health; Implementing Regulations for the State Children's Health Insurance Program*, 66 Fed. Reg. 2490, 2601-05 (Jan. 11, 2001) (final rule).

1-year period of uninsurance before receiving SCHIP coverage). Thus, the letter amounts to a marked departure from the agency's settled interpretation of the governing regulation, and case law indicates that such a change may be made only by a rule.[15] Moreover, the agency expressly relied on the letter to disapprove a request from the state of New York to amend its SCHIP plan to cover children with family incomes up to 400 percent of the FPL. The application of the letter to deny New York's proposed plan amendment only serves to confirm that the letter has binding effect and is, therefore, a rule.[16]

By letter of February 20, 2008, we requested the views of the General Counsel of the Department of Health and Human Services on whether the August 17 letter is a rule for purposes of the Review Act.[17] The response from the Director of the Center for Medicaid and State Operations within CMS did not directly address that issue. CMS indicated, however, that the letter is a "general statement of policy that announces the course which the agency intends to follow in adjudications concerning compliance with requirements already set forth in regulations."

As a conceptual matter, general statements of policy would appear to fit squarely within the definition of rule in the APA since they advise the public prospectively of the manner in which an agency proposes to exercise a discretionary power or what the agency will propose as policy,[18] and, in fact, courts have referred to them as rules.[19] While some cases seem to suggest that general statements of policy are not rules under the APA,[20] the better reading of these cases, in our opinion, is that statements of policy

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[15] *See SBC Inc. v. Federal Communications Commission*, 414 F.3d 486, 498 (3d Cir. 2005) (if agency's present interpretation of regulation is a fundamental modification of previous interpretation, the modification can only be accomplished through notice and comment rulemaking); *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) (settled policy of an agency is binding on the agency and may be changed only through a rule); *Alaska Professional Hunters Ass'n v. Federal Aviation Administration*, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999) (an agency is bound by settled interpretation given to its own regulation that agency can change only by rulemaking).

[16] *See Appalachian Power Co. v. Environmental Protection Agency*, 208 F.3d 1015, 1020-21 (D.C. Cir. 2000) (if an agency treats a pronouncement as if it were controlling, if it bases enforcement actions on the policies in the document, and if it leads private parties or states to believe it must comply with the pronouncement's terms, it is a substantive rule, not a general statement of policy); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (in subsequent administrative proceeding, agency cannot claim that prior statement of policy itself resolves contested issues).

[17] In documents filed in related litigation, the Department of Justice has characterized the August 17 letter as a rule. *See New York v. United States Dep't of Health and Human Services*, No. 07 Civ. 08621 (S.D.N.Y. filed Oct. 4, 2007) (Def's Mem. Supp. Mot. Dismiss, p. 33).

[18] *See U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* at 30, n.3.

[19] *See, e.g., Chrysler v. Brown*, 441 U.S. 281, 301 (1979) ("the central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice' on the other"); *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975) (general statement of policy is a rule directed at agency staff on how it will perform discretionary function); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (describing test for determining whether "a rule is a general statement of policy").

[20] *See, e.g., Sugar Cane Growers Cooperative of Florida v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002) (some agency pronouncements lack the firmness of a prescribed standard to be considered rules);

are not the type of rules for which the APA requires notice and comment procedures because they are tentative statements of future intent and by their nature do not have the force of law. Further, even if these cases are read to mean that general statements of policy are not rules under the APA, the August 17 letter does not have the characteristics of a general statement of policy identified in case law. Because the letter establishes a deadline by which "affected States" need to implement its measures or face the possibility of a corrective action by the agency, the letter evidences little, if any, of the tentativeness that is the hallmark of a policy statement.[21] Finally, as noted above, the agency has relied on the letter to disapprove a state plan amendment, treating the letter as if it were a binding rule.

CONCLUSION

The August 17 letter from CMS to state health officials is a statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy with regard to SCHIP. Accordingly, it is a rule under the Congressional Review Act. Therefore, before it can take effect, it must be submitted to Congress and the Comptroller General.

If you have any questions concerning this opinion, please contact Dayna K. Shah, Managing Associate General Counsel, at (202) 512-8208; Helen T. Desaulniers, Assistant General Counsel, at (202) 512-4740; or Kevin C. Milne, Deputy Assistant General Counsel, at (202) 512-4586.

Gary L. Kepplinger
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Enclosure

cc: James Stansel, Esq.
Acting General Counsel
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Syncor International Corp. v. Shalala, 127 F.3d 90, 94 (D.C. Cir. 1997) (the primary distinction between a rule and a general statement of policy is whether the agency intends to bind itself to a legal position); *Pacific Gas and Electric Co. v. Federal Power Commission*, 506 F.2d 33, 37 (D.C. Cir. 1974) (suggesting that policy statements are not rules under the APA).

