

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 430, 431, 434, 435, 438, 440, and 447

[CMS-2001-F4]

RIN 0938-AL83

Medicaid Program; Medicaid Managed Care

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Withdrawal of final rule with comment period.

SUMMARY: This document withdraws all provisions of the final rule with comment period on Medicaid managed care that we published in the **Federal Register** on January 19, 2001 (66 FR 6228) with an initial effective date of April 19, 2001. This January 19, 2001 final rule, which has never taken effect, would have combined Medicaid managed care regulations in a new part 438, implemented Medicaid managed care requirements of the Balanced Budget Act of 1997 (Pub. L. 105-33), and imposed new requirements on entities currently regulated as "prepaid health plans" (PHPs). The regulations set forth in the final rule being withdrawn have been superseded by regulations promulgated in a subsequent rulemaking initiated on August 20, 2001 (66 FR 43613). In addition, this document addresses comments received in response to an interim final rule with comment period that we published on August 17, 2001 in the **Federal Register** (66 FR 43090) that further delayed, until August 16, 2002, the effective date of the January 19, 2001 final rule with comment period.

DATES: The final rule with comment period amending 42 CFR parts 400, 430, 431, 434, 435, 438, 440, and 447 that was published in the January 19, 2001 **Federal Register** (66 FR 6228), delayed in the February 26, 2001 **Federal Register** (66 FR 11546) until June 18, 2001, delayed further in the June 18, 2001 **Federal Register** (66 FR 32776) until August 17, 2001, and further delayed in the August 17, 2001 **Federal Register** (66 FR 43090) until August 16, 2002 is withdrawn effective June 14, 2002.

FOR FURTHER INFORMATION CONTACT: Bruce Johnson, (410) 786-0615.

SUPPLEMENTARY INFORMATION:

I. Background

In a final rule published in the **Federal Register** (66 FR 11546) on February 26, 2001, we announced a 60-day delay in the effective date of the January 19, 2001 final rule with comment period implementing Medicaid managed care provisions in the Balanced Budget Act of 1997 (BBA). This 60-day delay postponed the effective date of the final rule until June 18, 2001. This delay in effective date was necessary to give newly appointed Department officials the opportunity for review and consideration of the new regulations. During that review, we heard from key stakeholders in the Medicaid managed care program, including States, advocates for beneficiaries, and provider organizations. These parties expressed strong (sometimes opposing) views about the January 19, 2001 final rule. In particular, concerns were expressed about revisions made in the final rule that were based on public comments we received on the proposed rule. Other commenters raised concerns about how we chose to implement those provisions in the final rule without further opportunity for public comment. As a result of these comments, on June 18, 2001, we published another final rule in the **Federal Register** that delayed the effective date of the January 19, 2001 final rule an additional 60 days, from June 18, 2001 until August 17, 2001, (66 FR 32776) for further review and consideration on the most appropriate way to address the concerns expressed by key stakeholders.

After careful consideration, we decided the best approach was to make some modifications to the January 19, 2001 final rule with comment period, and republish it as a proposed rule. This would enable the public the opportunity to comment on all of the provisions and revisions. Therefore, as noted above, on August 20, 2001 we published a new proposed rule in the **Federal Register** (66 FR 43613). In addition, in order to give us time to consider the public comments and take action on the new proposed rule, we also published an interim final rule with comment period on August 17, 2001 in the **Federal Register** (66 FR 43090) that further delayed until August 16, 2002, the effective date of the January 19, 2001 final rule with comment period.

In response to those comments submitted on the August 20, 2001 proposed rule, we have published, elsewhere in this **Federal Register** issue, a final rule amending the Medicaid regulations to implement the managed care provisions of the BBA, and to

establish new standards for prepaid health plans (PHPs), which are, under this new final rule, divided into two categories, prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). In light of the publication of the superseding final rule, we are withdrawing the provisions of the January 19, 2001 final rule with comment period.

II. Analysis of and Response to Public Comments on the August 17, 2001 Interim Final Rule With Comment Period

We received approximately 23 public comments expressing dissatisfaction with the delay in the effective date of the January 19, 2001 final rule with comment period.

Comment: Numerous commenters contended that "courts have held that the effective date of a regulation is a substantive term of the regulation itself, and the Administrative Procedure Act (APA) requires that the public be given prior notice and opportunity to comment before substantive terms of a regulation may be legally changed."

