



American Academy of Physical Medicine and Rehabilitation

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January 16, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013.

Sent electronically to <http://www.regulations.gov>

RE: File code CMS-4182-P

Dear Ms. Verma

I am writing on behalf of the American Academy of Physical Medicine and Rehabilitation, to submit comments on your proposed rule, entitled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," File code CMS-4182-P. The American Academy of Physical Medicine and Rehabilitation (AAPM&R) is the national medical specialty organization representing more than 10,000 physicians who are specialists in physical medicine and rehabilitation (PM&R). PM&R physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability, and are experts in designing comprehensive, patient-centered treatment plans. Physiatrists utilize cutting-edge as well as time-tested treatments to maximize function and quality of life.

We appreciate the opportunity to make comments on this proposed rule, which is intended to update the regulations concerning the Medicare Part D (prescription drug) and the Part C (Medicare Advantage) programs and to implement certain provisions of the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act. In addition, you state that "this regulation includes many provisions that will help address the opioid epidemic," a topic that is of great importance to many of our members. Most of our comments are addressed to the plan proposals related to opioids. We did address some of the other subjects of the rule, however not in as much depth as we would have liked, had there been more time to delve into them.

Suggestion: For future proposed changes, it would be easier to follow and comment on the provisions if each rule limited itself to one major category of changes. Combining several

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different changes in one proposed rule can be both confusing and to focus commenters more heavily on some of the changes than others.

Comments concerning the proposed drug management program:

- Comment: Through this portion of the proposed rule, CMS plans to integrate provisions from the CARA act into the current Part D Drug Utilization Review (DUR) policy, and The Overutilization Monitoring System (OMS) policy. This will be accomplished through a regulatory framework that allows Part D plan sponsors to voluntarily adopt drug management programs structured in specific ways to address potential overutilization of frequently abused drugs. You state that implementation of such a drug management program would be voluntary but then, on page 56341, you note that “We foresee that all plan sponsors will implement such drug management programs based on our experience that all plan sponsors are complying with the current policy as laid out in guidance, the fact that our proposal largely incorporates the CARA drug management provisions into existing CMS and sponsor operations, and especially, in light of the national opioid epidemic and the declaration that the opioid crisis is a nationwide Public Health Emergency.”
- Comment: It is unclear why, if CMS feels that the adoption of a drug management program consistent with CMS specifications is important, it does not make it mandatory. Perhaps all the plan sponsors will voluntarily adopt the drug management plan set out by CMS due to the reasons given above, but under the proposed rule the door remains open for the sponsor to choose not to implement the program.
- Suggestion: Please clarify why the program should not be made mandatory if it is a “best practice” or why it cannot have more flexibility if it is not.
- Comment: On page 56343-4, the definition of frequently abused drugs is quite confusing, perhaps because you are discussing the definition at different points of time. You start by noting that “Section 1860D-4(c)(5)(G) of the Act defines “frequently abused drug” as a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.” (Presumably, this is the current policy.) Next, you propose (emphasis added.) criteria the Secretary would use to determine whether a drug belongs within the “frequently abused” category and note that drugs designated as frequently abused will be posted, and/or put forth in a Call Letter. You then further clarify that, “While this is the approach we propose for future (emphasis

added) designations of frequently abused drugs, we are including a discussion of the designation for plan year 2019 in this preamble. For plan year 2019, consistent with current policy, we propose that opioids are frequently abused drugs.” So, taken together these statements clarify how frequently abused drugs will be determined after plan year 2019 but not how such a determination is made under the current policy (Is it by the definition given in Section 1860D–4(c)(5)(G of the Social Security Act?) nor how it will be determined for plan year 2019 (other than that opioids will be included.) It also leaves open the question of what policy should be used prior to plan year 2019 (should it continue to be the “current guideline?” and is the “current guideline” provided by the definition given in Section 1860D–4(c)(5)(G of the Social Security Act?)

