

PAIN CARE COALITION

A National Coalition for Responsible Pain Care

**American Academy of Pain Medicine • American Pain Society
American Society of Anesthesiologists**

By Hand Delivery

March 7, 2014

The Honorable Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

**Re: CMS-4159-P: Proposed Changes to 42 CFR 424.535
Revocation of Medicare Physician Enrollment Based on
Prescribing Practices**

Dear Administrator Tavenner:

The Pain Care Coalition is pleased to submit these comments on the Agency's January 10, 2014 proposed rule amending Medicare's enrollment regulations. (79 Fed. Reg. 2073) The member professional societies of the Pain Care Coalition collectively represent tens of thousands of clinicians, educators, and researchers specializing in the diagnosis, treatment, and management of both acute and chronic pain. The vast majority of clinicians treating patients in pain are enrolled in Medicare, and authorized by state law to prescribe medications to their patients in the course of their professional practice. Most are also registered with the Drug Enforcement Administration ("DEA"), and thus authorized to prescribe medications regulated under the Controlled Substances Act ("CSA"). The use of certain agents including anti-depressants, anti-epileptic drugs, and controlled substances including both opioids and benzodiazepines in the treatment of chronic pain is currently the subject of multiple governmental initiatives designed to protect against inappropriate use, overuse or misuse. That said, the ability of clinicians to prescribe these drugs within the framework of thoughtful, individualized care in appropriate circumstances remains indispensable for alleviation of pain and human suffering for millions of Americans, many of them beneficiaries of the Medicare program.

Overview of Position

The Coalition **strenuously opposes** the proposed changes to 42 CFR 424.535. If adopted as proposed, these changes would substitute the judgment of CMS and presumably its claims processing contractors for that of state licensure authorities and other professional oversight bodies traditionally responsible for regulating professional practice, including prescribing practices. In the guise of making “policy and technical” changes to Medicare Advantage and Part D drug plans, this aspect of the January 10 rulemaking **represents a major expansion of CMS authority over the practice of medicine** with consequences for a physician’s ability to treat Medicare patients that go far beyond either Part C managed care plans or Part D prescription drug plans. It does so (1) without demonstrating that CMS and its contractors have the expertise to make appropriate judgments about a clinician’s prescribing practices, (2) without clear and evidence-based criteria for making those judgments, and (3) without reasonable due process protections for clinicians whose prescribing practices come under scrutiny. Indeed, the proposal includes no transparent procedures under which CMS would exercise this substantial new authority.

While undoubtedly prompted by current concerns over the prescribing of particular drugs for a particular class of patients, this new authority could be used against any prescribing practice in the future. Indeed, it could become precedent for even more expansive “second guessing” of clinical judgment generally. In either circumstance, it could have a pronounced negative effect on clinician behavior, with a corresponding restriction on the access of Medicare patients to necessary, and covered, items and services.

Specific Comments

1. Revocation of Enrollment is a Disproportionate Remedy for Much of the Prescribing Conduct Subject to the Proposed Rule.

Revocation of a physician’s Medicare enrollment privileges is an “**all or nothing**” **remedy**, in stark contrast with the graduated disciplinary measures generally available to others judging professional practice. State medical boards, for example, generally can impose sanctions ranging from additional educational requirements to full loss of license. Hospital staff disciplinary committees and similar peer review activities generally start with education or restricted privileges before moving to more severe sanctions. Even DEA sanctions frequently affect only the physician’s ability to prescribe controlled substances, not his or her ability to prescribe other medications, or to continue to practice.

Other Medicare program sanctions are also of a graduated nature. Contractor and auditor claims reviews affect a subset of services, without necessarily jeopardizing

the entire practice. A Part D audit of prescribing practices might lead to the disallowance of certain drug claims, but the effect would be limited to Part D.

Revocation of Medicare enrollment, on the other hand, is an extreme sanction for most physician specialties. Not only is the physician not able to prescribe controlled substances, or other medications, or obtain Part D coverage for his patient's medications, he or she is **effectively prohibited from providing or ordering any service to or for any Medicare patient**. And loss of Medicare billing privileges may have related consequences under Medicaid and commercial payment programs that effectively preclude the physician from serving any patients.

A remedy of this magnitude should be available to CMS only under clear statutory authority from Congress, with appropriate criteria for its exercise, and only with the most careful substantive and procedural protections.

2. CMS Does Not have the Requisite Expertise to Make These Judgments, Particularly in the Case of Complex Pain Patients.

Neither the proposed rule nor the accompanying commentary demonstrates that CMS and its contractors have any particular expertise in evaluating physician prescribing practices generally or medication therapies for pain patients specifically.

