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

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 physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the proposed *Medicare Program Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (Proposed Rule). While the AMA appreciates efforts by the Centers for Medicare & Medicaid Services (CMS) to improve upon the existing regulation and oversight of Medicare Advantage (MA) and Medicare Prescription Drug Benefit Part D Plan (Part D) sponsors, there are proposed changes that represent major and troubling departures from beneficiary protections that have served as basic safeguards that ensure access to medically necessary treatments and services, particularly to the most vulnerable Medicare beneficiaries. The AMA is also concerned with the sweeping nature and scope of additional proposed changes that would harm patients and impose costly paperwork burdens on physician practices, re-allocating time and resources away from direct patient care. We strongly urge CMS to reconsider the impact the proposed changes would have on beneficiaries and physicians who are already facing an enormous number of new demands and requirements imposed by regulations promulgated under a number of new laws.

NEW CRITERIA FOR DRUG CATEGORIES OR CLASSES OF CLINICAL CONCERN

The AMA strongly opposes the CMS proposal to remove antidepressants and immunosuppressants in 2015 and antipsychotics in 2016 from the six protected classes of Part D drugs. Currently, Part D plans must include on their formularies "all or substantially all" of drugs within the specified six protected classes, which include antineoplastics, anticonvulsants,

antiretrovirals, antipsychotics, antidepressants, and immunosuppressants. Furthermore, CMS proposes criteria for identifying the protected classes through notice and comment. The AMA strongly recommends clarification to the proposed criteria. In brief, CMS' rationale with regard to three of the current six classes of protected drugs and the proposed criteria that are the basis for excluding these three classes of drugs from protected status, will impede patient access to medically necessary care and impose substantial paperwork burdens on patients and physicians who will have to go through an onerous and burdensome process to obtain medically necessary treatment—or not receive appropriate treatment at all.

Due to the important beneficiary protections and success of this Part D policy, the Affordable Care Act (ACA) includes explicit statutory authority for the creation of the six protected classes—a few short years ago. The ACA also includes authority for CMS to specify criteria for identifying the protected classes through notice and comment. The CMS proposed criteria are not reasonably designed to ensure adequate access to Medicare prescription drugs. Patients who are particularly vulnerable—subject to either physical or mental ailments that would impair their ability to advocate for themselves against a well-organized health insurance company without access to appropriate medication—would find navigating the myriad of Part D plan processes for obtaining medically necessary treatment very difficult and in some instances impossible, particularly the exceptions and appeals process.

The AMA strongly disagrees that the circumstances that gave rise to the six protected classes "have changed dramatically" and that physicians and Medicare beneficiaries are better prepared to navigate the Part D plan utilization policies and appeals process. While important changes have been made to the Part D program policies, in practice there remain ongoing challenges for patients and physicians. Patients continue to be auto-enrolled in Part D plans just as they were in 2005. As discussed more fully below in the section concerning Appeals and Complaints, physicians and patients still confront confusing and time consuming appeals processes, particularly since some plans can avoid streamlined adjudication requirements by inappropriately processing challenges to denials as complaints (which are not subject to expedited adjudication). Furthermore, if utilization strategies had remained the same over the past decade, physicians and patients might be more comfortable with navigating these policies, but instead, utilization strategies and policies across plans are different, increasingly complex, and clinically and administratively burdensome to manage for physician practices. In its 2013 Data Book, the Medicare Payment Advisory Commission (MedPAC) reported that Part D plans' application of drug utilization management tools, including quantity limits, step therapy, and prior authorization, had steadily increased from 2007 to 2013. The use of elaborate new utilization policies and iterations of complexity on existing ones is only expected to increase unless CMS takes steps to standardize and ensure adequate beneficiary notice and education concerning these practices. We do not believe that the Part D plan online compare function constitutes adequate notice and education concerning these Part D plan practices as far too many Medicare beneficiaries remain unfamiliar or unable to readily access this platform and plan specific appeals and exceptions practices and policies are not readily available.

