AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

February 26, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4159–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Dear Administrator Tavenner:

On behalf of the American Academy of Family Physicians (AAFP), which represents 110,600 family physicians and medical students across the country, I write to express our strong concerns with the unnecessary policy changes within the "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" proposed rule as published in the January 10, 2014, *Federal Register*.

Drug Categories or Classes of Clinical Concern and Exceptions

Though we recognize CMS is obligated to implement Section 3307 of the *Affordable Care Act*, the AAFP nevertheless strongly objects to needlessly upending successful formulary protections in place since 2005 for six protected drug classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection) for the Medicare Part D program by eliminating antidepressants and antipsychotics in 2015 from the protected classification. It is AAFP's prescribing policy to oppose any actions that limit patients' access to physician-prescribed pharmaceuticals. The changes in 2015 to the antidepressant and antipsychotic classification are particularly troubling to the AAFP since primary care physicians make the majority of depression diagnoses and prescribe more than half of all antidepressants.

The offered rationalizations for this significant change in Part D policy are based predominately on program cost and drug utilization. However the AAFP dismisses these arguments as "penny wise, pound foolish" because forcing patients to deviate from stable and clinically effective prescriptions could dramatically increase overall healthcare costs elsewhere. According to a study by the American Psychiatric Institute for Research and Education, the expected number of emergency department visits was 74 percent higher for Medicaid patients with reported medication access problems compared to patients without

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medication access issues. Similarly disturbing, among acute stay inpatients, the expected number of hospital days was 72 percent higher for patients with reported medication access problems.

Modifications to mental health medications are particularly problematic. If depression is untreated or becomes mismanaged due to a formulary or other change, then other chronic conditions such as diabetes typically become more complicated. Many mental health patients are treated with multiple antidepressant medications and finding medications that do not negatively interact with each other is difficult. We believe this effort to limit the Medicare Part D formulary would only exacerbate this challenge.

Enrollment Requirements for the Prescribers of Part D Covered Drugs

Though the vast majority of AAFP members are already enrolled and participate in the Medicare program, the AAFP, nevertheless, opposes requiring physicians who write prescriptions for covered Part D drugs to be enrolled in Medicare for their prescriptions to be covered under Part D.

We recognize that CMS is implementing Section 6405 of the *Affordable Care Act* in making this proposal. However, we oppose the requirement not out of the increased and unfunded administrative burden it imposes, but rather based on the belief that the Medicare covenant is between the beneficiary and the program and that Medicare benefits belong to the beneficiary.

This proposal is made under the justifications to improve CMS' ability to oversee the Medicare Part D program and to ensure that prescriptions covered by the Part D program are written by qualified health care practitioners. The AAFP concedes there is a reasonable expectation that a public or private payer should require certain information from physicians reimbursed by that payer; however, writing a prescription for a Part D drug typically does not result in any physician compensation. Therefore, this proposed requirement violates the beneficiary's covenant with the Medicare program, because it potentially prohibits a patient from receiving a benefit or service that the patient is entitled to by law.

Furthermore, prescribing authority is already tied to the physician having a U.S. Drug Enforcement Administration (DEA) number and not a National Provider Identifier. Since physicians must already establish a relationship with the federal government through the DEA to prescribe, the AAFP encourages CMS to explore implementation of Section 6405 through closer coordination with the DEA instead of the proposal made within this regulation.

We appreciate that CMS openly recognizes that this proposal would preclude all prescribers located outside of the United States, Puerto Rico, Guam, and the U.S. Virgin Islands, and the Northern Mariana Islands from prescribing Part D drugs, because they may not be eligible to enroll in the Medicare program. The AAFP suggests this is yet another reason not to finalize the policy as proposed.

We reiterate that we believe that this provision will not impact many of our members outside of residency. However, we voice concerns with this federal overreach that will predominately impact primary care practice models, especially small or rural practices.

The AAFP does appreciate that this policy, if finalized as proposed, would continue to allow physicians with a valid opt-out affidavit to prescribe under Part D.

Improper Prescribing Practices

This rule also proposes to deny or revoke a physician's Medicare enrollment if his/her DEA certificate is suspended or revoked or if the applicable state licensing or administrative body has suspended or revoked his/her ability to prescribe. As discussed earlier in this comment letter, since the AAFP encourages CMS to work more closely with DEA and other existing licensing bodies instead of adding yet another Medicare administrative burden onto the practice of medicine, the AAFP finds this particular proposal as reasonable.

The regulation also proposes to allow CMS to revoke a physician's Medicare enrollment if the agency determines that the physician has a pattern or practice of prescribing Part D drugs that:

- Is abusive and represents a threat to the health and safety of Medicare beneficiaries or
- Fails to meet Medicare requirements.

The AAFP notes that CMS does not define "abusive" or "threat to the health and safety of Medicare beneficiaries." Instead the proposed rule lists criteria that it would use to make this determination. We reviewed these criteria and in general, they seem reasonable. However we do question, "The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined)."

It is an unfortunate reality that physicians sometimes settle cases, even when the physician is not at fault because it can be cheaper than the legal fees to defend the case. Since this proposal would penalize physicians who do so, the AAFP questions the appropriateness of this particular criterion.

We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

Jeffrey J. Cain, M.D., FAAFP
Board Chair