[21] *See Pacific Gas and Electric Co.*, 506 F.2d at 36-45 (discussing the language of a "statement of policy" and noting that such a statement announces tentative intentions for the future); *cf. Community Nutrition Institute v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987) (agency prescribed standard from which regulated entities could obtain "exception" or risk enforcement action indicated standard was binding).

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Applicability of the Congressional Review Act to Letter on State Children's Health Insurance Program

The Centers for Medicare and Medicaid Services (CMS) issued a letter dated August 17, 2007 to certain state agencies concerning the State Children's Health Insurance Program. For the reasons discussed below, we conclude that the August 17 letter is a "rule" for the purpose of section 251 of the Contract with America Advancement Act of 1996,[1] commonly referred to as the Congressional Review Act (the Review Act). Therefore, in accordance with the Review Act, the letter must be submitted to Congress and the Comptroller General before it can take effect.

BACKGROUND

The State Children's Health Insurance Program

The State Children's Health Insurance Program (SCHIP), created in 1997, finances health care to low-income, uninsured children whose family incomes exceed the eligibility limits under their state's Medicaid program, but who cannot afford other health insurance coverage.[2] Like Medicaid, SCHIP is financed jointly by contributions from the federal government and the states. Under Medicaid, the federal government matches a portion of each state's Medicaid expenditures according to a matching rate that is based in part on the state's per capita income relative to the national average.[3] Under SCHIP, the federal government also matches a state's SCHIP expenditures, but at a rate that is generally higher than the Medicaid matching rate.[4]

To participate in SCHIP, a state must submit a state plan and must receive approval of the plan from CMS.[5] A state plan is a comprehensive written description of the operation of the state's SCHIP program, including eligibility standards and benefits provided, in sufficient detail for CMS to determine whether the plan meets applicable

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[1] Pub. L. No. 104-121, § 251, 110 Stat. 847, 868-74, *codified at* 5 U.S.C. §§ 801-808.

[2] *See* 42 U.S.C. § 1397aa. Medicaid finances health care for certain low-income families, children, pregnant women, elderly persons, and persons with disabilities. In general, under SCHIP, a state is allowed to cover children in families with incomes up to 200 percent of the federal poverty level or 50 percentage points above the state's Medicaid income eligibility limit as of March 31, 1997. *See* 42 U.S.C. §§1397jj(b)(1) and (c)(4).

[3] 42 U.S.C. §§ 1396b(a), 1396d(b).

[4] *See* 42 U.S.C. § 1397ee(a).

[5] 42 U.S.C. § 1397aa(b). The authority vested in the Secretary of Health and Human Services to approve and disapprove SCHIP state plans and plan amendments has been delegated to the Administrator of CMS. *State Child Health; Implementing Regulations for the State Children's Health Insurance Program*, 64 Fed. Reg. 60882, 60895 (Nov. 8, 1999) (proposed rule).

requirements.[6] The plan also assures CMS that the state will administer its program in accordance with those requirements.[7] Regulations require states to amend their state plans whenever necessary to reflect changes in federal law, regulations, policy interpretations, or court decisions, as well as changes in the operation of their programs, including, for example, changes in eligibility criteria or benefits.[8]

States have considerable flexibility under SCHIP in structuring their programs. They may expand their existing Medicaid programs to provide coverage to children who are eligible under SCHIP. Alternatively, they may implement separate child health programs. In addition, a state may have a combination of both a separate child health program and a Medicaid expansion.[9]

State SCHIP programs are subject to a number of statutory provisions that are designed to ensure that SCHIP coverage does not become a substitute for other public or private coverage. For example, section 2102(b)(3)(C) of the Social Security Act requires that a state plan include a description of the procedures used to ensure that state SCHIP coverage does not substitute for health insurance coverage under group health plans.[10] Under section 2102(c)(2) of the Social Security Act, states also must describe in their plans the procedures used to coordinate their SCHIP programs with other public and private programs.[11]

CMS has promulgated regulations designed to implement the statutory provisions to prevent substitution of coverage.[12] Among the regulations promulgated, section 457.805 of title 42, Code of Federal Regulations, requires that a state plan include a description of "reasonable procedures" to ensure that coverage provided under the state plan does not substitute for coverage provided under group health plans, referred to as "crowd out" provisions. Over time, states have proposed, and CMS has approved, a number of different measures to prevent substitution of coverage.

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[6] 42 C.F.R. § 457.50.

[7] *Id.*

[8] 42 C.F.R. § 457.60.