The Coalition is acutely aware of the public's concern over, and the heightened regulatory scrutiny surrounding, the use of certain controlled substances in the treatment of pain, and specifically their use in the treatment of chronic pain patients. Its member societies and many of their individual members are at the forefront of both public and private efforts to ensure that powerful pain medications are used only when medically indicated, and then judiciously and under careful physician supervision as part of an overall treatment plan. Finding the appropriate balance between alleviating pain and suffering, and risking adverse outcomes from overuse or abuse, has not been easy. But it is being diligently pursued by the professions, and by others in government entrusted with ensuring the appropriateness of medical practice.

The Coalition believes that the **primary role in this area should remain with state boards of medicine** (and other disciplines), just as it does with other aspects of professional practice. These are the traditional arbiters of acceptable care standards and they have been deeply involved, with the professions, in establishing appropriate boundaries on prescribing practices in the pain care field. They have developed substantial expertise in this area in recent years. They have ample authority to educate physicians, and where appropriate, discipline them, with respect to prescribing practices.

CMS should follow their determinations, and not substitute its judgment for theirs. For example, if a state board has revoked a physician's medical license, the Coalition would expect CMS to revoke that physician's Medicare enrolment. If the state board has limited a physician's prescribing privileges, but stopped short of license revocation, then the Coalition would understand CMS denying Part B or D claims coverage for

prescriptions consistent with the state board's imposed limitations, but not revocation of all billing privileges. For this reason, the Coalition opposes proposed paragraph 424.535 (a) (13) to the degree it would trigger enrollment revocation when the state medical board (or the DEA) has taken action of a lesser magnitude. If a state board has imposed some lesser sanction, e.g. remedial continuing medical education, then the Coalition would expect CMS to refrain from taking any action against the prescriber unless and until the state board imposed more severe sanctions, and only then in a manner consistent with the state action.

At the Federal level, the FDA plays a role through its program of "risk evaluation and mitigation strategies" ("REMS") targeted on specific medications. DEA also has its role, controversial though it may be in some cases, in determining whether controlled substances are being prescribed for a "legitimate medical purpose" in the "usual course of (the prescriber's) professional practice." But these roles are firmly based in specific statutory authorities, just as a state medical board's authority is based in and circumscribed by state law.

CMS, by contrast, has no similar statutory base, and no demonstrated expertise in making judgments about the appropriate role of medication therapy in the treatment of complex pain patients. Although the proposed rule does not provide details on the process by which CMS would become informed of improper prescribing practices, making informed public comment impossible, the Coalition can only presume that CMS would rely on its various contractors to forward cases of "improper prescribing practices" to CMS, and to provide the detailed case information on which CMS would make its determination to revoke enrollment. Medicare's claims processing agents and contract auditors such as the Recovery Audit Contractors have frequently been asked to make judgments about medical necessity, and, or quality of care issues. Their expertise in doing so has often been deficient, and held to be so by hearing officers and administrative law judges in the appeals process, generally on matters of less complexity than determining whether a pain practitioner's medication therapy, including dosing and duration, is appropriate. Your own Agency's most recent report to Congress on RAC appeals, for example, shows that over 40 percent of provider-appealed RAC audit recoveries are eventually overturned.

3. The Decision "Factors" Listed in the Proposed Rule Are Not True Standards and Are Too Vague to Be Consistently Applied.

Proposed paragraph 424.535 (a)(14) adds "improper prescribing practices" as a basis for revocation where CMS finds a pattern or practice of prescribing that falls into either of two categories: those that are "abusive" and represent a threat to patient health and safety under subparagraph (14)(i); and those that fail to meet Medicare requirements under subparagraph (14)(ii). **The rule does not define "improper" prescribing practices by reference to evidence-based guidelines or other indicia of acceptable care standards.** Instead, CMS simply lists a variety of factors that it will consider in making the apparently entirely discretionary determination that the prescribing has been "improper."

Some of these factors (e.g. those included by reference in proposed (a)(14)(i)(E) are more susceptible to consistent application than others, but most would leave CMS with **virtually unfettered discretion**. The inclusion of proposed (a)(14)(i)(H) which covers “any other relevant information” highlights both the degree of discretion CMS is reserving to itself, and the **lack of uniform standards** against which physician behavior would be judged. While this may not have been the Agency’s intent, we think the only true standard in this aspect of the proposal could be characterized as a “we will know it when we see it” standard.

