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The U. S. Department of Health and Human Services
Centers for Medicare and Medicaid Services

Comments on Proposed Regulations
File Code [CMS-4068-P]

Medicare Prescription Drug Benefit
42 CFR 423

The Fiscal Policy Institute, a nonpartisan research and education organization that focuses on the broad range of tax, budget, economic and related public policy issues that affect the quality of life and economic well-being of New York residents, respectfully submits these comments on the rules proposed by the Centers for Medicare and Medicaid Services (CMS) for the Medicare prescription drug benefit (42 CFR Part 423) as published in the Federal Register, Volume 19, No. 148, August 3, 2004. Our comments focus on two areas of concern: protections for Medicare recipients who are also eligible for Medicaid and the coordination between the Medicare prescription drug program and New York's very successful Elderly Pharmaceutical Insurance Program (EPIC).

DUAL ELIGIBLES

New York has 2.7 million Medicare beneficiaries. In New York, nearly one out of five Medicare recipients also receives Medicaid assistance. New York is home to more than 8 percent of the nation's "dual eligibles." The 537,000 "dual eligible" New Yorkers constitute the group most vulnerable during the transition from the existing Medicaid coverage of prescription drugs to the implementation of the new Medicare benefit. We believe the timing and implementation provisions of the proposed rules do not provide sufficient protections for this group.

Timing of Transition from Medicaid to Medicare Part D

The proposed rules end Medicaid coverage for prescription drugs for dual eligibles on January 1, 2006, giving dual eligibles only the six weeks from November 15, 2005 to December 31, 2005 to voluntarily enroll in a qualified Prescription Drug Plan (PDP) without losing coverage. Given the educational levels and high incidence of
mental and/or physical disabilities in this group of beneficiaries, six weeks is not sufficient to ensure that all dual eligibles will be able to complete the enrollment process.

In fact, the law and proposed rules anticipate that some of these individuals will not enroll voluntarily in a PDP. The statute and rules require that a dual eligible individual who fails to enroll in a PDP or MA-PD should be automatically enrolled into a PDP that has a monthly beneficiary premium equal to or below the subsidy amount available to low-income beneficiaries. If more than one such PDP serves the individual's region, the individual would be randomly assigned to one of the PDPs. The automatically assigned participant must be notified of the enrollment action and provided the opportunity to enroll in a different plan.

Unfortunately, the proposed rules do not allow automatic enrollment until the end of the initial enrollment period on May 15, 2006, which creates the likelihood that many dual eligibles will be left up to 4 1/2 months without prescription drug coverage. To protect against a gap in coverage for a significant number of beneficiaries, automatic enrollment must be completed at least several weeks before the loss of Medicaid benefits in order to provide automatically enrolled beneficiaries with notice of their enrollment in a PDP, information about the assigned plan, and an opportunity to change plans if the assigned plan does not fit their medical needs (e.g. uses a formulary which does not include a particular drug they wish to continue to use).

Recommendation #1: Extend Medicaid coverage of prescription drugs for dual eligibles through December 31, 2006 to ensure coverage during the transition to the Medicare prescription drug program.

Automatic Enrollment

In the preamble to the proposed rules (p. 46639), CMS requests comments on whether CMS or the states are best suited to perform the automatic and random enrollment functions for dual eligibles who fail to enroll in a PDP prior to the end of the enrollment period. As noted in the preamble, state officials have more readily available data identifying the dual eligibles in their state. In addition, states will already be involved in the enrollment process because they are required by both the proposed rules and the statute to make eligibility determinations for the low-income premium and cost-sharing subsidies. However, this added responsibility should include sufficient administrative payments to compensate states for the costs related to automatic enrollment. This is particularly important given the disincentives to enrollment inherent in the clawback provisions. Since the monthly amount of Medicaid savings that a state must "share" with the federal government is a function of the number of dual eligibles who have enrolled in Part D plans in any given month, a state could reduce the size of these required payments by slowing down the automatic enrollment process.