- Suggestion:** Please clarify how a “frequently abused drug” is determined for each of the time frames mentioned (before plan year 2019 begins, during plan year 2019, and after plan year 2019.)
- Comment:** You requested comments on whether non-opioid drugs should be included under the “frequently abused drugs” definition. However, it is not clear in the rule whether non-opioid drugs are already included under the current policy. On pages 56343-4, you discuss why opioids (with a few exceptions) fit into the definition of “frequently abused drugs” and note that “our current policy applies only to opioids.” However, in response to some comments about adding other specific drugs to the list of “frequently abused drugs,”, you state that, “we have not expanded the current policy to address non-opioid medications. However, we have stated that if a sponsor chooses to implement the current policy for non-opioid medications, we would expect the sponsor to employ the same level of diligence and documentation with respect to non-opioid medications that we expect for opioid medications.” This makes it appear that even though you state that you have not expanded the current policy “to address non-opioid medications,” you have nevertheless done just that. Finally, you propose that “if finalized, this rule would supersede our current policy, and sponsors would no longer be allowed to implement the current policy for non-opioid medications.” This statement again makes it appear that current policy allows for consideration of non-opioid drugs, despite the previous statement that “our current policy applies only to opioids.”
- Suggestion:** To effectively answer CMS’ question – “We seek feedback on allowing sponsors to continue to implement the current policy for non- opioid

medications with respect to beneficiary-specific claim edits,” CMS first needs to clarify what exactly the “current policy” is. Once that is done, we would need to apply the definition of “frequently abused drugs” to determine whether any non-opioid drugs might potentially meet the criteria set forth for determining whether something is a “frequently abused drug” (which may differ according to whether it is being judged under the current policy, or in the plan year 2019 policy, or in policies implemented in future years.) We would need the same kind of data that CMS used to qualify opioids for inclusion in the determination of a “frequently abused drug.”

If non-opioid drugs clearly will not meet the criteria to determine that they are “frequently abused drugs,” it would only confuse matters to include them in a program designed for “at-risk beneficiaries” unless the definition of “at-risk beneficiaries” is changed. Currently, the definition states that an At-risk beneficiary means a Part D eligible individual who is (among other requirements) determined to be at-risk for misuse or abuse of such frequently abused drugs under a Part D plan sponsor’s drug management program in accordance with the requirements of § 423.153(f);

Comment: In the proposed rule, you state that, “Beginning with plan year 2018, we adjusted these criteria to align with the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline)⁷ issued in March 2016 in terms of using 90 MME as a threshold to identify beneficiaries who appear to be at high risk due to their opioid use. In its guideline, after considering information from relevant studies and experts, the CDC identifies 50 MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME.” It is not clear how the identification of a threshold in the CDC guidelines aligns with the criteria you are specifying.

Suggestion If you do not intend to make use of the CDC recommendations for a 50 MME threshold, it would be less confusing if you did not reference it in your explanation.

You go on to state that, “Our criteria, which we will discuss more fully later in the preamble, also incorporate a multiple prescriber and pharmacy count to focus on beneficiaries who appear to be not only overutilizing opioids but who also are at increased risk due to potential coordination of care issues, such that the providers who are prescribing or dispensing opioids to these beneficiaries may not know that other providers are also doing so.” While this is certainly a worthy objective, the way the criteria is set forth appears to

make it the only objective since you also state, on page 36345, that “The clinical guidelines for use in drug management programs we are proposing for 2019 are: Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies OR 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. This does not allow for any identification of a potential abuser who received all his prescriptions from one prescriber (who may be a problem prescriber) or even 2 or 3 prescribers (who may either be problem prescribers and/or be unaware of the other prescriber’s existence.) Conversely, since you define the criteria as someone receiving an average daily MME ≥ 90 “for any duration during the most recent 6 months” (emphasis added) the criteria does not allow for an exception in those circumstances in which a patient with an acute need for pain relief is prescribed more than 90 MMEs for a day or so only, then tapered down.

Suggestion: You note that you have “described alternative clinical guidelines that we considered in the Regulatory Impact Analysis section of this rule. Stakeholders are invited to comment on those alternatives and any others which would involve identifying more or fewer potential at-risk beneficiaries.” However, of the six options given, none would be triggered in a case with less than 3 prescribers, which means none would capture abusive patterns caused by a problematic prescriber or by a prescriber who is unaware of another prescriber. Also, none of the options will allow for situations in which a patient has been on long-term dosages greater than 90 MMEs, is able to function well under that dosage, and attempts to wean him have been unsuccessful.

