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	Applicability to CMS Letter on State Children's Health Insurance Program

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Highlights of GAO-08-785T, a testimony before Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

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. 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 the Centers for Medicare & Medicaid Services (CMS).

On August 17, 2007, CMS issued a letter purporting to clarify statutory and regulatory requirements related to preventing SCHIP substitution for other insurance coverage in states wishing to cover children with effective family incomes in excess of 250 percent of the federal poverty level (FPL). The letter indicates that CMS will apply measures identified in the letter to state proposals to cover these children, as well as to states that already cover them, and may take corrective action against states that fail to adopt the measures within 12 months.

In response to a request from the Chairman of the Subcommittee on Health Care, Senate Committee on Finance, and a member of that Subcommittee, GAO considered whether the letter is a rule under the Congressional Review Act (the Review Act). This testimony is based on the resulting opinion, *Applicability of the Congressional Review Act to Letter on State Children's Health Insurance Program*, B-316048, April 17, 2008.

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CONGRESSIONAL REVIEW ACT

Applicability to CMS Letter on State Children's Health Insurance Program

What GAO Found

The definition of "rule" in the Congressional Review Act incorporates by reference the definition of "rule" in the Administrative Procedure Act (APA), with some exceptions. The APA definition of rule includes three elements relevant to GAO's consideration of the SCHIP letter: 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. GAO concluded that the letter meets these criteria and that none of the exceptions in the Review Act apply. GAO found the letter to be of general 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 states that have already enrolled such children. In addition, GAO found it to be of future effect, that is, concerned with policy considerations for the future rather than the evaluation of past or present conduct. Finally, GAO found that the letter is designed to implement, interpret, or prescribe law or policy since 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.

The history of the regulatory provision regarding substitution of coverage supported the view that the August 17 letter is a rule. In issuing the proposed and final rules to implement SCHIP, CMS indicated that it could not require states to adopt any particular measures to prevent substitution of coverage, stating that it did not have a statutory or empirical basis for doing so. 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 to prevent substitution of coverage. Thus, the letter amounts to a marked departure from the agency's settled interpretation of the regulation regarding substitution of coverage, and case law indicates that such a change may be made only by rule. Moreover, the agency expressly relied on the letter to disapprove a state request to amend its SCHIP plan to cover children with family incomes in excess of 250 percent of the FPL, confirming that the letter has binding effect and is, therefore, a rule.

In response to GAO's inquiries, CMS stated that the letter is a general statement of policy announcing the course that the agency intends to follow in adjudications concerning compliance with requirements already set forth in regulations. The GAO opinion explained that statements of policy would appear to fit within the definition of rule in the APA and that courts have referred to them as rules. However, GAO also concluded that the August 17 letter does not have the characteristics of a statement of policy identified in case law. It evidences little, if any, of the tentativeness that is the hallmark of a policy statement, and the agency has relied on the letter to disapprove a state plan amendment, treating the letter as if it were a binding rule.

United States Government Accountability Office

Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to participate in today's hearing on the August 17, 2007, letter issued by the Centers for Medicare & Medicaid Services (CMS) on the State Children's Health Insurance Program (SCHIP). My testimony focuses on GAO's April 17, 2008, opinion, which addressed whether the CMS letter is a rule for purposes of section 251 of the Contract with America Advancement Act of 1996,¹ commonly referred to as the Congressional Review Act (the Review Act).² In that opinion, we concluded that the letter is a rule under the Review Act, which, consistent with the Act's requirements, must be submitted to Congress and the Comptroller General before it can take effect.

Background

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 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

⁵ 42 C.F.R. § 457.60.

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

² Applicability of the Congressional Review Act to Letter on State Children's Health Insurance Program, B-316048, April 17, 2008. The opinion is available at http://gao.gov/decisions/other/other.htm.

³ See 42 U.S.C. § 1397aa.

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).

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, 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. For example, according to the letter, states should impose cost sharing in approximation to the cost of private coverage and establish a minimum of a 1-year period of uninsurance for individuals prior to receiving coverage. In addition, the letter states 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. The letter indicates that CMS will apply the measures to states' proposals to cover children with effective family incomes in excess of 250 percent of the FPL, as well as to states that already cover such children. According to the letter, CMS may take corrective action against states that fail to adopt the identified measures within 12 months.

Discussion

The definition of "rule" in the Review Act incorporates by reference the definition of "rule" in the Administrative Procedure Act (APA), with some exceptions. To determine whether the August 17 letter is a rule under the Review Act, we thus considered whether the letter is a rule under the APA

⁶ 42 U.S.C. § 1397bb(b)(3)(C).

⁷ 42 C.F.R. § 457.805.

and whether it falls within any of the exceptions contained in the Review Act.⁸ Section 551(4) of the APA defines the term rule in pertinent 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"⁹ This definition of rule has been said to include "nearly every statement an agency may make."¹⁰

Agency statements that create binding legal norms—those that, for example, grant rights, impose obligations, or affect private interests—are rules under the APA.¹¹ 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

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 concluded that none of these three exceptions apply to the August 17 letter.

⁹ 5 U.S.C. § 551(4).

¹⁰ Batterton v. Marshall, 648 F.2d 694, 700 (D.C. Cir. 1980) (citing 5 U.S.C. § 551(4)).

¹¹ Id. at 700-02.

guidance documents and manuals have been held to be rules.¹² Agency documents that clarify or explain existing legal requirements also have been held to be rules.¹³ 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 it is intended to include almost all rules that an agency issues and reaches far more than those that must be promulgated according to the notice and comment requirements of section 553.¹⁴

The APA definition of rule includes three elements relevant to our consideration of the SCHIP letter: 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. We concluded that the August 17 letter meets these criteria. We found the letter to be 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

¹² 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).