[9] 42 U.S.C. § 1397aa(a); 42 C.F.R. § 457.70.

[10] 42 U.S.C. § 1397bb(b)(3)(C). CMS explained in the preamble to a final rule implementing SCHIP that the potential for substitution of SCHIP coverage for private coverage exists because SCHIP coverage may be less expensive than private coverage or provide better coverage than some individuals or employers could purchase with their own funds. *See State Child Health: Implementing Regulations for the State Children's Health Insurance Program*, 66 Fed. Reg. 2490, 2602 (Jan. 11, 2001) (final rule).

[11] 42 U.S.C. § 1397bb(c)(2).

[12] *See* 64 Fed. Reg. at 60921-23; 66 Fed. Reg. at 2601-2610.

The August 17, 2007 Letter

On August 17, 2007, CMS issued a letter to state health officials (SHO #07-001) for the stated purpose of clarifying how CMS "applies existing statutory and regulatory requirements" for states that want to extend coverage under their SCHIP programs to children in families with effective family incomes above 250 percent of the federal poverty level (FPL). Specifically, the letter indicates that it is "clarifying that the reasonable procedures adopted by States to prevent crowd-out pursuant to 42 C.F.R. 457.805 should include . . . five general crowd-out strategies with certain important components." The five crowd out strategies identified in the letter are:

1. imposing waiting periods between dropping private coverage and enrollment in SCHIP;
2. imposing cost sharing in approximation to the cost of private coverage;
3. monitoring health insurance status at the time of application;
4. verifying family insurance status through insurance databases; and
5. preventing employers from changing dependent coverage policies that would favor a shift to public coverage.

In addition, the letter indicates that CMS "will expect" that these states incorporate the following components into their strategies to prevent substitution of coverage:

1. the cost sharing requirement under the state plan compared to the cost sharing required by competing private plans must not be more favorable to the public plan by more than 1 percent of the family income, unless the public plan's cost sharing is set at the 5 percent family cap;
2. the state must establish a minimum of a 1-year period of uninsurance for individuals prior to receiving coverage; and
3. monitoring and verification must include information regarding coverage provided by a noncustodial parent.

The letter also indicates that CMS will seek a number of assurances from states, including an assurance that the state has enrolled at least 95 percent of the children in the state with family incomes below 200 percent of the FPL who are eligible for SCHIP or Medicaid.

According to the August 17 letter, CMS will expect states that seek to amend their SCHIP state plans and section 1115 demonstrations[13] to cover children with effective family incomes above 250 percent of the FPL to include these specific measures. Furthermore, the letter indicates that CMS will apply the "review strategy" described in the letter to instances in which SCHIP plans and section 1115 programs already include these children. The letter indicates that states will be expected to amend their SCHIP plans or section 1115 demonstration programs in accordance with the

[13] Section 1115 of the Social Security Act authorizes the Secretary of Health and Human Services to conduct demonstration programs likely to assist in promoting the objectives of specified programs. 42 U.S.C. § 1315; 42 U.S.C. § 1397gg(e).

provisions of the review strategy within 12 months or CMS "may pursue corrective action."

DISCUSSION

The Review Act is intended to keep Congress informed about the rulemaking activities of federal agencies and to allow for congressional review of rules.[14] The Review Act provides that before a rule can take effect, the agency promulgating the rule must submit to each House of Congress and the Comptroller General a report containing a copy of the rule; a concise general statement concerning the rule, including whether it is a major rule; and the proposed effective date of the rule.[15] Among other things, the Review Act sets forth a procedure for congressional disapproval of agency rules, specifically a joint resolution of disapproval effective upon signature by the President. The Review Act provides that no determination, finding, action, or omission under the Review Act shall be subject to judicial review.[16]

The definition of the term "rule" in the Review Act incorporates by reference the definition in the Administrative Procedure Act (APA), with some exceptions. Our analysis of whether the August 17 letter is a rule under the Review Act thus entails determining whether it is a rule under the APA and whether it falls within any of the exceptions contained in the Review Act.[17] The APA definition of rule has been said to include "nearly every statement an agency may make."[18] This definition is as follows:

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[14] *See* 142 Cong. Rec. H3005 (daily ed. Mar. 28, 1996) (statement of Rep. McIntosh); *see also New York v. American Electric Power Service Corp.*, Nos. 2:04 CV 1098, 2:05 CV 360, 2006 WL 1331543, at *13 (S.D. Ohio Mar. 21, 2006); *United States v. Southern Indiana Gas and Electric Co.*, No. IP99-1692-C-M/S, 2002 WL 31427523, at *3 (S.D. Ind. Oct. 24, 2002); *Texas Savings & Community Bankers Ass'n v. Federal Housing Finance Board*, No. A 97 CA 421 SS, 1998 WL 842181, at *7 (W.D. Tex. June 25, 1998).