Part D utilization management policies and appeals processes translate into additional physician, patient, and staff hours expended to obtain medically necessary treatment. Barriers to medical treatment will adversely impact patient compliance and adherence to medication treatment recommendations and may drive physicians and other health care providers to utilize less appropriate treatment options because patients will be deterred by the barriers and added out-of-pocket expenses. Furthermore, physician practices, under the burden of other health care delivery reforms and mandates, will not have the capacity to assist the large number of patients impacted by this new policy. The concerns are pronounced when Medicare beneficiaries are seeking treatment for mental health or are in need of immunosuppressant therapy because they may be less prepared to advocate for the appropriate treatment because of their medical condition.

Immunosuppressants are used across a variety of disciplines including dermatology, rheumatology, organ transplantation, and certain autoimmune diseases, to name a few. These drugs are noted for wide variability in patient response and tolerance, so multiple options would be necessary. From a clinical perspective immediate access to immunosuppressant therapy generally would be essential to avoid major or life-threatening clinical consequences since it could be expected that the patient's condition left untreated would result in emergency care.

Given the heterogeneity of the mental health disorders that Medicare beneficiaries may have, the range of potential drug and disease-specific situations is too broad and varied for CMS to capture with specific formulary requirements. It was immediately evident that CMS' assessment of the range of options needed when prescribing antidepressants did not account for the implication of drug side effects, comorbidities, or drug-drug interactions. It appears that CMS concluded antidepressants are typically the only prescription medication beneficiaries are taking. In fact, among the most expensive patients in the health care system are those who have psychiatric conditions like depression and other medical comorbidities like heart disease or diabetes. Tampering with a multiple drug regimen in a population of elderly or disabled patients on medication to manage multiple chronic conditions will lead to numerous problems with side effects, drug interactions, and other adverse events.

As detailed by the American Psychiatric Association (APA) in a February 25, 2014 letter to leadership of the Committee on Energy and Commerce concerning the proposal to remove anti-depressants from protected class status:

> …the choice among antidepressants should be made on the basis of a variety of important factors including tolerability of side effects, precisely because all antidepressants are not comparable in these respects. The selective quoting from our guidelines and flawed clinical logic apparently led CMS to conflate the supposed "interchangeability" of drugs within the classes of both antidepressants and antipsychotics with overall evidence for efficacy, when this is just one element of a drug's appropriateness for an individual patient.

> CMS also cited the APA Treatment Guidelines in support of its claim that there is a "lack of unique effects for distinguishing individual drug products when initiating drug therapy" and that "treatment guidelines … generally do not advocate a preference of one SSRI drug over another for initiation of therapy." CMS's conclusion is not supported by the evidence it cites. It misinterprets and misrepresents APA's clinical practice guidelines multiple times as justification for limiting patient access to medically necessary psychotropic medications.

If mental illnesses go untreated, or are inappropriately treated, a patient's risks of hospitalization, a persistent or significant disability, or death are heightened, particularly when a patient needs treatment for acute symptoms like suicidality or psychosis, but also during his/her ongoing "maintenance" treatment.

If the agency's goal is to improve quality and reduce costs for patients with psychiatric disorders on Part D drugs, reducing access is unlikely to achieve that outcome in contrast to reform of the health care payment and delivery system for such patients. There are 15 projects funded by the Center for Medicare & Medicaid Innovation to address patients with psychiatric and physical chronic conditions. Often these involve encouraging teams of psychiatrists and primary care physicians to better coordinate patient care. CMS should be building on these delivery and payment reforms rather than limiting coverage of patients' drugs.