Take, for example, proposed (14)(i)(A) dealing with the supporting diagnosis. Complex pain syndromes are typically much more challenging from a diagnostic perspective than most other conditions or diseases. Lab and imaging tests are not available to confirm or rule out the presence of pain or its intensity, and patient symptoms and the manner in which patients report those symptoms often vary widely. Two physicians diagnosing two similar patients may end up with different diagnostic conclusions. Where would CMS go to determine which was correct, or whether they might both support a particular prescription even though different?

Or consider proposed (14)(i)(C) dealing with “excessive” dosing “linked” to patient overdoses. Some might argue that the overdose itself is proof of the excessive dosing. But nothing could be further from the truth. Few overdose deaths result from patients taking medications as directed. And in many, if not most such deaths, there are other complicating factors at play which lead to the adverse event. How many overdoses will there have to be? How weak or strong is the linkage? What other relevant factors will go into deciding whether the dosage was excessive? How does CMS make these determinations?

The decision factors in proposed subparagraph (14)(ii) also fail to provide physicians with clear standards on which they can rely. The DEA “factor” in (14)(ii)(B) is particularly problematic. Presumably it includes judgments that a physician is prescribing outside the “usual course” of professional practice. This has been an elusive standard for the DEA, as primarily a law enforcement agency, to apply, and CMS did not provide justification why the Agency and its contractors are in a better position to apply it in the course of fulfilling their claims payment responsibilities.

Furthermore, there is already a direct linkage between CSA violations and physician exclusion from Medicare under existing statutory provisions administered by the Office of Inspector General (“OIG”). 42 U.S.C.1320a-7(a)(4) and (b)(3). However, the OIG’s exclusion authority is triggered **only after a prescriber has been convicted** of a CSA related felony (in the case of mandatory exclusion) or misdemeanor (in the case of permissive exclusion). Under the CMS proposal, CMS could revoke a physician’s enrollment, having essentially the same effect on the physician as an OIG exclusion, but based on CMS’ discretionary judgment alone, and not a prior conviction in court with all of the substantive and procedural protections available in a criminal prosecution.

4. The Proposed Rule Does Not Articulate a Process Through Which CMS Would Make These Judgments.

Despite the unprecedented scope of the new authority which the proposed rule would grant to CMS, the proposal does not identify procedural ground rules or protections for those whose prescribing practices are being judged. Because none have been proposed, the Coalition finds it nearly impossible to comment meaningfully on what should have been a fundamental aspect of this proposed rule. Given the potential impact on a practitioner of the loss of all Medicare billing privileges, CMS should have made clear how it intends to make these discretionary judgments, and proposed procedural due process protections for physicians whose prescribing practices would be subject to CMS scrutiny under the rule.

5. The Proposed Rule Overlaps Substantially with the OIG's Existing Exclusion Authority and is Thus Unnecessary to Protect either Beneficiaries or the Medicare Program.

The proposed rule is in effect a new permissive exclusions authority, much like that already held by the OIG, but without a statutory base, and to be implemented in the sole discretion of CMS with no apparent procedural protections against arbitrary use of that authority. This proposed duplication does not appear necessary to protect the program or its beneficiaries. And while the overlap between what CMS proposes here, and what Congress has already provided for, is not complete, it is certainly substantial. We have noted above the existing authority to exclude practitioners based on conduct regulated by the DEA and found to violate the CSA.

At a more “macro” level, virtually all conduct proposed to be covered by the proposed rule (improper diagnosis, insufficient patient evaluation, excessive dosing, state disciplinary actions, and adverse events, among other “factors”) could already be the basis for an OIG exclusion action under 42. U.S.C. 1320a-7(b)(6)(B). That provision of existing law authorizes exclusion of any individual or entity that “has furnished or caused to be furnished items or services to patients **substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards** of health care”.

The Coalition simply fails to see why the Medicare program needs additional authorities, much less those as defective as proposed here, to protect the program or its beneficiaries.

Conclusion

For all of the aforesaid reasons, the Pain Care Coalition opposes the proposed changes to 42 CFR 424.535 identified above. We urge your careful consideration of these concerns, which we believe are fundamental to ensuring that qualified pain practitioners are able to provide quality pain care to the millions of Medicare beneficiaries afflicted with acute and, or chronic pain. The Coalition, and the Societies

and professionals it represents, would be pleased to assist you and your staff in any way we can as you and others within the Department seek responsible policy solutions to matters involving the use of prescription drugs in the treatment of pain patients.

Respectfully submitted,

A handwritten signature in black ink that reads "James P. Rathmell, MD". The signature is written in a cursive style with a large, prominent "J" and "R".

James P. Rathmell, M.D.
Chairman