[15] 5 U.S.C. § 801(a)(1). On the date the report is submitted, the agency also must submit to the Comptroller General and make available to each House of Congress certain other documents, including a cost-benefit analysis, if any, and agency actions relevant to the Regulatory Flexibility Act and the Unfunded Mandates Reform Act of 1995, and any other relevant information or requirements under any other legislation or any relevant executive orders. 5 U.S.C. § 801(a)(1)(B)(i)-(iv). For rules that federal agencies identify as major rules, the Comptroller General is required under the Review Act to provide a report to the committees of jurisdiction in each House on whether the agency complied with certain procedural requirements. 5 U.S.C. § 801(a)(2)(A).

[16] 5 U.S.C. § 805. A number of federal courts have concluded that an agency's failure to submit a rule in accordance with the Review Act is not reviewable. *See American Electric Power Service Corp.*, 2006 WL 1331543, at *13; *United States v. American Electric Power Service Corp.*, 218 F. Supp. 2d 931, 949 (S.D. Ohio 2002); *Texas Savings & Community Bankers Ass'n*, 1998 WL 842181, at *7. One court has ruled that the Review Act does not preclude review of the agency's failure to submit a rule as required by the Review Act. *See Southern Indiana Gas and Electric Co.*, 2002 WL 31427523, at *5–*6.

[17] The Review Act excepts the following from its definition of rule: (1) rules of particular applicability, including a rule that approves or prescribes for future application rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. § 804(3). As discussed below, the letter is not a statement of particular applicability; rather, it substantially affects all states that seek to cover children with effective family incomes in excess of 250 percent of the FPL, as well

> [T]he whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing[.][19]

Agency statements that create binding legal norms--those that, for example, grant rights, impose obligations, or affect private interests--are rules under the APA.[20] These rules--usually called legislative rules--generally must be promulgated through notice and comment rulemaking procedures under 5 U.S.C. § 553. Courts have found that other agency pronouncements also are rules as defined in 5 U.S.C. § 551, even if they do not create binding legal norms and are not subject to notice and comment rulemaking requirements under section 553. For example, agency guidance documents and manuals have been held to be rules.[21] Agency documents that clarify or explain existing legal requirements also have been held to be rules.[22] Whether a particular agency pronouncement is a rule under section 551, therefore, does not turn on whether the rule is subject to notice and comment rulemaking requirements under section 553.

Legislative history of the Review Act confirms that the Review Act is intended to include within its purview almost all rules that an agency issues and is not limited to those rules that must be promulgated according to the notice and comment

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as those states that already cover these children. The letter does not relate to agency management or personnel, and it does not relate to "agency organization, procedure, or practice" with no substantial affect on non-agency parties. Accordingly, we do not believe that any of these three exceptions applies to the August 17 letter.

[18] *Batterton v. Marshall*, 648 F.2d 694, 700 (D.C. Cir. 1980).

[19] 5 U.S.C. § 551(4).

[20] *Batterton*, 648 F.2d at 700-02.

[21] *See Reno v. Koray*, 515 U.S. 50, 60–61 (1995) (internal agency guideline was a rule under the APA); *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 99–100 (1995) (provision of the Medicare Provider Reimbursement Manual was a rule under the APA); *Appalachian Power Co. v. Environmental Protection Agency*, 208 F.3d 1015, 1021–22 (D.C. Cir. 2000) (agency guidance document can be rule under the APA); *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 601–02 (5th Cir. 1995) (FDA Compliance Policy Guide was a rule, but was exempt from notice and comment procedures as a statement of policy or interpretative rule).

[22] *See, e.g., A.D. Transport Express, Inc. v. United States*, 290 F.3d 761, 768 (6th Cir. 2002) (order explaining agency regulation is an interpretative rule under the APA); *Guardian Federal Savings and Loan Ass'n v. Federal Savings and Loan Insurance Corp.*, 589 F.2d 658, 664 (D.C. Cir. 1978) (agency statements that clarify laws or regulations are rules under the APA).

requirements in section 553 of the APA. In his floor statement during final consideration of the bill, Representative McIntosh, a principal sponsor of the legislation, pointed out that rules subject to congressional review are not just those rules subject to APA notice and comment requirements:

> Although agency interpretive rules, general statements of policy, guideline documents, and agency policy and procedure manuals 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 a rule.[23]