CMS not only cites changes in circumstances which have not changed enough to warrant removing the current drugs from protected class status, but also asserts that this policy modification will allow plans to negotiate cost savings. However, CMS acknowledges that plans are already able to negotiate for preferred status among protected status drugs to garner greater discount(s)—even within protected classes. In addition, the cost savings projected would primarily come from antipsychotics and the amount of savings should be offset by the corresponding increase in health care costs associated with patients not receiving appropriate medical treatment and the paperwork burden on patients and physician practices seeking appropriate patient treatment. CMS does not provide data or other evidence demonstrating inappropriate utilization of antidepressants, antipsychotics, or immunosuppressants in the Part D program. (There is concern with the use of antipsychotics among beneficiaries in nursing facilities, but this is being addressed through targeted efforts that would not harm patients who require access to treatment.) Other than a blanket assertion of potential for overutilization, the proposed rule provides no concrete clinical evidence this is a problem in the Part D program for antidepressants, immunosuppressants, or antipsychotics. (In fact, draft CMS Part D and C call letters have identified overutilization of drugs other than antidepressants, immunosuppressants, and antipsychotics and the AMA has commented extensively on how to target that identified and documented overutilization.) The Part D program's existing beneficiary protections cited as obviating the need for protected class status are not adequate for ensuring beneficiary access for all the reasons outlined above.

All of the forgoing reasons underpinned the original decision to include antidepressants, antipsychotics, and immunosuppressants in the protected class of drugs. The clinical reasons for this decision have not changed, the circumstances of patients and physicians have not changed materially so as to warrant such a reversal of agency policy, and finally the current structure of the Part D program is not adequate justification for such changes.

CMS then proposes the following new criteria for purposes of establishing protected classes:

(1) Restricted access to the drugs in the category or class would have major or life-threatening clinical consequences for individuals who have a disease or condition treated by drugs in the category or class; and
(2) There is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within a category or class, such as drugs used in the treatment of cancer.

Based on the above criteria, all three classes of drugs—antidepressants, antipsychotics, and immunosuppressants should qualify for protected drug status. CMS' definition of "major" clinical consequences is not reasonable nor accurately reflects the consequences of lack of access to the appropriate drug within these classes of drugs. Nor does the agency adequately explain its view that all three fail to meet the second criteria. The AMA strongly encourages CMS to revoke this proposal.

MANDATORY PRESCRIBER ENROLLMENT IN MEDICARE

The AMA shares CMS' concerns about prescriber fraud and prescription drug abuse. Since 2005, the AMA, along with many other stakeholders in the health care community, has supported and helped secure passage of the National All Schedules Prescription Electronic Reporting Act (NASPER) as an essential tool in combating prescription drug abuse and diversion. Since then, the sense of urgency has only increased, and the AMA continues to work on a number of fronts to combat diversion and drug abuse while at the same time preserving access to medically necessary treatment for pain.

We have serious concerns, however, about CMS' proposal to require prescribers of Part D drugs to enroll in Medicare. CMS has said that its goal in making this proposal is to ensure that Part D sponsors have accurate information regarding prescriber licensing as a program integrity measure. We are unclear as to why the proposed enrollment requirement is necessary to reach that goal. According to the Office of the Inspector General of the Department of Health and Human Services (HHS/OIG), the National Plan and Provider Enumeration System (NPPES) contains National Provider Identifier (NPI) records and state licensure information. Under regulations promulgated by CMS in 2012, in fact, Part D sponsors are required to check the NPPES to verify Part D prescriber information.

CMS' proposal to replace its 2012 requirement that Part D sponsors verify prescriber information via the NPPES with a new requirement that Part D prescribers enroll or opt-out of Medicare will cause considerable harm to Medicare beneficiaries for a number of reasons. First, CMS' proposal to maintain a list of enrolled physicians is likely to cause enormous difficulties. In the context of CMS' enrollment requirement for physicians who order and refer clinical laboratory, imaging, home health, and durable medical equipment, prosthetics, and orthotics (DMEPOS), CMS' list of enrolled physicians was often inaccurate and incomplete, leading to confusion for physicians, suppliers, and beneficiaries.

