Forensic Forum

CMS Asserts Broad Authority Over Physician Prescribing Practices

“Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided...”

Thus begins Title XVIII of the Social Security Act, otherwise known as Medicare, as enacted by the Congress in 1965. This “non-interference” provision represented a fundamental commitment by the Medicare program’s framers to both America’s physicians, and to the elderly who would be served by the new Federal health insurance program. At a time when “States’ rights” were perhaps more jealously protected than they are today, it also reflected a commitment by the Congress to the States that Medicare would not usurp the States’ traditional role of licensing medical and other health professions, and overseeing their professional conduct.

With the benefit of what is now almost 50 years hindsight, the provision looks almost quaint, or, more cynically, an empty promise long since negated by the Federal Government’s incursion into the regulation of medical practice. A recent rulemaking from the Centers for Medicare and Medicaid Services (“CMS”), reflects, in the view of the Pain Care Coalition and the professional societies it represents, just how far that important commitment has been eroded.

In a rulemaking commenced in early January, CMS proposed to establish “improper prescribing practices” as new grounds for revoking a physician’s enrollment in the Medicare program. (“the CMS Proposal”) The revocation of Medicare enrollment would be a fatal blow to almost any physician practice. The physician could no longer submit claims for payment of services rendered to Medicare patients, and other providers, for example, pharmacies, could no longer submit claims for items and services prescribed by the physician.

While undoubtedly prompted by legitimate public health concerns about prescription drug abuse and diversion, including those relating to the prescribing of controlled substances for patients with chronic pain, the Pain Care Coalition (“the Coalition”) feared that this new authority would be used against any prescribing practice in the future. Indeed, it would become precedent for even more expansive “second guessing” of clinical judgment generally. In either circumstance, it would have a pronounced negative effect on clinician behavior, with a corresponding restriction on the access of Medicare patients to necessary pain care and related services. As a result the Pain Care Coalition (“the Coalition”) responded quickly and forcefully to the CMS Proposal, submitting a lengthy and detailed critique to CMS Administrator Marilyn Tavenner. Unfortunately, that message fell on deaf ears, and CMS proceeded to finalize its proposal in late May of 2014.

The Coalition recognizes that the use of certain agents including antidepressants, antiepileptic 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. Indeed, the Coalition supports many of these initiatives. At the same time, the Coalition believes strongly that 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.

A Fundamentally Flawed Approach

The Coalition strenuously opposed the CMS Proposal, which is now a final rule, as fundamentally flawed. It substitutes 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. It 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 CMS’ legitimate interest in protecting against abuse and diversion of drugs in the Medicare population. 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, evidence-based criteria for making those judgments; and 3) without reasonable due process protections for clinicians whose prescribing practices may come under scrutiny.

In our argument to Administrator Tavenner, the Coalition stressed a number of distinct points.

First, 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 Drug Enforcement Administration (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. For example, a Medicare Part D drug plan sponsor’s 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, conversely, is an extreme sanction for most physician specialties, including pain medicine. Not only is the physician not able to prescribe controlled substances, or other medications, or obtain Part D coverage for his or her patient’s medications, he or she is effectively prohibited from providing or ordering any service to or for any Medicare patient. Loss of Medicare billing privileges may also have related consequences under Medicaid and commercial payment programs that would effectively preclude a sanctioned physician from serving any patients.

The Coalition believed that a remedy of that magnitude should be available to CMS only under clear statutory authority from Congress, with appropriate criteria for his exercise, and only with the most careful substantive and procedural protections. Unfortunately, CMS has chosen to assert that authority for itself. At the same time, commentary accompanying the final rule states that implementation will be focused only on those cases “so egregious that the physician or practitioner’s removal from the Medicare programs is needed to protect Medicare beneficiaries.” In other words, “trust us” to use this new authority sparingly and judiciously, and not in a manner that will impact legitimate prescribing. The Coalition hopes this will prove to be the case. If it is not, the professions will need to respond, and respond forcefully.

Second, the rulemaking fails to demonstrate that CMS and its contractors have any particular expertise in evaluating physician prescribing practices generally or medication therapies for pain patients specifically.

The Coalition recognizes the public’s concern over, and the heightened regulatory scrutiny surrounding, the use of certain controlled substances in the treatment of pain, and specifically in the treatment of patients with chronic pain. It pointed out to CMS that American Academy of Pain Medicine (AAPM), American Pain Society (APS), American Society of Anesthesiologists (ASA), 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. It readily acknowledged that finding the appropriate balance between alleviating pain and suffering, and risking adverse outcomes from overuse or abuse, has not been easy.