While it is understandable that you want to cast as wide a net as possible without an excessive number of false positives, that may not be the optimal way to guard against abuse. You note that “Plans are expected to perform case management for each beneficiary identified in OMS and respond using standardized responses.” As already explained above, the proposed system leaves entire categories of patients either being missed or being identified in error as possibly abusive. One way to alleviate that might be to give plan sponsors more flexibility in considering cases which are possibly suggestive of abuse but don’t meet the criteria (e.g. a patient receiving 120 MMEs daily with one physician prescribing 90 MMEs and a second prescribing 30 MMEs.) This appears to be your current position but you are declining to carry it forward. In such cases the drug sponsor could have the option to

investigate further or document why he chose not to investigate further. For patients who are on higher than 90MMEs daily, there could be an option to add a modifier of some sort to the code, justifying why it was medically necessary to prescribe that amount – e.g. a modifier for a patient who has been on long-term dosages greater than 90 MMEs, is able to function well under that dosage, and attempts to wean him have been unsuccessful. There could even be limitations to how often such a modifier could be used before the case defaulted into provisions such as the “lock-in” of prescribers or pharmacies.

Comment: You propose that “Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.” We agree. That seems to be a reasonable way to look at it, as partners in the same medical practice may be on call for each other and/or need to authorize a prescription refill but shouldn’t be considered as “multiple” prescribers. Your experience appears to have borne that out.

Comment: You state that “We are particularly interested in receiving comments on whether CMS should adjust the clinical guidelines so that more or fewer potential at-risk beneficiaries are identified, and if more are identified, whether the additional number would result in a manageable program size for plan sponsors (or too few beneficiaries to be meaningful).” As explained above, we are concerned that the inflexibility around identifying potential cases of abuse may result in both under and over investigation, increasing the burden on both plan sponsors and prescribers. A patient’s physician or an experienced Plan Sponsor may have a better sense of certain triggers that fall outside CMS parameters.

Suggestion: We recommend that CMS consider additional ways to make the program more flexible, perhaps convening a technical expert panel made up of physicians and Plan Sponsors. We also suggest considering the type of prescriber involved and his or relationship to the patient. A physician who specializes in pain management likely treats a very different population than a family practice physician or an internist. Also, a physician who is treating a patient over the long term is very different from an emergency room physician consulted for an acute episode of pain.

Comment: Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a

contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual.

You note that “Consistent with this, we propose that an exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long- term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) Has a cancer diagnosis.” The language in the proposal is slightly different, which may have an unforeseen effect. First, does whether a beneficiary “elects” hospice differ from a beneficiary who “receives” hospice? Second, the proposal seems to expand the concept of long-term care. Please clarify what you mean by a “long-term care facility.” Are you referring to a long-term care hospital (as defined under section 1861ccc of the Social Security Act)? To a SNF (as defined under section 1861j which refers to section 1819(a) of the Social Security Act)? We would like to convey our concern about exempting SNF care under the proposed Drug Management Program, even with a single pharmacy. There is no shortage of opiate issues in nursing homes but that problem will not be addressed if they are exempt.

Suggestion: Please confirm that the differences in the phrasing are intentional and, if they change the meaning, please explain the rationale for the change.

Comment: Exempt beneficiaries – You requested feedback on whether the categories suggested below should be considered exempt, though you have not currently chosen to do so. Our recommendations differ according to the categories, as described below:

Suggestion(s) See below

1. You note that some commenters suggested exempting beneficiaries who are receiving palliative and end-of-life care, since not all patients receiving this type of care are necessarily enrolled in hospice or reside in an LTC facility.

We concur with that recommendation although some limitations may be necessary when the exemption is due to the receipt of palliative care.

2. You also noted that commenters suggested exempting beneficiaries in assisted living or in various other health care facilities, such as group homes and adult day care centers, where medication is supervised.

We do not concur with this recommendation as the persons cared for in these environments may or may not be receiving properly supervised medication, and may or may not even be receiving necessary medication.

3. Other commenters suggested exempting beneficiaries with debilitating disorders or receiving medication-assisted treatment for substance abuse disorders.

We do not support such a blanket exception as the population covered under those descriptions is both too variable and too vulnerable.

Comment: Requirements of Drug Management Programs – Some suggestions and comments are found elsewhere in this letter. In general, we question the need for the level of complexity and inflexibility built into the program.

Comment: Written Policies and Procedures – We question the need to be so specific in the requirements.

Comment: Case Management/Clinical Contact/ Prescriber Verification. Again, we do not think the level of complexity, inflexibility and specificity is needed.

Comment: Limitations on Access to Coverage for Frequently Abused Drugs - Some of the issues we are concerned about regarding this limitation are covered elsewhere in this letter.