Recommendation #2: Automatic enrollment of dual eligibles should be performed by the state and CMS should reimburse the states for 100% of their administrative costs relating to the enrollment of dual eligibles in Part D plans.
Continuity of Access to Specific Prescription Drugs

There are significant concerns for continuity of care for dual eligibles and their access to needed prescriptions. The proposed rules would force dual eligibles to enroll (or be automatically enrolled) in the “benchmark” or average plans in their areas because the low-income subsidy they will receive will only cover the premium for these plans. The formularies for these plans may not be as comprehensive as the drug coverage these individuals currently have through New York's Medicaid program. Without access to the coverage they need, dual eligibles may be forced to switch medications. For the many New York dual eligibles who are suffering from HIV/AIDS, such switches can be deadly. For these and other dual eligibles, denying them access to appropriate prescription drugs for weeks may also prove costly for the state's already overburdened Medicaid program. If dual eligibles are forced off the appropriate prescription drugs, a significant number will be forced into more expensive hospital care.

The statute and regulations include an appeals process to enable plan participants to gain access to drugs not included on a plan's formulary if a particular drug is found to be medically necessary. Unfortunately, the process proposed in these rules is extremely complex and difficult to navigate for people having a psychiatric crisis, facing cognitive impairments, or in the midst of aggressive chemotherapy—to list just a few examples. Moreover, the timelines established are extremely drawn out; for example, an expedited determination could take as long as two weeks. Additionally, drug plans are not required to provide an emergency supply of medications until at least two weeks after the initial request for a formulary exception.

Recommendation #3: Coverage of medications for dual eligibles should be grandfathered into the new Part D benefit. For the very vulnerable dual eligible population, for those with life-threatening diseases, such as HIV/AIDS, mental illness, cancers, and other extreme conditions (groups which could be classified as having pharmacologically complex conditions), drug plans must be required to cover their existing medications.

COORDINATION WITH NEW YORK'S EPIC PROGRAM

Ability of SPAPs to Provide Consumer Advice

New York provides prescription drug insurance to more than 350,000 elderly New Yorkers through its very successful Elderly Pharmaceutical Insurance Program (EPIC). While the statute and the proposed rules prohibit SPAPs from discriminating based on the PDP in which the beneficiary is enrolled, the law does not prohibit a State from providing consumer advice to its citizens as to which plan might work best with a SPAP, which plan offers the best value, etc. The preamble on page 46697 offers an interpretation of the nondiscriminatory provisions of the statute that would prevent SPAPs from steering participants to a one plan over another. This restrictive interpretation, which extends beyond any statutory language or intent is wrong and could
be harmful to program participants. Given the complexity of the new program and the trust and confidence that State Pharmaceutical Assistance Programs such as EPIC have gained with the elderly population, it would be wrong to ban SPAPs from providing such assistance.

**Recommendation #4:** Given the intense need for consumer assistance and the value of the EPIC network, we urge that the language in the preamble regarding the interpretation of "nondiscrimination" should be dropped.

**SPAPS as Fallback Providers**

The requirements that Subpart Q (Sections 423.851-875) imposes on entities that would be interested in providing a ‘fallback plan’ to serve an area not served by at least two plans are so severe that fallback plans may not, in fact, be available. The requirements in the rules exceed the requirements found in the statute making it entirely possible that some rural areas may have no service except regional PPOs and HMOs. Congress clearly did not intend that seniors would have to join a managed care plan for all their health care services in order to get the prescription drug benefit. Allowing SPAPs such as EPIC to serve as the fallback plan for these areas is a logical and cost effective alternative to the proposed rules. EPIC already serves more than 350,000 New Yorkers in all areas of the state and should be allowed to offer a fallback plan rather than forcing seniors to join a managed care plan.

**Recommendation # 5:** The requirements in this section of the rules should be scaled back to make it more certain that fallback plans will submit bids where such plans may be needed.

**Recommendations #6:** If no private plan is available as a fallback plan, the rules should allow SPAPs such as EPIC to offer such plans.

Respectfully submitted:

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