Our prior opinions on the status of agency pronouncements under the Review Act reflect the breadth of the term "rule," applying a definition of the term that reaches pronouncements beyond those that require notice and comment rulemaking.[24]

The APA definition of rule includes three elements relevant to our consideration of whether the August 17 letter is a rule: an agency statement is a rule if it is of general applicability; of future effect; and designed to implement, interpret, or prescribe law or policy. An examination of the text of the letter itself indicates that it meets these criteria. The letter is of general, rather than particular, applicability since it extends to all states that seek to enroll children with effective family incomes exceeding 250 percent of the FPL in their SCHIP programs, as well as to all states that have already enrolled such children.[25] In addition, it is of future effect since it concerns policy considerations for the future rather than the evaluation of past and present conduct.[26] Further, by its own terms, the letter purports to clarify and explain statutory and

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[23] 142 Cong. Rec. H3005 (daily ed. Mar. 28, 1996) (statement of Rep. McIntosh).

[24] *See, e.g.*, B-287557, May 14, 2001 ("record of decision" issued by the Fish and Wildlife Service of the Department of Interior in connection with a federal irrigation project was a rule); B-274505, September 16, 1996 (memorandum issued by Secretary of Agriculture in connection with the Emergency Salvage Timber Sale Program was a rule).

[25] *Cf. U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* 13 (1947) (the term "rule" includes statements of particular applicability applying either to a class or to a single person).

[26] *See Bowen* v. *Georgetown University Hospital*, 488 U.S. 204, 216 (1988) (Scalia, J., concurring) ("future effect" means that statement will have legal consequences for the future); *see also U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* at 13-14 (rulemaking regulates the future conduct of either groups of persons or a single person and is essentially legislative in nature because it operates in the future and is primarily concerned with policy considerations, while adjudication is concerned with the determination of past and present rights and liabilities.)

regulatory requirements. The very first sentence explains that the letter "clarifies how [CMS] applies existing statutory and regulatory requirements" with regard to requests from states to extend coverage under SCHIP to children with effective family incomes above 250 percent of the FPL. The letter also purports to explain the requirements under 42 C.F.R. § 457.805 regarding state efforts to prevent substitution of coverage and the measures that states seeking to cover these populations should take to prevent substitution of coverage. In addition, the letter indicates that the requested assurances help ensure the coordination of SCHIP coverage with other coverage, thus indicating that the assurances promote the implementation of one of the statutory objectives for state plans.[27] In particular, it indicates that states that already have included coverage under their SCHIP programs for children with effective family incomes above 250 percent of the FPL are expected to adjust their state plans accordingly. Because the letter purports to provide an explanation of statutory and regulatory requirements and to explain how the provisions adopted effectuate both legal requirements and policy choices attendant to administration of SCHIP, the document on its face is designed to implement, interpret, or prescribe law or policy within the meaning of section 551(4) of the APA.

The history of 42 C.F.R. § 457.805, the regulation that the August 17 letter purports to clarify, supports our view that the letter is a rule. In the preamble to the proposed rule to implement SCHIP, CMS considered whether to require states to adopt a set of particular measures to prevent substitution of coverage and expressly declined to impose such a requirement. CMS concluded that, based on its interpretation of the governing statute and evidence, it did not have a basis upon which to require such measures. CMS explained its position as follows:

> The other option that we considered was to require a set of specific procedures that each State would have to use to address substitution [of coverage]. We rejected this option because the statute authorizes States to design approaches to prevent substitution, not the Federal government. We also recognized that there is not substantial evidence favoring any specific approach to reduce the potential for substitution.[28]

CMS confirmed this interpretation in a final rule.[29] The August 17 letter, however, explains that CMS's experience and information derived from the operation of SCHIP

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[27] Among the statutory provisions that the letter expressly refers to is section 2101(a) of the Social Security Act, which provides, in pertinent part:

> Purpose.–The purpose of this title [XXI] is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

42 U.S.C. § 1397aa(a).

[28] 64 Fed. Reg. at 60921-22.

[29] *See* 66 Fed. Reg. at 2601-05.

programs have made it clear that the potential for substitution is greater at higher income levels. The letter further states that CMS will expect states to undertake five specific measures, include three components as part of those measures, and make three additional assurances in order to cover children with effective family incomes above 250 percent of the FPL under SCHIP. In this respect, the letter amounts to a marked departure from the agency's interpretation of the regulation regarding substitution of coverage in the preambles to the proposed and final rules. Accordingly, because of this new regulatory interpretation and because an agency may only change a settled interpretation of its own rules through the promulgation of an amending rule, the letter serves the same purpose as a rule.[30]

CMS's application of the August 17 letter only serves to confirm that the letter has binding effect and is, therefore, a rule. In April 2007, the state of New York requested permission from CMS to amend its SCHIP plan to provide coverage to children with family incomes up to 400 percent of the FPL. CMS expressly relied on the August 17 letter to deny the request. In a letter dated September 7, 2007 to the state of New York, CMS stated, in part, the following:

> New York has not demonstrated that its program operates in an effective and efficient manner with respect to the core population of targeted low-income children. Specifically, it has failed to provide assurances that the State has 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. As outlined in an August 17, 2007, letter to State Health Officials, such assurances are necessary to ensure that expansion to higher income populations does not interfere with the effective and efficient provision of child health assistance.