Response: None of these commenters cited the court cases upon which they purport to rely for the proposition that withdrawing a regulation that has never taken effect constitutes a change in the regulations. We are not aware of any case that suggests that an agency must go through notice and comment to delay the effective date of a regulation that has not taken effect (or to withdraw a regulation, as we are doing here). Under the APA, notice and comment generally is required to promulgate new rules or to change rules that are already in place. Currently, the Medicaid managed care regulations that are in effect are those set forth in part 434, because the regulations published on January 19, 2001 have not become effective. We would agree that notice and comment is required to change the Medicaid managed care regulations in part 434, and we have done so in the final rule responding to comments on the August 20, 2001 proposed rule. We do not agree, however, that notice and comment is required in order to delay the effective date of regulations that have been published in the **Federal Register** but have never taken effect. In that case, there is no "rule" in effect, just an announcement of a "future" rule. We do not believe that notice and comment was required to change the effective date of a "future rule." Nor do we believe that notice and comment is required in order to withdraw a rule before it takes effect. We note that even if notice and comment were required, we have engaged in public notice and

comment on the final rule that supersedes the rule we are withdrawing.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: April 17, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 14, 2002.

Tommy G. Thompson,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 430, 431, 434, 435, 438, 440, and 447

[CMS-2104-F]

RIN 0938-AK96

Medicaid Program; Medicaid Managed Care: New Provisions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Medicaid regulations to implement provisions of the Balanced Budget Act of 1997 (BBA) that allow the States greater flexibility by permitting them to amend their State plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without obtaining waivers if beneficiary choice is provided; establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services; and eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs, such as, the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition against enrollee cost-sharing.

EFFECTIVE DATE: These regulations are effective on August 13, 2002. States will have until June 16, 2003, to bring all aspects of their State managed care program (that is, contracts, waivers, State plan amendments and State operations) into compliance with the final rule provisions.

FOR FURTHER INFORMATION CONTACT:

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Subpart C—Kristin Fan, (410) 786-4581.

Subpart D—Deborah Larwood, (410) 786-9500.

Subpart F—Tim Roe, (410) 786-2006.

Subpart H—Donna Schmidt, (410) 786-5532.

Subpart I—Tim Roe, (410) 786-2006.

Subpart J—Bruce Johnson, (410) 786-0615.

SUPPLEMENTARY INFORMATION:

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I. Background

A. General

In 1965, amendments to the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program for providing financial assistance to individuals with low incomes to enable them to receive medical care. Under the Medicaid program, each State establishes its own eligibility standards, benefits packages, payment rates and program administration in accordance with certain Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the State's Medicaid "State plan" that we must approve. In addition to approving State plans and monitoring States for compliance with Federal Medicaid laws, the Federal role also includes providing matching funds to State agencies to pay for a portion of the costs of providing health care to Medicaid beneficiaries. Medicaid beneficiaries typically include low-income children and their families, pregnant women, individuals age 65 and older, and individuals with disabilities. (Throughout this preamble,

we use the term "beneficiaries" to mean "individuals eligible for and receiving Medicaid benefits." The term "recipients" in the regulations text has the same meaning as the term "beneficiary.")

When the Medicaid program was created, coverage typically was provided through reimbursements by the State agency to health care providers who submitted claims for payment after they provided health care services to Medicaid beneficiaries. This reimbursement arrangement is referred to as "fee-for-service" (FFS) payment. Before 1982, 99 percent of Medicaid beneficiaries received Medicaid coverage through fee-for-service arrangements. Since 1982, State agencies increasingly have provided Medicaid coverage through contracts with managed care organizations (MCOs), such as health maintenance organizations (HMOs). Through these contracts an MCO is paid a fixed, prospective, monthly payment for each beneficiary enrolled with the entity for health coverage. This payment approach is referred to as "capitation." Beneficiaries enrolled in capitated MCOs are required to receive health care services provided under the MCO's contract, through the MCO that receives the capitation payment. The Omnibus Budget Reconciliation Act (OBRA) of 1981 (Pub. L. 97-35 enacted on August 13, 1981) allowed State agencies to mandate that Medicaid beneficiaries enroll in MCOs, which increased the use of MCOs. In most States, mandatory enrollment takes place for at least certain categories of beneficiaries. To achieve this mandatory enrollment, before the enactment of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105-33, enacted on August 5, 1997), States were required to obtain a waiver of a Medicaid statutory requirement for beneficiary "freedom of choice" of providers. (State programs that offered beneficiaries voluntary enrollment in MCOs do not require these waivers.) As a result, in 1997, just before the passage of the BBA, almost 8.5 million Medicaid beneficiaries, or 43 percent of all Medicaid beneficiaries, were enrolled in MCOs for a comprehensive array of Medicaid services. Some of these beneficiaries and additional Medicaid beneficiaries were enrolled in other organizations that received capitated payment for a limited array of services, such as behavioral health or dental services. These organizations that receive capitation payment for a limited array of services are referred to as "prepaid health plans (PHPs)."

While the Act was further amended in the 1980s and in 1990 to address certain