¹³ 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).

¹⁴ 142 Cong. Rec. H3005 (daily ed. Mar. 28, 1996) (statement of Rep. McIntosh) (noting that although agency interpretive rules, general statements of policy, guideline documents, and agency policy and procedure manuals may not be subject to notice and comment requirements, they are covered under the congressional review provisions of the new chapter 8 of title 5).

such children.¹⁵ In addition, we found it to be of future effect, that is, concerned with policy considerations for the future rather than the evaluation of past or present conduct.¹⁶ Finally, the letter 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, we found that the letter is designed to implement, interpret, or prescribe law or policy.¹⁷

The history of the regulatory provision regarding substitution of coverage supported our view that the August 17 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 to prevent substitution of coverage, stating that it did not have a statutory or empirical basis for doing so.¹⁸ CMS confirmed this interpretation in a final rule.¹⁹ 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

¹⁷ See A.D. Transport Express, Inc., 290 F.3d at 768 (order explaining agency regulation is an interpretative rule under the APA); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 664 (agency statements that clarify laws or regulations are rules under the APA).

¹⁸ 64 Fed. Reg. at 60921-22.

¹⁹ 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).

¹⁵ 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).

¹⁶ 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).

strategies as "reasonable procedures" to prevent substitution of coverage (for example, a minimum 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 regulation regarding substitution of coverage, and case law indicates that such a change may be made only by rule.²⁰

We also found it significant that CMS had expressly relied on the letter to disapprove a state's request to amend its SCHIP plan to cover children with family incomes above 250 percent of the FPL. Specifically, 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 denied New York's request with specific reliance on the terms of the August 17 letter. For example, CMS indicated that the state failed to provide assurances that it had enrolled at least 95 percent of the children with family incomes below 200 percent of the FPL and that "as outlined in an August 17, 2007, letter, . . . 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." CMS also cited the fact that the state's proposal did not include a 1-year period of uninsurance for populations over 250 percent of the FPL. CMS concluded stating that its disapproval was "consistent with the August 17, 2007, letter to State Health Officials discussing how ... existing statutory and regulatory requirements should be applied to all States expanding SCHIP effective eligibility levels above 250 percent of the FPL." This application of the letter to deny New York's proposed plan

²⁰ 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).

amendment served to confirm that the letter has binding effect and is, therefore, a rule. 21

During the course of our work, 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.²² 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." 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.

As discussed in our opinion, 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.²³ Further, courts have referred to them as rules.²⁴ While some cases seem to

²³ See U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act at 30, n. 3.

²⁴ 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").

²¹See 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 they must comply with the pronouncement's terms, it is a rule); *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).

²² 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).

suggest that general statements of policy are not rules under the APA,²⁵ the better reading of these cases, in our view, is that statements of policy are rules under section 551 of the APA but 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, we found that the August 17 letter does not have the characteristics of a general statement of policy identified in case law. One case provided a particularly 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,²⁶ the United States Court of Appeals for the District of Columbia Circuit considered a pronouncement, styled a "statement of policy," that expressed the Federal Power Commission's (Commission) view of how deliveries of natural gas should be prioritized during periods of shortage. The court held that the pronouncement was a general statement of policy, noting the tentative nature of the statement and the Commission's acknowledgment that any particular decisions on curtailment could only be made in further proceedings. Among other things, 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." In addition, the Commission itself intended the statement only "to state initial guidelines as a means of facilitating curtailment planning and the adjudication of curtailment cases." In effect, the Commission statement was a starting point to frame consideration of future proposals.

²⁵ 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. v. Federal Power Commission*, 506 F.2d 33, 37 (D.C. Cir. 1974) (suggesting that policy statements are not rules under the APA).

²⁶ 506 F.2d 33 (D.C. Cir. 1974).

We analyzed CMS's August 17 letter under the criteria used by the court to determine that the Commission's pronouncement was simply a statement of policy and concluded that the letter does not meet the criteria. The specific measures identified in the letter 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. In addition, the letter contains no indication that the strategies are only guidelines that may or may not be applied in subsequent proceedings or express reference to exceptions 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; 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.²⁷ Because the letter establishes a deadline by which "affected States" need to implement its measures or face the possibility of corrective action, we found that it evidences little, if any, of the tentativeness that is the hallmark of a policy statement.

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 subsequent administrative proceedings. If the agency relies solely on the pronouncement itself to determine rights and obligations of others, the agency has treated the policy statement as if it were a binding rule, not a

²⁷ *Cf. Community Nutrition Institute v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987) (agency pronouncement instructing regulated entities to obtain "exception" from standard in announcement indicated pronouncement was intended to be binding).

	letter to deny the state of New York's request to amend its SCHIP plan led us to conclude that the letter is not a policy statement. This conclusion was reinforced by our observation that the August 17 letter 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. ²⁹
Conclusion	We concluded that the August 17, 2007, letter to state health officials is a rule for the purpose of the Review Act on the grounds that it is a statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy with regard to SCHIP. Furthermore, we found that the letter does not come within any of the exceptions to the definition of rule contained in the Review Act. We expressed 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.
	Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you or other Members of the Subcommittee may have.
Contacts and Acknowledgments	For further information regarding this testimony, please contact Dayna Shah at (202) 512-8208 or shahd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page

general statement of policy.²⁸ CMS's express reliance on the August 17 $\,$

²⁸See Public Citizen, Inc. v. United States Nuclear Regulatory Commission, 940 F.2d 679, 682-83 (D.C. Cir. 1991) (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).

²⁹ 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).

of this statement. Major contributors to this testimony were Helen Desaulniers and Kevin Milne.

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