In explaining the applicable requirements under 42 C.F.R. § 457.805, CMS went on to state additional grounds for its denial of New York's request to amend its SCHIP plan:

> At the high proposed family income eligibility levels, reasonable procedures [to prevent substitution of coverage] should include a full range of procedures to discourage substitution. New York's proposal does not include procedures to prevent such substitution that include a 1-year period of uninsurance for populations over 250 percent of the FPL. Additionally, New York's proposed cost sharing has not met the requirement that cost sharing under the State plan compared to cost sharing required by competing private plans not be more favorable to the public plan by more than 1 percent of the family income, nor has the State proposed to set its cost sharing at the 5 percent family cap. . . .

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[30] *See SBI Inc. v. Federal Communications Commission*, 414 F.3d 486, 498 (3d Cir. 2005) (if an agency's present interpretation of a regulation is a fundamental modification of a previous interpretation, the modification must be accomplished through notice and comment rulemaking); *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) (a settled policy of an agency is binding on the agency and may be changed only through a rule); *Alaska Professional Hunters Ass'n v. Federal Aviation Administration*, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999) (an agency is bound by settled interpretation given to its own regulation that the agency can change only by rulemaking).

> For these reasons . . . I am unable to approve this [State Plan Amendment] for expanding coverage. This disapproval is consistent with the August 17, 2007 letter to State Health Officials discussing how these existing statutory and regulatory requirements should be applied to all States expanding SCHIP effective eligibility levels above 250 percent of the FPL.

CMS's action demonstrates that the letter represents the agency's decision to bind itself to the application of the letter's terms and to give the letter present and binding effect.[31]

By letter of February 20, 2008, we requested the views of the General Counsel of the Department of Health and Human Services (HHS) on whether the August 17 letter is a rule for purposes of the Review Act.[32] The written response from the Director of the Center for Medicaid and State Operations within CMS did not address this issue. The response stated that it would be inappropriate to address legal issues related to the August 17 letter because the letter is the subject of a number of lawsuits.[33] Nevertheless, CMS indicated that the August 17 letter is a "general statement of policy that announces the course which the agency intends to follow in adjudications concerning compliance with requirements already set forth in regulations." The agency also referred us to a document prepared by the Department of Justice, which asserted that the August 17 letter was a general statement of policy.

The agency's characterization of the August 17 letter as a general statement of policy raises one issue relevant to our consideration: whether a general statement of policy is a rule under section 551(4) of the APA.[34] The term "general statements of policy" is not defined in the APA or in its legislative history. The Attorney General's Manual on the Administrative Procedure Act, which the United States Supreme Court has frequently referred to as an authoritative source for interpreting provisions of the

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[31] *See Appalachian Power Co.*, 208 F.3d at 1020-21 (if an agency treats a pronouncement as if it were controlling, if it bases enforcement actions on the policies in the document, and if it leads private parties or states to believe it must comply with the pronouncement's terms, it is a rule); *Public Citizen, Inc. v. United States Nuclear Regulatory Commission*, 940 F.2d 679, 682 (D.C. Cir. 1991) (where language and context of a statement are inconclusive, court will turn to agency's actual application to determine nature of agency pronouncement); *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988) (because agency used policy statement to determine regulated entities' obligations, policy statement is, therefore, a rule); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (form of a regulation is not controlling; substance and effect will determine whether agency statement is a rule).

[32] *See* GAO, *Procedures and Practices for Legal Decisions and Opinions*, GAO-06-1064SP (Washington, D.C.: Sept. 2006), *available at* www.gao.gov/legal/resources.html.

[33] In documents filed in litigation, the Department of Justice has characterized the letter as an interpretative rule. *See New York v. United States Dep't of Health and Human Services*, No. 07 Civ. 08621 (S.D.N.Y. filed Oct. 4, 2007) (Def's Mem. Supp. Mot. Dismiss, p. 33).