However, the Coalition urged CMS to recognize that these issues are being diligently pursued by the professions, and by others in government entrusted with ensuring the appropriateness of medical practice. In particular, the Coalition reminded CMS that the primary role lies with and 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 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 enrollment. If the state board has limited a physician’s prescribing privileges, but stopped short of license revocation, then the Coalition would understand CMS denying Medicare Part B or D claims coverage for prescriptions consistent with the state board’s imposed limitations, but not revocation of all billing privileges. If a state board has imposed some lesser sanction, for example, remedial continuing medical education, then CMS should refrain from taking any action against the prescriber unless and until the state board imposes more severe sanctions, and only then in a manner consistent with the state action. Unfortunately, the final rule contains no assurance that CMS will defer to state disciplinary actions.

The Coalition also noted the role FDA plays with its program of risk evaluation and mitigation strategies (“REMS”) targeted to improve provider awareness about the proper use of specific high-risk 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 rulemaking does not provide details on the process by which CMS will become informed of improper prescribing practices, the Coalition presumes that CMS will rely on its various
contractors to forward cases of improper prescribing practices to CMS and to provide the detailed case information on which CMS will 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.8

Third, the bases on which CMS will identify prescribing practices as “improper” fall far short of being true standards and are much too vague to be consistently applied. Under the rule, improper prescribing is defined in terms of “any basis for revocation of enrollment 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; and those that fail to meet “Medicare requirements.” Of particular concern is the fact that the rule does not define “improper” by reference to any 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 are more susceptible to consistent application than others, but most will leave CMS with virtually unfettered discretion. In the Coalition’s view, this aspect of the rule can be fairly characterized as no more than a “we will know it when we see it” standard.

For example, one factor in determining whether the prescribing is “abusive” will be “whether there are diagnoses to support the indications for which the drugs were prescribed.” Since complex pain syndromes are often much more challenging from a diagnostic perspective than many other conditions or diseases, two clinicians diagnosing two similar patients may end up with different diagnostic conclusions. How will CMS, with much less diagnostic expertise in this field, make this determination?

Another factor is “excessive” dosing “linked” to patient overdoses. A very real risk here is that the overdose itself becomes proof of the excessive dosing. But as the Coalition pointed out to CMS, 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 CMS rule answers none of these questions.

The decision factors leading to a determination that prescribing was improper because it failed to meet Medicare requirements also fail to provide physicians with clear standards on which they can rely. For example, such factor is whether the prescriber has a practice of prescribing outside the scope of his or her DEA registration.12 Presumably this includes judgments by CMS or its contractors 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 for why the Agency and its contractors are in a better position to apply it in the course of fulfilling their claims payment responsibilities.

Highlighting our concern with this aspect of the rule is the fact that there is already a direct linkage between Controlled Substances Act (“CSA”) violations and physician exclusion from Medicare under existing Social Security Act provisions administered by the Office of Inspector General (“OIG”). 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 Medicare revocation rule, 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.

Fourth, the rulemaking did not articulate a process through which CMS will make these highly discretionary judgments. Despite the broad scope of the new authority, and the impact revocation of enrollment will have on a physician practice, CMS offers no procedural ground rules or protections for those whose prescribing practices will be judged. In the Coalition’s view, this omission leaves practitioners in considerable peril if the new authority is used against them.

Fifth, the Coalition believes that the new authority overlaps substantially with the OIG’s existing exclusion authority and was thus simply unnecessary to protect either patients or the Medicare Program. It is, in practical effect, a new permissive exclusion 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 procedural protections against arbitrary use of that authority.

We have noted above the OIG’s existing authority to exclude practitioners based on conduct regulated by the DEA and found to violate the CSA. At a much more “macro” level, virtually all conduct covered by the new rule (improper diagnosis, insufficient patient evaluation, excessive dosing, state disciplinary actions, and adverse events, among others “factors”) can already be the basis for an OIG exclusion under another provision of existing law. That provision authorizes exclusion from Medicare 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 failed to see why the Medicare program needed additional authorities.

For all of the reasons noted above, the Pain Care Coalition views the CMS rulemaking as a clear violation of the noninterference principle set forth in the Medicare law. It is bad policy—bad for physicians, bad for patients and bad for the traditional role of the States in regulating medical practice. CMS’s decision to proceed with this rule, despite substantial public comment in opposition to it, much of which mirrored the concerns raised by the Coalition, is deeply disappointing. Indeed, it is deeply disturbing.

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Notes


6. For example, CMS’ most recent report to Congress on RAC appeals shows that over 40 percent of provider-appealed RAC audit recoveries are eventually overturned.


13. See 42 U.S.C.1320a-7(a)(4) and (b)(3).


15. The Pain Care Coalition advocates for responsible pain care policies at the Federal level on behalf of the American Academy of Pain Medicine, American Pain Society and American Society of Anesthesiologists.