“Lock-in” tool for Part D plans to limit an at-risk beneficiary’s access to coverage for frequently abused drugs. Subject to our concerns about the identification of at-risk beneficiaries, when one has been identified, this tool for prescriber and/or pharmacy lock-in could prove a useful method for controlling inappropriate or abusive drug behavior, since it limits the beneficiary to certain prescribers and/or pharmacies and/or allows establishment of a specific claims edit.

- Comment:** Requirements for Limiting Access to Coverage for Frequently Abused Drugs – Before limiting access to a drug, the Plan Sponsor must do certain other things, including instituting Case Management, notifying the prescriber, and obtaining agreement to the restriction, and notifying the beneficiary. We are concerned about potential consequences if the prescriber is part of the problem, particularly with requiring prescriber agreement with the restriction.
- Suggestion:** There should be some alternatives for the Plan Sponsor to follow if he or she believes the prescriber may be purposefully prescribing inappropriately, particularly if a pattern has been identified.
- Comment:** Beneficiary Notices and Limitation of Special Enrollment Period – We question the necessity for having such an inflexible method of notification, including language approved by the Secretary, substantial documentation of rights and remedies for the patient, listing of available resources, etc.
- Suggestion:** Simplify the notification requirements and allow some flexibility in how they are put together. For example, a case manager could have a standalone explanation of the review process or of available documentation that could be presented along with the notification rather than having to make it up for each individual patient.

Limitation on the Special Enrollment Period for LIS Beneficiaries with an At-Risk Status

- Comment:** Based on the 2015 data in CMS' OMS, more than 76 percent of all beneficiaries estimated to be potential at-risk beneficiaries are LIS-eligible individuals. Such individuals, unlike other Part D enrollees, can make changes in their plan enrollment throughout the year. Other Part D enrollees can generally only make changes once a year, during the annual election period. Therefore, without the planned limitations on special enrollment periods for LIS beneficiaries, if that beneficiary was found to be a person with a status of "at-risk," he or she could attempt to lift any restrictions by simply changing plans.
- Suggestion:** We concur with restricting the special enrollment period for LIS beneficiaries. One question that was not immediately clear and that might make the need for this limitation less necessary is whether the Plan Sponsor who originally placed the patient in "at-risk" status, has a duty to inform the new plan in which the beneficiary plans to enroll of the first plan's determination that the patient was "at-risk." Although the second plan would

have the option to either carry forward that determination or to decide it was not warranted now, at least it would need to think about and justify its decision.

Flexibility in the Medicare Advantage Uniformity Requirements

Comment: CMS has determined that statutory provisions and the regulation at § 422.100(d) mean that the agency has the authority to permit MA organizations the uniformity requirement notwithstanding, the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria the uniformity requirement) are treated the same. The benefit and cost sharing flexibility applies to Part C benefits but NOT Part D benefits. CMS plans to propose revising its interpretation of the existing statute and regulations to allow MA plan segments to vary by benefits in addition to premium and cost sharing, consistent with the MA regulatory requirements defining segments at § 422.262(c)(2). However, MA plans are prohibited by statute from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. Therefore, CMS will review benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations. CMS requests comments and/or questions about the implementation of this flexibility.

Suggestion: It is difficult to visualize exactly how this would work, though it sounds reasonable in concept. We would agree with providing this increased flexibility as long as the design is examined by CMS to ensure it is non-discriminatory, and that the regulation be withdrawn if unforeseen problems arise.

Maximum Out-of-Pocket Limit for Medicare Parts A and B Services

Comment: CMS has a goal to establish future maximum out-of-pocket (MOOP) limits based on the most relevant and available data, or combination of data, that reflects beneficiary health care costs in the MA program and maintains benefit stability over time. The flexibility provided by these proposed changes would permit CMS to annually adjust mandatory and voluntary MOOP limits based on changes in market conditions and to ensure the

sustainability of the MA program and benefit options. Consistent with past practice, CMS will continue to publish annual limits and a description of how the regulation standard was applied. CMS would use the annual Call Letter and other guidance documents to explain its application of this proposed regulatory standard and the data used to identify MOOP limits in advance of bid deadlines, which will provide MA organizations adequate time to comment and prepare for changes. In addition, CMS plans to transition any significant changes under this proposal over time to avoid disruption to benefit designs and minimize potential beneficiary confusion. CMS also proposes to clarify that CMS may use Medicare FFS data to establish annual MOOP limits.

Suggestion: In order to agree with this expanded flexibility, we would need to know that it does not give MA plans such excessive flexibility that it could allow them to undercut other Medicare plans and/or to pay physicians less than they are justified in expecting.