[34] "General statements of policy" are expressly excepted from notice and comment rulemaking requirements under section 553 of the APA. In court filings submitted by the Department of Justice in separate litigation, HHS contends that the August 17 letter is not subject to notice and comment rulemaking requirements.

APA,[35] defines the term as "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power."[36] A statement of policy, therefore, as the U.S. Court of Appeals for the District of Columbia Circuit has stated, announces the agency's tentative intentions for the future, and "what the agency seeks to establish as policy."[37] In this way, the general statement of policy serves a number of useful functions, including the facilitation of long range planning within the regulated industry and the promotion of uniformity in areas of national concern.[38]

Section 551(4) includes within the meaning of rule a statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. As a device that provides information on the manner in which an agency will exercise its authority or what the agency will seek to propose as policy, a general statement of policy would appear to fit squarely within this category. Further, in discussing policy statements under the APA, courts have referred to them as rules.[39]

Nevertheless, some court decisions seem to suggest that general statements of policy are not rules under the APA, which would raise, of course, the question whether they are rules under the Review Act.[40] The holdings of these cases did not address whether the agency pronouncements were rules for the purpose of section 551, but, instead, whether they were rules that should have been promulgated according to notice and comment rulemaking requirements under section 553 or whether they were subject to review. The better reading of these cases, in our opinion, is not that general statements of policy are not rules under 551, but that statements of policy are

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[35] *See, e.g., Guernsey Memorial Hospital*, 514 U.S. at 99; *Georgetown University Hospital*, 488 U.S. at 218.

[36] *U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* at 14.

[37] *See Pacific Gas and Electric Co. v. Federal Power Commission*, 506 F.2d 33, 38 (D.C. Cir. 1974).

[38] *Id.*

[39] *See, e.g., Chrysler v. Brown*, 441 U.S. 281, 315 (1979) ("the central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice' on the other"); *Professionals and Patients for Customized Care*, 56 F.3d at 596 (discussing whether policy statement at issue is interpretative rule or legislative rule); *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975) (general statement of policy is a rule directed at agency staff on how it will perform discretionary function); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (describing test for determining whether "a rule is a general statement of policy").

[40] *See, e.g., Sugar Cane Growers Cooperative of Florida v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002) (some agency pronouncements lack the firmness of a prescribed standard to be considered rules); *Syncor International Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997) (the primary distinction between a rule and a general statement of policy is whether the agency intends to bind itself to a legal position); *Pacific Gas and Electric Co.*, 506 F.2d at 37 (suggesting that policy statements are not rules under the APA).

not *legislative* rules because they are tentative statements of future intent and by their nature do not have the force of law.

Even if general statements of policy are not rules for purposes of section 551, however, the August 17 letter does not qualify as a general statement of policy. In determining whether a particular agency pronouncement is a general statement of policy, courts begin with the language of the document itself and the agency's own characterization of the pronouncement.[41] Although courts give deference to an agency's characterization, the label that an agency puts on the exercise of its administrative power is not conclusive.[42] In general, if the language of the pronouncement indicates that the agency's views are tentative or simply a guide as to how the agency may exercise its authority, and the agency in fact does not treat the statement as a binding norm, then the document may be a policy statement. If, however, the document, either by its terms or as applied by the agency, imposes requirements or obligations, it would not be considered a general statement of policy.

One case in particular, cited by the Department of Justice in the memorandum included in CMS's response to our request for the agency's views, provides a useful explanation of the type of language typically found in an agency general statement of policy. In *Pacific Gas and Electric Co. v. Federal Power Commission*,[43] the United States Court of Appeals for the District of Columbia Circuit determined that a Federal Power Commission pronouncement was a general statement of policy exempt from notice and comment rulemaking requirements. The pronouncement, styled a "statement of policy," expressed the Commission's view of how deliveries of natural gas should be prioritized during periods of shortage. The pronouncement stated that the Commission intended to follow this priority schedule unless a particular pipeline company demonstrated that a different curtailment plan (governing allocation of available supply among customers) better served the public interest. After the statement was issued, a number of parties objected to the Commission's statement, most of whom were the natural gas customers that had been assigned a low priority under the priority schedule. Among their objections was the claim that the statement was in effect a substantive rule, and not a statement of policy.

In reaching its conclusion that the statement was indeed a statement of policy, the court noted the tentative nature of the statement, as well as the Commission's acknowledgment that any particular decisions on curtailment could only be made in further proceedings. Specifically, the court found it significant that the statement indicated it was the curtailment policy that the Commission "proposes to implement" and the "plan preferred by the Commission," which "will serve as a guide in other proceedings." The Commission itself intended the statement only "to state initial guidelines as a means of facilitating curtailment planning and the adjudication of

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[41] *Professionals and Patients for Customized Care*, 56 F.3d at 596.