In addition, CMS' proposed implementation timeline is insufficient. In the context of physician enrollment for orders and referrals of clinical laboratory, imaging, home health, and DMEPOS, CMS repeatedly delayed the requirement, which was initially proposed in October of 2009 and finally fully implemented with claims edits in January of this year, due to various operational and implementation difficulties. CMS' proposed January 1, 2015 implementation date for enrollment of Part D prescribers does not allow sufficient time to implement this requirement; at least a full year following the enactment of a major regulatory requirement like this is required to fully educate physicians.

Implementation problems mean denied access to medically necessary medications and treatments for Medicare beneficiaries. While we understand CMS' desire to ensure that the Part D program is sound, we believe that beneficiary access to care, including Part D benefits should be the primary concern of CMS as they consider this proposal. Access to medication is unique in that immediacy is a key concern. If a pharmacy will not dispense a drug because a provider is not enrolled, the patient will be negatively affected. If CMS' list is incomplete, or the prescriber's enrollment application is held up with the Medicare Administrative Contractor (MAC), or the prescriber's information is incomplete on PECOS, it is the patient who will be denied access to their medications.

For these reasons, we strongly urge CMS to rescind its proposal to require prescribers of Part D drugs to enroll in Medicare. The negative effects of this proposal on Medicare beneficiary access to care far outweigh the scant benefit to Medicare program integrity.

If, in spite of the aforementioned concerns, CMS proceeds to finalize this policy, we strongly urge CMS to look to its own experience in implementing the enrollment requirement for physicians who order and refer clinical laboratory, imaging, home health, and DMEPOS services. We also strongly request that CMS finalize its proposed "opt-out" provision; physicians who do not wish to participate or enroll in Medicare should have the option not to do so, and their patients should continue to have access to coverage for medically necessary drugs. CMS should also ensure that enrollment may be effectuated either through the Medicare legacy system or PECOS. Lastly, we ask that CMS revisit its proposal regarding foreign prescriptions. While we are sensitive to issues concerning inappropriate prescribing by foreign prescribers, CMS' proposal to essentially no longer allow Part D coverage for foreign prescriptions may be a sea change and should be studied further before finalized.

OVERPAYMENTS

Part C and Part D plans are currently obliged to return overpayments per Section 6402 of the ACA, and we support CMS efforts to provide clear guidance regarding how those entities may comply with this obligation. We are concerned that audits of physician claims will increase as MA plans and Part D sponsors seek to comply with this requirement. To ensure an appropriate balance between protecting the Medicare trust funds and relieving physician practices of undue burden, we ask that CMS define the parameters of this requirement in accordance with our below suggestions.

First, to ensure consistency with other CMS overpayment initiatives, CMS should provide for a three-year look back period. As evidenced by the initial development of CMS' new Unified Program Integrity Contractors (UPICs), CMS has made clear that streamlining and avoiding inconsistencies in its audit programs is a goal. In that vein, CMS should be mindful that the Medicare and Medicaid Recovery Audit (RAC) programs allow for a three-year look back period. CMS and medical societies have spent substantial resources over a number of years in regard to the Medicare and Medicaid RAC programs to educate physicians about the overpayment look back period of three years. To finalize a different, substantially longer look back period in the context of Section 6402 would confound those efforts, cause confusion, and prove unduly burdensome for physicians.

Second, to avoid overly-aggressive audits by Part C and Part D plans, CMS should make clear that it is not imposing an ongoing duty to proactively search for overpayments absent receipt of information that an overpayment may exist. Such a requirement would be extremely burdensome for plans and by extension physicians, as it would impose a boundless duty to troll medical records in search of unknown vulnerabilities. Moreover, the statute does not impose such a requirement. We understand that CMS' requirements for periodic self-audits and compliance checks will be promulgated in a separate rulemaking pursuant to section 6401(a) of the ACA; that rulemaking is a more appropriate vehicle for CMS' proposals on those topics. CMS should make clear that Part C and Part D plans are not obliged to proactively search for an overpayment without reason to believe that a specific overpayment exists.