Cost Sharing Limits for Medicare Parts A and B Services

Comment: The cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. CMS has previously provided guidance that MA plans must pay at least 50 percent of the contracted (or Medicare allowable) rate and that cost sharing for services cannot exceed 50 percent of the total MA plan financial liability for the benefit. Cost sharing consists of service category deductibles, copayments or co-insurance. CMS proposes to amend § 422.100(f)(6) to permit use of Medicare FFS to evaluate whether cost sharing for Part A and B services is discriminatory to set the evaluation limits announced each year in the Call Letter. In addition, CMS proposes to use MA utilization encounter data as part of that evaluation process. CMS seeks comments and suggestions on this proposal.

Suggestion: It is not clear what purpose is served by determining whether use of Part A and B services is discriminatory if that is the currently accepted practice. Does CMS plan to change the methodology if use of the Part A and B services is shown to be discriminatory? We would recommend providing more information on what the object of this change would be and what would be done depending on the findings.

Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review

Comment: Currently, CMS will only approve a bid submitted by a Medicare Advantage (MA) organization if its plan benefit package is substantially different from those of other plans offered by the organization in the area with respect to key plan characteristics such as premiums, cost sharing, or benefits offered. However, CMS thinks that the current meaningful difference methodology may force MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs. Implementation of the proposed regulation to allow more flexibility for MA beneficiaries and plans will allow MA organizations to: 1. tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data, 2. establish Provider Specific Plans (PSPs) designed to offer enrollees benefits through a subset of the overall contracted network in a given service area (sometimes referred to as narrower networks), and, 3. beginning in CY 2019, provide different cost sharing and/or additional supplemental benefits for enrollees based on defined health conditions within the same plan (Flexibility in the Medicare Advantage Uniformity Requirements).

Suggestion: Although we support increasing the flexibility of the types of plans offered by MA organizations, we are concerned by the example of narrow networks. Previous studies have shown that such narrow networks too often do not provide beneficiaries with a reasonable number of choices when it comes to hospitals, physicians, or services offered, and often the beneficiary is unaware of the limitations until they are in need of services. Rehabilitation, critical to the ultimate well-being of many patients, is often not recognized by organizations focused on decreasing costs, and a narrow network may well leave a beneficiary without access to necessary rehabilitation services.

Part D Prescriber Preclusion List

Comment: CMS proposes to focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers, through use of a preclusion list of prescribers who fall within either of the following categories:

- Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

- Have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

The preclusion list would be in lieu of requiring providers to enroll before ordering drugs for a Medicare patient, particularly opioids.

Suggestion: AAPM&R agrees with the use of a preclusion list rather than requiring prescribers to enroll in order to prescribe for Medicare patients. An enrollment requirement could lead to restrictions on who could enroll and could end up excluding prescribers who should not be excluded. However, we are concerned that the above requirements for putting a prescriber on the preclusion list are too narrowly drawn. There should be some way to include physicians or other prescribers on the preclusion list who have a history of problematic opioid prescriptions, or at least to flag such prescriptions if they would meet the requirements under the Plan Sponsor Drug Management Plan and don't meet any exemption.

Provisional Coverage

Comment: When a beneficiary tries to fill an opioid prescription from a provider on the preclusion list, CMS proposes a 90-day provisional coverage period. A beneficiary would have one 90-day provisional coverage period with respect to an individual on the preclusion list. The sponsor/PBM would track one 90-day period from the date the first drug is dispensed to the beneficiary. This dispensing event would trigger a written notice and a 90-day period for the beneficiary to fill any prescriptions from that particular precluded prescriber and to find another prescriber during that 90-day time period.

Suggestion: AAPM&R is concerned that a 90-day provisional coverage period with no other qualifications attached would be too broad. One alternative might be to only allow a provisional coverage period if the prescriber is on the exclusion list for reasons other than problematic prescriptions. Or, to require additional scrutiny during the "provisional" period, with a notation that the prescription will be cancelled if the physician is found to have problematic opioid prescribing patterns.

Thank you for your time and consideration of these comments. If you would have any questions or would like further information, please contact AAPM&R's Health Policy Manager, Kate Stinneford, at kstinneford@aapmr.org or at 847-737-6022.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Standaert', with a long horizontal flourish extending to the right.

Christopher J. Standaert, MD
Chair, Innovative Payment and Practice Committee
American Academy of Physical Medicine and Rehabilitation