PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

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Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
Document Identifier: CMS—10538
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Document Identifier: CMS-10538: Notice of the proposed information collection from the public for "Prior Authorization Form for Beneficiaries Enrolled in Hospice."

Dear CMS:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the notice of the proposed information collection from the public relating to the "prior authorization form for beneficiaries enrolled in hospice. PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, FEHBP, and Medicare Part D.

Our comments largely relate to the need for further clarification on the content of the proposed information collection under the Paperwork Reduction Act (PRA), as detailed below.

1. Clarification on whether use of PA form is mandatory. The justification for the draft "Hospice Information for Medicare Part D Plans PA Form" (the "PA Form") in the supporting material accompanying the draft PA form states, "CMS will encourage use of this form as soon as it is approved and will likely propose requiring its use in future rulemaking."[1] We seek further clarity on what this means.

    a. If CMS proposes in future rulemaking to require use of the PA form, will it be necessary to go through another PRA review after the proposed rulemaking or will approval through this PRA process be sufficient for whatever may happen in future rulemakings?

    b. We are also confused about the last section in the introductory material to the form, which is entitled "Limited Customization of the Format."[2] Specifically, this section states that, "Sponsor may customize the form by including a plan logo and to facilitate electronic submission of the required information. Beginning in 2015, no other modifications are permitted." We are not sure how the statement, that no other modifications are permitted, fits in with the statement that the use of the form is not

[1] Supporting Statement – Part A Prior Authorization From for Beneficiaries Enrolled in Hospice, page 1.
[2] Please note that while the Table of Contents notes that the section is on page 6, the pages are not numbered.

mandatory. We strongly urge that CMS clarify not only that use of the form is not mandatory but also that plans may use alternative formats.

2. Consistency on use of terms. The PA form on the first page notes that there is a separate line for each medication that is "Unrelated to Terminal Illness and/or Related Conditions." Yet, in the Supporting Statement on page 4, the reference states that the proposed form would only be used when a drug is "totally unrelated" to the beneficiary's illness and related conditions. We assume the correct terminology is "unrelated" not "totally unrelated," we believe these words make a difference and would suggest that consistent terminology be used.

3. Specifics on completion of the PA form. Based on the introductory text accompanying the PA form, it appears that if a coverage determination is made on any other form for a drug that rejects for a beneficiary that has elected hospice, "A3 reject," the plan is expected to request that the PA form be completed. This raises several questions as listed below:[3]

    a. The PA form states a hospice representative can complete the form. Such representatives are typically nurses. However, based on guidance in Chapter 18 of the Medicare Prescription Drug Manual, a nurse cannot request a coverage determination. It would be helpful to get clarification on exactly who can complete the form.

    b. When does the clock start for the coverage determination request (at the time the original form was received or when the correct PA form is received)?

    c. It is unclear whether that the plan is required to complete the PA form when an oral request is received. We recommend that it be made clear that the completion of the PA form is not required when an oral request is received.

    d. It states that the form has to be signed by the hospice representative or prescriber, if an oral request is received. It is not clear if the plan has to then send out that form to receive signature, and if so, how that impacts the turn-around time for the coverage determination request. As noted above, we recommend that signature not be required on the PA form when an oral request is received as that will mean the beneficiary will not be able to get the drugs at POS.

    e. If the prescriber is unaffiliated with the hospice provider, we assume that the plan can follow current guidance and take the information of the unaffiliated prescriber.

    f. Does the plan have to report the coverage determinations for hospice drugs separately in the data validation submission?

    g. Can non-prospective requests be initiated from the hospice provider? If so, does this still fall under a coverage determination exception request since it does not follow Chapter 18 guidance?

[3] We assume that some of the questions listed are answered in the FAQs posted by CMS in August 2014 at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Hospice-FAQs-v08062014.pdf, but we would appreciate confirmation (e.g., as to exactly who can complete the form).

4. Other comments on PA form

    a. The PA form does not allow for a question set to determine appropriateness for drugs with Utilization Management (UM) associated (e.g., is the patient currently treated with the requested medication, list all medications the patient has previously tried and failed, etc.). Without it, the plan will have to conduct additional follow up with the hospice/prescriber after initial submission of the hospice fax form. Plans should have the ability to add the appropriate questions in order to determine appropriateness for drugs with UM.

    b. In the "Purpose of the Form" section at the top of page 1, the third box should be relabeled more broadly than "A3 Reject Override" (e.g., "Hospice Reject Override") so it is clear to parties not familiar with specific reject codes.

    c. The diagnosis information in the "Patient Information" section on page 1 should be removed, as it is not required or necessary.

    d. The section currently labelled "Hospice Pharmacy Benefit Manager (PBM) Information" should be relabeled to "Part D Plan Pharmacy Benefit Manager (PBM) Information."

    e. In the "Signature of the Hospice Representative or Prescriber" section, there should be a "Title" line under the Representative signature so the plan/PBM can be informed of the role the signer has at the hospice.

    f. The word "Prescriber" in the "Signature of the Hospice Representative or Prescriber" section should have an asterisk so it aligns with the statement below it.

5. Date for use. We note that the Supporting Statement provides the expectation that the standardized form should be available for use beginning January 1, 2015. Since comments are not even due until December 2, and since we assume changes will be made to the final form, we further assume that the expectation as to when the form will be in use will be postponed to a date sufficiently after release of the final proposed form to allow for plans to adopt such form. Specifically, we request that CMS provide at least a 90-day period for implementation.

6. Drugs in the 4 classes. The PA form includes a box to enter the medications related to each of the four classes subject to PA: analgesics, antinauseant (antiemetic), laxative, and antianxiety (anxiolytic). We note that there is no universal source or commonly accepted list of exactly what drugs are in each of these categories. While we are not sure this necessitates a change in the format, we note for the record that efforts to develop more uniformity in this regard would be beneficial to facilitating standardization of this effort for all stakeholders.

Thank you in advance for your consideration of these comments.

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President – Regulatory Affairs