BROADENING RELEASE OF PART D DATA

The AMA strongly urges CMS to apply appropriate safeguards when releasing Part D data. The AMA supports access to encrypted PDE prescriber data that generally allows sufficient use with the added protection of not divulging the prescriber's identity. We strongly urge CMS to refrain from releasing non-final data, given this information can easily be misinterpreted and may cause false conclusions that impact providers. The data should not be used for commercial purposes; furthermore, governmental and state entities already have access to this information therefore public release of this information is not needed to strengthen program integrity efforts.

We strongly encourage CMS to focus first on data release to improve care quality. We urge that CMS present such data in a way that considers the quality of the services provided, include an explanation of the data limitations, and allows prescribers the opportunity to correct their information (to the extent prescriber level information is identified). To enhance quality improvement efforts and ensure physicians are not misclassified, data should include patient non-compliance with prescriptions. This will allow physicians the ability to specifically identify their patients who do not comply with medication orders and improve patient care. Furthermore, to the extent that CMS does release this information then CMS needs to consider ways to incorporate Part D data into CMS quality improvement calculations.

EXPANSION OF QUALITY IMPROVEMENT PROGRAM REGULATION

We do not support further expansion of CMS' MA quality improvement requirements as the last expansion has raised ongoing concerns that it undermines patient-centered care determinations by penalizing physicians who deliver care tailored to individual patient needs. MA organizations must have a written quality improvement program plan approved by CMS and the MA plans are often tailoring their physician quality programs around CMS' payment cut points on MA plans. Currently, chronic care improvement programs must be measureable, reported on annually and have a clinical focus (as determined by CMS). However, under the expanded requirements, MA organizations are setting unrealistic targets on physicians. Often compliance must be at 100 percent for a physician to qualify for a payment incentive regardless of whether the physician is providing appropriate and medically necessary care. There are instances when meeting the measure(s) is contrary to appropriate care and the plan does not incorporate exceptions for when the level of measurement is not applicable. Perversely, the quality reporting requirements may drive inappropriate and harmful care in certain instances. For example, an MA plan in Michigan is requiring a physician to hit a 100 percent threshold on the HEDIS Comprehensive Diabetes Care Management measures to be eligible for an incentive. The 100 percent threshold is due to the cut points CMS has set for MA plans to score well under the MA 5-Star Rating System.

NETWORK MODIFICATIONS – PATIENT NOTICE AND CONTINUITY OF CARE

The AMA urges CMS to exercise regulatory oversight to ensure that MA plans meet network adequacy requirements that protect the interests of Medicare beneficiaries—and seek input on significant changes to the networks beyond Part D plan sponsors proposing changes and include impacted state stakeholders such as insurance commissioners, state medical associations, and patient organizations. In late 2013 during the Medicare Open Enrollment period, a number of MA plan sponsors modified their provider networks for CY 2014 without adequately notifying beneficiaries that they would lose access to their provider in 2014. Continuity of care for patients is a basic component of quality and efficient care that leads to improved health outcomes. The substantial reduction in provider networks by MA plans will have a significant adverse impact on Medicare beneficiaries, especially if reasonable steps are not mandated for purposes of providing beneficiaries actual notice of changes on a timely basis,

particularly during election periods. Furthermore, physicians and other healthcare providers must be provided adequate notice and rationale supporting such determinations, particularly those couched as terminations by plans to reduce costs and/or improve quality. The AMA urges CMS to require MA plans to:

- Provide and document that patients received actual, accurate and timely notice of whether their current physicians will be in network during election periods;
- Ensure that patients know that they can retain their physician by choosing fee-for-service or by choosing a product with an out-of-network benefit if their plan provides one;
- Provide physicians information needed to challenge network adequacy based on CMS regulations and toll all appeal deadlines until physicians receive such information;
- Provide information on how many patients have been impacted and which physicians to state medical societies, state insurance commissioners, and organizations representing patients; and,
- Be required to inform CMS when the percentage of physicians removed from the networks exceeds 10 percent.