[42] *See id.* (what the agency in fact does in relation to an agency statement is dispositive); *United States Gypsum Co. v. Muszynski*, 209 F. Supp. 2d 308, 309–10 (S.D.N.Y. 2002) (an advisory memorandum that was applied by agency as a rule was a rule).

[43] 506 F.2d 33 (D.C. Cir. 1974).

curtailment cases." In addition, the statement also indicated that, although it informed the public of the types of plans the Commission might approve, there was no assurance that any such plan would be approved. Finally, the court noted that the statement indicated that during subsequent proceedings to determine particular curtailments, affected parties would have an opportunity not only to challenge the merits of the proposed plan, but to demonstrate that the plan was inappropriate in particular circumstances. In effect, the Commission statement was a starting point to frame consideration of future proposals.

If we analyze CMS's August 17 letter using the criteria used by the court to determine that the Commission's pronouncement was simply a statement of policy, we conclude that the letter does not meet the criteria. The August 17 letter evidences little, if any, language of tentativeness or inconclusiveness. The specific measures are not characterized as "proposals" or measures that are under development or to be implemented or adopted by later action. On the contrary, the letter sets forth specific strategies that states seeking to expand their SCHIP populations should implement as "reasonable procedures" to prevent substitution of coverage. While states previously identified and adopted one or more of the specified strategies, the August 17 letter indicates that all of them should be included as "reasonable procedures." There is no indication that the strategies are only guidelines that may or may not be applied in subsequent proceedings. In addition, the letter contains no express mention that exceptions will be considered in particular instances. Finally, the time frame specified in the letter for states to conform to the CMS "review strategy" evidences the agency's intention to give the letter present and binding effect:

> CMS will apply this review strategy to SCHIP state plans and section 1115 demonstration waivers that include SCHIP populations, and will work with States that currently provide services to children with effective family incomes over 250 percent of FPL. We expect affected States to amend their SCHIP state plan (or 1115 demonstration) in accordance with this review strategy within 12 months, or CMS may pursue corrective action.

If the letter were simply precatory or tentative in nature, then there would be no need to establish a deadline by which states would need to implement the measures in the letter or face the possibility of a corrective action by the agency.[44] The inference to be drawn from the letter, therefore, is that states that do not conform to or adopt the measures described in the letter will likely be found to be not in compliance with SCHIP requirements.

In addition to the particular language of a statement, courts look to an agency's actions in relation to the statement to determine whether it is a general statement of policy. As a number of courts have noted, a critical test of whether a rule is a general statement of policy is its practical effect in a subsequent administrative proceeding. In subsequent proceedings, if the agency relies solely on the pronouncement itself to

[44] *Cf. Community Nutrition Institute v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987) (agency prescribed standard from which regulated entities could obtain "exception" or risk enforcement action indicated standard was binding).

determine rights and obligations of others, the agency has treated the policy statement as if it were a binding rule, not a general statement of policy.[45] As we explained above, CMS's express reliance on the August 17 letter to deny the state of New York's request to amend its SCHIP plan leads us to conclude that the letter is not a policy statement. Our conclusion that the August 17 letter is not a general statement of policy is reinforced by our observation that it reflects a significant change in the agency's settled interpretation of 42 C.F.R. § 457.805, which policy statements by their nature do not do.[46]

CONCLUSION

Based on our analysis of the August 17, 2007 letter to state health officials, it is our opinion that the letter is a rule for the purpose of the Review Act. The letter, as discussed above, is a statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy with regard to the SCHIP program. Furthermore, we do not believe that the August 17 letter comes within any of the exceptions to the definition of rule contained in the Review Act.

We express no opinion on the applicability of any other legal requirements, including, but not limited to, notice and comment rulemaking requirements under the APA, or whether the August 17 letter would be a valid interpretation of statutes or regulations. As a legal matter, the resolution of such issues is not necessary to our determination whether the August 17 letter is a rule for purposes of the Review Act.

Accordingly, given our conclusions above, and in accordance with the provisions of 5 U.S.C. § 801(a)(1), the letter must be submitted to Congress and the Comptroller General before it can take effect.

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[45] *See Public Citizen, Inc.*, 940 F.2d at 682-83 (courts look to agency's actual application of statement to determine its nature if language and context of agency statement are not conclusive); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (in subsequent administrative proceeding, agency cannot claim that prior statement of policy itself resolves contested issues).

[46] *See Syncor International Corp.*, 127 F.3d at 94 (a general statement of policy does not impose, elaborate, or interpret a legal norm, but explains the agency's manner of enforcing the existing legal norm).