The AMA also requests that CMS emphasize that MA plans have an obligation to comply with all relevant federal and state laws even if not explicitly outlined in MA guidance materials and regulations. Specifically, late last year MA plan sponsors modified networks in a fashion that raised questions about whether the sponsors and CMS had adequately ensured compliance with the Title VI of the Civil Rights Acts and section 504 of the Rehabilitation Act when evaluating the network modifications. The AMA urges CMS to evaluate and document the extent to which consideration was given to the impact on low and moderate income beneficiaries of the network modifications.

APPEALS AND COMPLAINTS

The appeals and exceptions process for Part D and MA plans continues to be far too complicated which benefits Part D and MA plans to the detriment of beneficiaries. **The exceptions and appeals mechanism and policies for Part C and Part D fail to provide an adequate means to protect beneficiary access to medically necessary care**. The AMA has repeatedly raised this issue in Part C and Part D comment letters to the agency.

At the MedPAC meeting in September 2013, a presentation included findings consistent with AMA's comments concerning the Part D exceptions and appeals process. Reportedly, in MedPAC focus groups of Medicare beneficiaries and physicians, both patients and physicians were unaware of how the exceptions and appeals process work and were not able to distinguish between the different levels of appeals. More tellingly and important, a majority of beneficiaries did not know they had appeal rights. Physicians reported that they had to deal with at least one plan in their practice with particularly burdensome medical necessity requirements including insisting on speaking directly with the physician or failing to provide a dedicated phone line for physician offices. These are clear examples of diverting scarce physician and staff time away

from direct clinical care. Patients were not generally encouraged to use the exceptions and appeals process, but counseled to rely on alternative solutions such as switching plans, providing office samples, or seeking manufacturer assistance, because these were more likely to result in obtaining medically necessary medication—which is not surprising given the resource intensive, adversarial, and confusing appeals process.

Reportedly, CMS' 2012 audit of Part D plans found that Part D plans are struggling with Part D coverage determinations, appeals, and grievances. Examples of Part D plan shortcoming include: failure to make timely coverage determinations; failure to notify the beneficiaries of their coverage decisions; inadequate effort to obtain information to make appropriate clinical determination. Medicare beneficiaries and physicians pay the cost for these persistent and systemic failures by Part D plans to maintain a mandatory safety valve for accessing medically necessary care. Shockingly, a large number of dismissals were reported for technical reasons that MedPAC presenters concluded suggest beneficiaries (and physicians) may be confused or having difficulty navigating the appeals process—not because the patient was seeking inappropriate treatment options. The foregoing is not surprising since the Part D plans have full-time staff well-versed in the exceptions and appeals process dedicated to this process and patients and physicians are at a disadvantage since they are not paid to process an appeal. It is not surprising given the resource and information disadvantage that the appeals and exception process would be an option of last resort to the extent physicians and beneficiaries are even aware it is available.

Furthermore, it is not clear that Part D plans are complying with mandatory timeframes for adjudicating exceptions and appeals. Recently, a Medicare beneficiary who is a retired physician contacted the AMA after his request to challenge a coverage denial for a prescription was processed as a complaint instead of an exception request or appeal. We urge CMS to evaluate the extent to which Part D plans are processing beneficiary appeals/exception requests as complaints.

The forgoing underscores the measures and mechanisms that MA and Part D plans have in place that limit Medicare beneficiary rights through byzantine design. This negatively impacts all Medicare beneficiaries including beneficiaries and the physicians who assist them who are very versed in the Medicare program. This underscores that the Medicare protections are far more robust on paper than in practice and leave even the most well-informed and able struggling to obtain medically necessary and appropriate medical care. We strongly urge CMS to further investigate this practice among all MA and Part D plans and further evaluate how to simplify and standardize appeals across programs and identify immediate mechanisms to quantify and assess MA and Part D plan compliance with this obligation.

REVOCATION OF MEDICARE ENROLLMENT

CMS has proposed a number of changes that would permit CMS to revoke the enrollment of physicians and other eligible professionals under a number of newly articulated bases. While the AMA understands efforts by the agency to revoke the enrollment of individuals who prescribe without the appropriate licensure or a Drug Enforcement Agency Certificate, the agency exceeds its statutory authority by defining a basis for revocation of enrollment based on prescribing that is "abusive" and represents a threat to the health and safety of Medicare beneficiaries or otherwise fails to meet Medicare requirements. The AMA strongly opposes the agency's attempt to directly regulate the practice of medicine, establish black box clinical practice guidelines, and pre-empt the authority of states to provide oversight over physician (and other licensed health professionals) medical practice. The AMA strongly urges CMS to refer prescribers who "fall outside the norm of appropriate prescribing" based on agency analytics and benchmarking to the appropriate state licensing board since such bodies are specifically set-up and qualified to make such assessments and issue determinations that can be relied upon by CMS under other provisions of this proposed rule change to revoke enrollment, if appropriate.

First, CMS proposes to deny or revoke a physician's Medicare enrollment if the physician's DEA certificate is suspended or revoked or if the applicable state licensing or administrative body has suspended or revoked his/her ability to prescribe. It is rational, reasonable, and consistent with the agency's general grant of authority to administer the Medicare program to provide that prescribers lacking appropriate licensure or subject to licensure suspension should be barred from participation in the Medicare program. However, to the extent CMS finalizes the proposal to revoke or deny enrollment based on a licensure or DEA certificate suspension, the AMA urges CMS to remove barriers to re-enrollment if and when such suspensions are lifted in a timely manner and make specific provision to ensure for such an occurrence.

The AMA questions whether the denial or revocation of a prescriber's DEA certificate should preclude the prescriber from legally prescribing non-Controlled Substances even where the prescriber maintains legal authority to do so and is in good standing with a state professional licensing body. CMS does not provide any documented evidence that physicians who have had their DEA certificate terminated or previously suspended are demonstrated to have prescribing practices that are outside the norm across the spectrum of all therapeutic options. We urge CMS to establish a review process that would apply in individual circumstances, as warranted, which would include referral to state board or consultation with specialty societies, in these instances. If a physician decides not to seek a DEA certificate after revocation or withdraws registration voluntarily, the physician would remain barred from Medicare enrollment for the remainder of their professional career under this proposed rule even if the physician otherwise maintained good professional standing. Since CMS has increased program integrity controls to prevent dispensing Controlled Substances written by a prescriber without an appropriate DEA certificate, this permanent bar from the Medicare program would be excessive and unreasonable. The AMA strongly urges CMS to revise the proposed regulation consistent with the above comments as the agency states in the proposed rule that these improper practices "may" be duplicated in the

Medicare program—a blanket supposition made without any basis in fact or on actual evidence of a general nature or specific to any given physician or prescriber.

Second, CMS proposes to establish authority 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.

CMS specifically declines to 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. A number of the criteria identified by CMS are beyond the expertise of CMS regulators to evaluate and would represent an unprecedented move by a federal agency to directly regulate the practice of medicine and supplant the role of state licensing boards that are specifically set-up to evaluate the very criteria governing professional conduct CMS now proposes to undertake.

The AMA urges CMS to use the proposed criteria and collect information consistent therewith and establish a review process that would apply in individual circumstances, as warranted. This process must provide physicians notice and opportunity to provide relevant information. After consideration of the relevant information, CMS would refer to state licensing boards where the agency concludes the prescribing represents a threat to the health and safety of Medicare beneficiaries. The AMA urges CMS to strike references to abusive prescribing as the standard has not been defined, is highly subjective potentially, and we could expect over time is likely to be inconsistent with community and clinical standards of care as defined by the medical profession. Furthermore, the discretion it would confer on the agency is not rationally related to the statutory authority cited by the agency for this section of the proposed rulemaking.

The AMA appreciates the opportunity to provide comment and thanks you for considering our views.

Sincerely,

James L. Madara, MD